MODULE

Biosafety Resource Book

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LEGAL ASPECTS

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MODULE

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LIST OF ABBREVIATIONS

ABS	Access and benefit-sharing
AIA	Advanced Informed Agreement
ASEAN	Association of Southeast Asian Nations
BCH	Biosafety Clearing-House
CBD	Convention on Biological Diversity
Codex	Codex Alimentarius
COP-MOP	Conference of the Parties serving as the meeting of the Parties to the Protocol
CPB	Cartagena Protocol on Biosafety
CPM	Commission on Phytosanitary Measures
DNA	Deoxyribonucleic acid
EC	European Commission
EIA	Environmental Impact Assessment
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FFP	Food, or feed or for processing
GATT	General Agreement on Tariffs and Trade
GDP	Good Development Principles
GMO	Genetically modified organism
IP	Identity preservation
IPPC	International Plant Protection Convention
ISPM	International Standard for Phytosanitary Measures
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN	International Union for Conservation of Nature
LMO	Living modified organism
NGO	Non-governmental organization
OECD	Organisation for Economic Co-operation and Development
OIE	Office International des Epizooties
PGRFA	Plant Genetic Resources for Food and Agriculture
PRA	Pest Risk Analysis
SPM	Sanitary and Phytosanitary Measures
SPS	Sanitary and Phytosanitary Agreement
TBT	Technical Barriers to Trade
TRIPS	Agreement on Trade-related Aspects of Intellectual Property Rights
UN	United Nations
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organization
UPOV	International Union for the Protection of New Varieties of Plants
USDA	United States Department of Agriculture
WHO	World Health Organization
WTO	World Trade Organization

CHAPTER 1

INTRODUCTION: OVERVIEW OF EXISTING LEGAL FRAMEWORKS ON BIOTECHNOLOGY AND BIOSAFETY

Legal provisions to regulate biotechnology and biosafety issues exist at every level of government. This includes transnational (e.g. the United Nations [UN]), regional (such as the European Union [EU] or the African Union [AU]), national, and subnational levels.

Biosafety is defined as a "Set of measures or actions addressing the safety aspects related to the application of biotechnologies and to the release into the environment of transgenic plants and organisms, particularly microorganisms, that could negatively affect plant genetic resources, plant, animal or human health, or the environment" (UNEP Glossary, 2007).

The term "**biosafety**" is generally used to describe frameworks of policy, regulation and management to control potential risks associated with the use of new biotechnologies ("New biotechnologies" being a term used to differentiate processes that use modern techniques of biotechnology, such as recombinant DNA techniques, from traditional breeding and improvement techniques used in agriculture), including their use, release and transboundary movements. Biosafety frameworks may also address risk communication and other issues such as potential positive or negative socio-economic impacts. Many of the legal instruments addressing biosafety have primary goals, such as the preservation of biodiversity, consumer protection, public participation and information, development and trade, and address biosafety only indirectly.

BIOSAFETY
Generally used to describe frameworks of policy, regulation, and management to control potential risks associated with the use of new biotechnologies.

BOX 1.1

BIOSAFETY AND AGRICULTURAL BIOTECHNOLOGY INSTRUMENTS (GLOWKA, 2003)

BIOSAFETY AND AGRICULTURAL BIOTECHNOLOGY INSTRUMENTS
A classification of instruments addressing agricultural biotechnology and biosafety into three different areas: biosafety instruments, food safety instruments, and consumer protection instruments.

Glowka (2003) proposes a classification of instruments addressing agricultural biotechnology and biosafety into three different areas: biosafety instruments, food safety instruments, and consumer protection instruments.

Biosafety instruments represent the primary source of law on modern biotechnology in the world today. Biosafety instruments address the risks posed to the environment and human health when GMOs are released into the environment either for research (e.g. small-scale or field-testing) or for commercial purposes. Biosafety instruments also address contained use of GMOs.

Food safety instruments address the risks posed to humans by genetically modified foods. The general goal of these instruments is to minimize risks to humans presented by GMOs or their products used as foods themselves or as ingredients in food. Ideally the entire human food chain is examined, moving from the farm to the kitchen table. A related area is animal feed safety.

Consumer protection instruments address a range of issues primarily in that area of biotechnology related to food or feed products. The labelling of end products resulting from genetic engineering, such as food or animal feed, is the primary area addressed. In general, these instruments are designed to (1) protect the consumers' right to know and the right to make informed choices and (2) ensure fair trade practices to ensure that consumers are not victimized by false or misleading claims about a product.

Legal frameworks on biosafety include binding and non-binding international and regional agreements and national laws, regulations and guidelines. This chapter explains the different levels, types, and purposes of these instruments and how they may interrelate. Chapter 2 of this module explains specific international instruments, and Chapter 3 discusses elements of different legal frameworks and biosafety instruments and how they are transposed into national biosafety frameworks.

LEGAL FRAMEWORKS ON BIOSAFETY
Include binding and non-binding international and regional agreements and national laws, regulations and guidelines, dealing with the regulation of biotechnology and biosafety.

International instruments to regulate biotechnology and biosafety include treaties, conventions, and agreements that have been agreed upon by several nations. A number of existing agreements have been launched and are implemented by UN agencies, although not all its Members are signatories or parties to all these agreements. In addition, the World Trade Organization (WTO), with its 153 Members[1], plays a large role in determining how biotechnology is regulated at the national level.

Among regional instruments, the EU regulatory framework is one of the most extensive, covering issues including import, cultivation, monitoring and labelling of GMOs or GMO-derived material. Some subnational instruments may also have a role in this framework.

International and regional instruments provide guidance and general principles that are then adopted into national legislation and regulatory policy and applied at the national level. Different countries may choose different means of implementing internationally agreed principles, through both binding and non-binding national instruments.

INTERNATIONAL AND REGIONAL INSTRUMENTS
Provide guidance and general principles that are then adopted into national legislation and regulatory policy and applied at the national level.

In some national legal systems, international agreements may need to be ratified or transposed into national law by the signatories to be put into practice. This makes national frameworks particularly relevant for the implementation of international and regional agreements.

1 As of January 2010

States also enact their own biotechnology legislation. There is a wide range of solutions that may be adopted at national level, including a variety of schemes, frameworks and instruments for addressing biosafety and other issues related to biotechnology, such as liability and redress and coexistence among genetically modified, conventional and organic crops. In addition, legislation not expressly directed at regulating biotechnology may nonetheless apply to specific areas, including living modified organisms (LMOs) or genetically modified organisms (GMOs). Trade issues intervene as well, with questions of whether GMO regulation may affect free markets among signatories to trade agreements.

BINDING AND NON-BINDING INSTRUMENTS
Instruments that either entail an obligation under international law or do not have any binding force, also referred to as hard law and soft law.

This plethora of legal instruments operating at different levels may create confusion and, on occasion, overlaps and conflicts. It is therefore important to understand the range of options for national biosafety legislation and the current status and context for addressing biosafety issues.

1.1 TYPES OF INSTRUMENTS USED TO REGULATE BIOTECHNOLOGY

International instruments include several different types of treaties and agreements addressing – directly or only indirectly – biotechnology and biosafety. These instruments comprise both **binding** (i.e., entailing an obligation under international law) and **non-binding instruments** ("hard" and "soft" law).

TREATY
An international agreement concluded between States in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation.

The Vienna Convention on the Law on Treaties (1969), defines a **treaty** as: "*an international agreement concluded between States in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation*" (article 2[1][a]). Key to this definition is that a treaty is an *international* agreement and that it is governed by *international law*.

BOX 1.2

DEFINITIONS OF HARD AND SOFT LAW (UNEP GLOSSARY, 2007)

Hard law
Term used to describe the legally binding nature of various agreements or provisions, which leave no or little room for discretion.

Soft law
The term used for quasi-legal instruments which do not have any binding force, or those whose binding force is somewhat "weaker" than the binding nature of traditional law, often referred to as "hard law". In the international context, soft law consists of non-treaty obligations which are therefore non-enforceable and may include certain types of declarations, guidelines, communications and resolutions of international bodies.

BOX 1.3

DEFINITIONS: ACCESSION, RATIFICATION, AND IMPLEMENTATION (UNEP GLOSSARY, 2007)

Accession: Act whereby a state becomes a party to an international agreement already negotiated and closed for signature. Accession has the same legal effect as ratification, although an acceding state has not signed the agreement.

Ratification: Formal process by which a head of state or appropriate government official or authority signs a document which signals the consent of the state to become a party to an international agreement once the agreement has entered into force and to be bound by its provisions.

Implementation: For a party to an international agreement, [the] process of adopting relevant policies, laws and regulations, and undertaking necessary actions to meet its obligations under the agreement.

DEFINITIONS: ACCESSION, RATIFICATION, AND IMPLEMENTATION
Provides definitions of the different processes of how a state can deal with international agreements.

This means that parties signing the agreement cannot unilaterally interpret it, and agree to be governed by international law – the presiding authority is not the nation, but the governing body or system created by the treaty in question and the rules of interpretation are not any national legal system but the principles commonly agreed by the treaty and the principles of international law.

BINDING INSTRUMENTS carry the force of law and require signatories to comply with the agreements as adopted.

Binding instruments (hard law) carry the force of law and require signatories to comply with the agreements as adopted (as discussed earlier, this may include ratification and/or transposition of agreements into national frameworks through implementing legislation). Some binding agreements introduce mechanisms for dispute resolution.

NON-BINDING AGREEMENTS are normally the result of processes that involve consensus building among countries; hence, their "moral authority" is a result of the legitimacy of this consensus.

Non-binding agreements (soft law) include codes of conduct, guidelines, manuals on "best practices", recommendations, declarations of principle, and action programmes. As opposed to binding agreements, these do not create binding obligations and are not legal instruments enforceable by the national institutions. Consequently, there is no formal need for ratification or transposition into national legislation and no means of compulsory compliance. Non-binding agreements offer the advantage of being faster and simpler to adopt than binding agreements, and provide more flexible means for update and amendment.

Non-binding agreements are normally the result of processes that involve consensus building among countries; hence, their "moral authority" is a result of the legitimacy of this consensus. They are often implemented as "de facto" legislation and can later become or be incorporated into binding agreements (Hannam and Boer, 2002). Creation under the auspices of internationally recognized organizations (such as UN organizations); legitimacy through participation in framing and drafting by representatives of a broad range of international and national authorities; and adoption by a majority of international actors (especially states) can create both practical and moral incentives to comply.

Table 1.1 | Definitions and examples of international instruments

Instrument	Definition	Binding or non-binding	Example	Goals – from selected examples
Code of conduct	Set of rules to guide behaviour and decisions	Non-binding	FAO Code of Conduct on Responsible Fisheries	Establish principles, serve as reference, provide guidelines, provide standards of conduct, etc.
Guidelines	Statement, indication of procedure; guidance for decisions	Non-binding	UNEP Technical Guidelines on Biosafety http://www.unep.org/biosafety/Documents/Techguidelines.pdf	Help achieve "international information exchange, cooperation, harmonization, and agreement"
Best practices	Benchmarks using techniques considered to be the most effective/efficient	Non-binding	OECD Best Practice Guidelines for Biological Resource Centres http://www.oecd.org/dataoecd/7/13/38777417.pdf	A target and guidelines for managing and improving the quality of biological resource centres that store and supply biological materials and information
Recommendations	Formal expression of an advisory nature of the will of the governing body of an international organization or international agreement.	Non-binding	European Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:348:0018:0026:EN:PDF	Facilitating a coordinated approach to adopting sampling and detection techniques
Declaration (of Principle)	A formal statement of aspirations issued by a meeting. Usually issued by high-level representatives.	Non-binding unless required by treaty	1992 Rio Declaration on Environment and Development	Principle 15 on precaution: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (http://www.unep.org/Documents.Multilingual/Default.asp?DocumentID=78&ArticleID=1163).

Instrument	Definition	Binding or non-binding	Example	Goals – from selected examples
Position Statement	A statement of goals related to a particular subject	Non-binding	United Kingdom Joint Nature Conservation Committee position statement on biotechnology	"We are solely concerned with potential impacts of GMO releases on the living environment and on sustainable use of our natural resources, including protected sites and the wider countryside. We have no locus on matters of public health and safety. The agencies, working through the JNCC, advocate using the precautionary principle where commercial releases are proposed…" (http://www.jncc.gov.uk/page-2992)
Programme of Action	Guidance for designing and implementing policies to achieve joint goals, often as expressed in other agreements	Non-binding	UNEP Global Programme of Action for the Protection of the Marine Environment from Land-Based Activities http://www.gpa.unep.org/	"…preventing the degradation of the marine environment from land-based activities by facilitating the realization of the duty of States to preserve and protect the marine environment. It is designed to assist States in taking actions individually or jointly within their respective policies, priorities and resources, which will lead to the prevention, reduction, control and/or elimination of the degradation of the marine environment, as well as to its recovery from the impacts of land-based activities" (GPA)
Treaty	International agreement concluded between states in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation (Vienna Convention on the Law of Treaties).	Binding	International Treaty on Plant Genetic Resources for Food and Agriculture http://www.planttreaty.org/	"No country is self-sufficient in plant genetic resources; all depend on genetic diversity in crops from other countries and regions. International cooperation and open exchange of genetic resources are therefore essential for food security. The fair sharing of benefits arising from the use of these resources has for the first time been practically implemented at the international level through the Treaty and its Standard Material Transfer Agreement" (www.planttreaty.org)

Instrument	Definition	Binding or non-binding	Example	Goals – from selected examples
Convention	A binding agreement between states. Generally used for formal multilateral instruments with a broad number of parties.	Binding	Convention on Biological Diversity www.cbd.int	"The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding" (Article 1, CBD, at http://www.cbd.int/convention/articles.shtml?a=cbd-01)
Protocol	(1) International legal instrument appended or closely related to another agreement, which constitutes a separate and additional agreement and which must be signed and ratified by the parties to the convention concerned. Protocols typically strengthen a convention by adding new, more detailed commitments. (2) Rules of diplomatic procedure, ceremony and etiquette. (3) Department within a government or organization that deals with relations with other missions.	Binding	Cartagena Protocol bch.cbd.int/protocol	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 (Article 1, CPB, at http://www.cbd.int/biosafety/articles.shtml?a=cpb-01)

Instrument	Definition	Binding or non-binding	Example	Goals – from selected examples
Agreement	(1) Generic term for an international legally binding instrument. In this sense, encompasses several instruments, such as treaties, conventions, protocols or oral agreements. (2) Specific term used to designate international instruments that are sic "less formal", thus corresponding to soft law and deal with a narrower range of subject matter than treaties.	Binding	Agreement on Application of Sanitary and Phytosanitary Measures (SPS)	Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade (Article 2, Section 3, SPS at http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm)

Where available, definitions are *adapted from*: UNEP - Glossary of Terms for Negotiators of Multilateral Environmental Agreements (2007).

Binding agreements include treaties, conventions and international agreements. Other terms used for "treaty" include "Compact, Solemn Declaration, Administrative Agreement, Protocol of Decisions, Platform, Concordat, Agreed Minute and Terms of Reference" (Aust, 2000).

One may differentiate between agreements that deal directly with biosafety, such as the Cartagena Protocol on Biosafety (CPB) (see section 2.2.2), and others that affect it indirectly, such as the WTO SPS (section 2.2.3) agreement, which do not mention biosafety directly, but nonetheless have a direct bearing on adoption of national biosafety frameworks. Some agreements may overlap, interrelate, or conflict, especially those on trade and those on biosafety.

Table 1.2 | **International agreements related to biosafety**
(see section 2 for additional discussion)

International agreements	Trade related	Non-trade related
Binding	Convention on Biological Diversity Cartagena Protocol on Biodiversity Agreement on Application of Sanitary and Phytosanitary Measures Agreement on Technical Barriers to Trade International Plant Protection Convention Law of the Sea Agreement on Trade-related Aspects of Intellectual Property Rights	Aarhus Convention The International Treaty on Plant Genetic Resources for Food and Agriculture
Non-binding	Codex Alimentarius International Union for Conservation of Nature position statement The Code of Conduct for the Import and Release of Exotic Biological Control Agents (1996)	Organization for Economic Co-operation and Development safety considerations Agenda 21 United Nations Industrial Development Organization Code of Conduct FAO Code of Conduct on Responsible Fisheries United Nations Environment Programme Technical Guidelines on Biosafety The UN Guidelines for Consumer Protection

INTERNATIONAL AGREEMENTS RELATED TO BIOSAFETY
A list of international instruments having a direct or indirect bearing on biosafety frameworks is provided.

Table 1.2 shows several agreements related to biosafety, including binding, non-binding and trade-related agreements. The relationships between these agreements will be discussed in section 2.5.

CHAPTER 2

INTERNATIONAL FRAMEWORKS ON BIOSAFETY

2.1 DESCRIPTION OF SELECTED LEGAL INSTRUMENTS ADDRESSING BIOSAFETY

DESCRIPTION OF SELECTED LEGAL INSTRUMENTS ADDRESSING BIOSAFETY
This section describes some of the most influential and widely applicable legal instruments addressing biosafety.

This section describes some of the most influential and widely applicable legal instruments addressing biosafety. Discussed first are binding instruments, followed by a discussion of non-binding instruments that nonetheless form an important part of international practice. Both categories include standard-setting instruments, which produce international standards and guidelines. A more inclusive list of instruments may be found in Annex 1.

2.2 INTERNATIONAL BINDING INSTRUMENTS ON BIOSAFETY

The following international agreements are binding upon their signatories and are highly relevant to biosafety and biotechnology. Most of them are directly aimed at regulating products of biotechnology; others do not explicitly mention biotechnology but have trade-related effects on biosafety decisions.

This section looks at eight important, binding international agreements. The Convention on Biological Diversity (CBD) and its Cartagena Protcol on Biosafety (CPB), The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), the Agreement on Technical Barriers to Trade (TBT), and the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) condition how governments regulate GMOs or LMOs. The Aarhus Convention includes specific provisions related to biosafety. The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) is not directly related to biosafety issues but interacts with the CBD. The International Plant Protection Convention (IPPC), the Office International des Epizooties (OIE) and the Codex Alimentarius (Codex) serve as a basis for standards some of which include provisions on biosafety.

INTERNATIONAL BINDING INSTRUMENTS ON BIOSAFETY
A discussion of eight important binding international agreements on biosafety is provided. Most of them are directly aimed at regulating products of biotechnology; others do not explicitly mention biotechnology but have trade-related effects on biosafety decisions.

2.2.1 The Convention on Biological Diversity (CBD) (1992)[1]

Definition: Biodiversity (UNEP Glossary, 2007)

Biodiversity
Shorthand for biological diversity. Variability among living organisms from all sources including terrestrial, marine and other aquatic ecosystems, and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

CONVENTION ON BIOLOGICAL DIVERSITY (CBD)
The Convention establishes three main goals: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits from the use of genetic resources.

The **Convention on Biological Diversity (CBD)** addresses biosafety in two articles: Article 8(g) and Article 19. Article 8(g) requires each contracting party domestically to regulate or manage the risks associated with the use and release of LMOs resulting from biotechnology likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, including risks related to alien invasive species. Risks to human health are also to be taken into account.

1 Entered into force 23 December 1993. As of January 2010, 193 Parties (168 Signatures).

The principles of prevention and precaution apply to the use and release of LMOs. The distinction between LMO and GMO arises because the CBD does not apply to processed food containing or derived from GMOs, but only to GMOs that are intended to be used directly as agricultural inputs, food, feed, or for processing (FFP).

Contracting parties undertake to introduce appropriate procedures to require impact assessment of proposed projects likely to have significant adverse effects on biodiversity (Art. 14[1][a]). The objective is to avoid or minimize such effects. Public participation in the procedures should be allowed where appropriate. Other relevant obligations include those on reciprocity, notification, exchange of information with other states and international organizations where activities in one party or state may adversely affect the biodiversity of another party or an area beyond the limits of any national jurisdiction (Art. 14[1][c, d]). Parties are to create emergency response arrangements at the national level and joint contingency plans with other states (Art. 14[1][e]). Parties are under obligation to transfer environmentally sound technology (including biotechnology) relevant to the conservation and sustainable use of biodiversity (Art. 16[1]).

BOX 2.1

ENVIRONMENTAL IMPACT ASSESSMENT (EIA)

Environmental Impact Assessment

Process by which the environmental consequences of a proposed project or programme are evaluated and alternatives are analysed.

EIA is an integral part of the planning and decision-making processes.

Article 19 refers to "Handling of biodiversity and distribution of its benefits." The first two sections obligate signatories to ensure that source countries for genetic material also share in biotechnological research and benefits based on the genetic resources they provide. Article 19(3) anticipates a protocol to the CBD "setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity", which resulted in the adoption in 2000 of the CPB (discussed below in section 2.2.2). Article 19(4) of the CBD creates a bilateral obligation for a state party to provide information on an LMO prior to providing it to another party. This information includes any available information on the regulatory measures taken by the exporting party and any available information on the potential adverse impact of a particular LMO.

2.2.2 The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2000)[2]

THE CARTAGENA PROTOCOL ON BIOSAFETY
The objective of the Protocol is to contribute to ensuring adequate levels of protection in the field of safe transfer, handling and use of LMOs that may have adverse effects on the conservation and sustainable use of biodiversity taking into account risks to human health focusing in particular on transboundary movements.

The objective of the Protocol is to contribute to ensuring adequate levels of protection in the field of safe transfer, handling and use of LMOs that may have adverse effects on the conservation and sustainable use of biodiversity, taking into account risks to human health, focusing in particular on transboundary movements (Art. 1).

The Protocol specifically applies to transboundary movement, transit, handling and use of LMOs that may have adverse effects on biodiversity conservation and sustainable use, taking into account risks to human health (Art. 4). The Protocol applies only to the movement of LMOs between contracting parties. There is only one exception to the scope of the Protocol: it does not apply to the transboundary movement of LMOs that are pharmaceuticals for human use that are addressed by other relevant international agreements or organizations (Art. 5).

2 Entered into force 23 December 1993. As of January 2010, 193 Parties (168 Signatures).

In general, each party is obligated to take the necessary and appropriate legal, administrative and other measures to implement the Protocol's obligations and to ensure that the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that prevents or reduces risks to biodiversity, taking into account any risk to human health (Art. 2). Each party can take more protective action to conserve and sustainably use biodiversity, provided the action is consistent with the Protocol (Art. 2[4]).

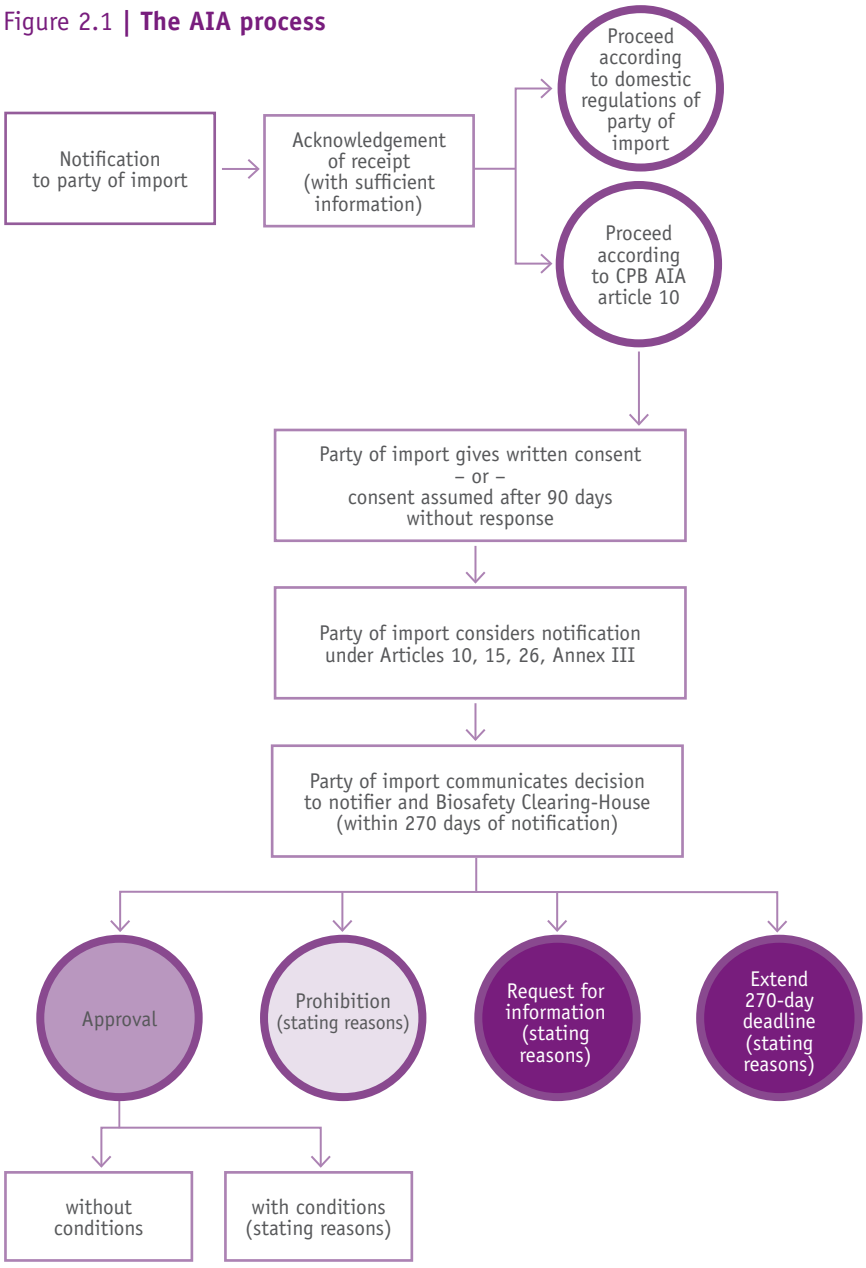
ADVANCED INFORMED AGREEMENT (AIA)
Describes the process for notification and subsequent approval of a first-time import of LMOs intended for introduction into the environment in order to avoid potential adverse effects on the conservation and sustainable use of biodiversity in the receiving environment.

The Biosafety Protocol focuses on the evaluation of and notification between the state parties for LMOs destined for export and subsequent import. It sets out an **Advanced Informed Agreement (AIA)** describing the process for notification and subsequent approval of a first-time import of LMOs intended for introduction into the environment in order to avoid potential adverse effects on the conservation and sustainable use of biodiversity in the receiving environment (Art. 7[10, 12]).

The AIA procedure requires, prior to the first intentional introduction into the environment of the importing party: (a) the notification of the party of export containing certain information, (b) the acknowledgment of its receipt, and (c) the written consent of the importing party (see Figure 2.1) (Art. 8, Art. 9). Criteria are provided for decision-making on importation (Art. 10). Most notably, decisions of the contracting party of import must be made according to a risk assessment (Art. 15).

There are four categories of exceptions to the AIA procedure – LMOs in transit (Art. 6[1]); LMOs for contained use (Art. 6(2); LMOs identified in a decision of the Conference of Parties/Meeting of Parties (COP-MOP) as not likely to have adverse effects on biodiversity conservation and sustainable use (Art. 7[4]); and LMOs intended for direct use as food, feed or for processing (Art. 11).

Figure 2.1 | **The AIA process**



Adapted from: Mackenzie *et al.*, 2003.

BIOSAFETY CLEARING-HOUSE (BCH)
Created under the Protocol, to (a) facilitate information exchange and (b) assist parties in implementing the Protocol, with particular attention to developing countries and countries that are centres of origin and of genetic diversity.

For LMOs intended for direct use as food or feed, or for processing, the contracting party that makes a final decision for domestic use must notify the **Biosafety Clearing-House (BCH)** (Art. 11).

The BCH was established to (a) facilitate information exchange and (b) assist parties in implementing the Protocol, with particular attention to developing countries and countries that are centres of origin and of genetic diversity (Art. 20[1]).

The exemption for AIA does not apply to decisions on field trials. Even though AIA does not apply, a contracting party may still take an import decision under its domestic regulatory framework, provided this is consistent with the Protocol (Art. 11[4]).

When it lacks a domestic regulatory framework, a developing country contracting party, or a party with a transition economy, can declare through the BCH that its decision on the first import of an LMO for direct use as food, feed or for processing will be pursuant to a risk assessment (Art. 11[6]). Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects should not prevent the contracting party of import from taking a decision, as appropriate, in order to avoid or minimize potential adverse effects (Art. 11[8], Art.10[6]).

BOX 2.2

DEFINITIONS OF RISK ASSESSMENT AND RISK MANAGEMENT

Risk assessment:
The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the

associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

From: WTO SPS, Annex A: Definitions, available at http://www.wto.org/english/docs_e/legal_e/15sps_02_e.htm#annA

Risk assessment:
The [risk assessment] methodology described in Annex III of the Protocol follows the conventional risk assessment paradigm, beginning with identification of a potential hazard, such as characteristics of an LMO, which may have an adverse effect on biodiversity. Risks are then characterized based on combined evaluation of the likelihood of adverse effects, and the consequences should those effects be realized.

From CBD discussion of risk assessment, available at http://www.cbd.int/biosafety/issues/risk.shtml

Risk management is the second step in conventional risk assessment, and incorporates the information gained during the risk assessment phase in order to make appropriate decisions on how to manage any risks that may exist. It is a key element in the conventional risk analysis paradigm, and is discussed in several international agreements (see selections below).

...establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment...

From CBD Article 16, Risk Management

Risk management measures for foods derived from modern biotechnology should be proportional to the risk, based on the outcome of the risk assessment and, where relevant, taking into account other legitimate factors....

From Codex Principles for the risk analysis of foods derived from modern biotechnology

Pest risk management (for quarantine pests) is the "Evaluation and selection of options to reduce the risk of introduction and spread of a pest."

Adapted from: ISPM 11, 2004.

RISK ASSESSMENT AND RISK MANAGEMENT
Short definitions of these processes are provided. For details, please refer to Module 3: Risk analysis

Risk assessment and risk management are key requirements in the CPB for decisions on whether to allow the import of an LMO. The risk assessment must be consistent with criteria enumerated in Annex III (Art. 15). The Protocol also specifies general risk management measures and criteria. Risk analysis procedures are discussed further in section 3.6 of this manual.

Under Article 26, the contracting parties reaching import decisions under the Protocol or under domestic legal measures implementing the Protocol may account for socio-economic considerations arising from the impact of LMOs on biodiversity conservation and sustainable use, especially with regard to the value of biodiversity to indigenous and local communities. The parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of LMOs, especially on indigenous and local communities (Art. 26[2]).

SUSTAINABLE USE
Use in a way and at a rate that does not lead to the long-term degradation of the environment, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

BOX 2.3

SUSTAINABLE USE (UNEP GLOSSARY, 2007)

Sustainable use

Use in a way and at a rate that does not lead to the long-term degradation of the environment, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

The Protocol contains explicit public participation and access to information provisions. Article 23 specifies that the parties shall promote and facilitate public awareness, education, and participation on issues related to LMOs and biodiversity; that they shall consult with the public in open decision-making processes about LMOs; and that they make the public aware of the information available through the BCH.

The Protocol also contains provisions on **LMO handling, packaging and transportation**. Each contracting party must take the necessary measures to ensure that LMOs subject to intentional transboundary movement within the Protocol's scope are handled, packaged and transported under safety conditions in order to avoid adverse effects on biodiversity conservation and sustainable use (Art 18[1]).

LMO HANDLING, PACKAGING AND TRANSPORTATION
Ensuring that LMOs subject to intentional transboundary movement within the Protocol's scope are handled, packaged and transported under safety conditions in order to avoid adverse effects on biodiversity conservation and sustainable use.

BOX 2.4

TRANSBOUNDARY MOVEMENT (UNEP GLOSSARY, 2007)

Transboundary movement
Movement from an area under the national jurisdiction of one state to or through an area under the national jurisdiction of another state or to or through an area not under the national jurisdiction of any state.

TRANSBOUNDARY MOVEMENT
Movement from an area under the national jurisdiction of one state to or through an area under the national jurisdiction of another state or to or through an area not under the national jurisdiction of any state.

Article 29 of the Protocol includes a governing body, the Conference of the Parties (COP), which serves as the meeting of the parties, to keep under regular review the implementation of the Protocol and make, within its mandate, the decisions necessary to promote its effective implementation.

2.2.3 The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS, 1994)

The SPS Agreement entered into force on 1 January 1995 (with the establishment of the WTO). As of January 2010 the WTO has 153 Members; all Members automatically accede to all multilateral WTO agreements and agree to use the WTO dispute resolution process.

Article 20 of the General Agreement on Tariffs and Trade (GATT) of the WTO allows governments to act on trade in order to protect human, animal or plant life or health, provided they do not discriminate or are used as a disguised protectionism.

AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES
Establishes a framework for the protection of food safety, animal and plant health in the context of all sanitary and phytosanitary measures which may directly or indirectly affect international trade.

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) establishes a framework for the protection of food safety, animal and plant health in this context.

One of the objectives of the SPS Agreement is to encourage the harmonization of **sanitary or phytosanitary measures (SPMs)** on the basis of internationally-accepted scientific standards (Article 3). Because of this, the activity of the recognized standard-setting bodies – Codex, IPPC, and OIE – is central to the SPS Agreement's implementation in the context of food safety, plant and animal life and health, respectively. The Agreement applies to all SPMs which may directly or indirectly affect international trade, and is binding upon all WTO Member States.

SANITARY OR PHYTOSANITARY MEASURES (SPMs)
The SPS agreement provides a multilateral framework of rules to guide the development, adoption and enforcement of sanitary and phytosanitary measures to minimize their negative impacts on trade.

The SPS Agreement also specifically aims to prevent Members from using SPMs as disguised trade restrictions, and notes that they must not create arbitrary or unjustified discrimination among Members where the same conditions exist. However, where conditions differ and, in particular, for developing countries, special provisions apply (Art. 10). "Special and differential treatment" may apply in these cases, allowing longer timeframes for compliance and the potential for exemptions (Art. 10[3]).

The SPS Agreement does not explicitly mention GMOs. However, when GMOs are traded internationally and may pose a threat to human, animal or plant life or health in an importing country, the SPS Agreement applies to national SPMs designed to address the threats prior to import. In general, the Agreement provides a multilateral framework of rules to guide the development, adoption and enforcement of SPMs to minimize their negative impacts on trade (Preamble, Para. 4).

The SPS agreement allows countries to set their own standards, but it also establishes that when these standards are implemented as SPMs they must be applied only to the extent necessary to protect human, animal, plant life or health (Art. 2[1]).

A **Member State's SPMs** must only be applied to the extent necessary, must be based on scientific principles and must not be maintained without sufficient scientific evidence (Art. 2[2]). SPMs must also not arbitrarily or unjustifiably discriminate between Member States where identical or similar conditions prevail and should not be applied in a manner that would constitute a disguised restriction on international trade (Art. 2[3]).

MEMBER STATE SPMs
Must only be applied to the extent necessary, must be based on scientific principles and must not be maintained without sufficient scientific evidence.

The SPS Agreement aims at enhancing trade harmonization among Member States. For this purpose, it establishes that Members should base their SPMs on international standards, guidelines and recommendations (Art. 3[1]). Using accepted international standards allows States to demonstrate that their measures are based on accepted scientific evidence and do not create unnecessary barriers to trade. The Codex Alimentarius, the IPPC and the OIE are recognized in the Preamble as relevant international standard-setting bodies.

Countries wishing to introduce standards and SPMs resulting in a higher level of protection than that offered by an international standard, guideline or recommendation are allowed to do so provided that there is scientific basis to justify the measure (Article 3.3).

Member States must ensure that SPMs are based on assessment of risks to human, animal or plant life or health according to the risk assessment techniques developed by the relevant international organizations (Article 5.1). Measures diverging from the standards adopted by the internationally-recognized organizations, or risk assessments based on techniques different from those elaborated in the framework of these organizations and resulting in greater restrictions on trade must be based on sufficient scientific evidence. Member States can also take relevant **economic factors** into account when assessing risk and establishing risk management measures (Article 5.3).

ECONOMIC FACTORS
Can be taken into account when assessing risk and establishing risk management measures. Economic measures include the potential damage to production or lost sales, the costs of control or eradication of a pest, and the relative cost effectiveness of alternative approaches to limit risks.

Economic measures include the potential damage to production or lost sales, the costs of control or eradication of a pest, and the relative cost effectiveness of alternative approaches to limit risks (Art. 5[3]). Other factors to take into consideration when establishing the appropriate level of protection should include minimizing negative trade effects, avoiding arbitrary or unjustifiable distinctions in the levels a Member State considers appropriate in different situations and ensuring SPMs are not more trade-restrictive than required for an appropriate level of protection (Art. 5 [4-6]).

Member States may provisionally adopt SPMs when scientific evidence for the measures is insufficient (Art. 5[7]). They may seek additional information to enable them to assess any risk in an objective manner and to review the SPM within a reasonable period of time. A Member State can request an explanation from another Member State when the former believes a specific SPM is constraining or could constrain its exports and is not based on an international standard, guideline or recommendation (Art. 5[8]). Members must notify changes in their SPM according to the procedure stipulated in the Annex to the SPS Agreement (Art. 7).

AGREEMENT ON TECHNICAL BARRIERS TO TRADE
Aimed at ensuring that regulations, standards, testing and certification procedures do not create unnecessary obstacles to trade. It is relevant to biotechnology products because it applies to packaging, marking and labelling requirements associated with products resulting from biotechnology.

2.2.4 The Agreement on Technical Barriers to Trade (TBT) (1994)[3]

The Agreement on Technical Barriers to Trade (TBT) is an Agreement signed under the auspices of the WTO. It is aimed at ensuring that regulations, standards, testing and certification procedures do not create unnecessary obstacles to trade. It is relevant to biotechnology products because it applies to packaging, marking and labelling requirements associated with products resulting from biotechnology.

3 Entered into force 1 January 1995 (with the establishment of the World Trade Organization).

The TBT Agreement recognizes countries´ right to adopt the technical regulations and standards they consider appropriate to achieve ¨**legitimate trade objectives**" such as national security, preventing deceptive trade practices, protecting human health or safety, animal or plant life or health, or the environment, consumers' protection and prevention against deceptive practices and other objectives such as quality, technical harmonization or simply trade facilitation, taking account of the risks of non-fulfillment (Art. 2.2). In assessing such risks, relevant elements for consideration are, *inter alia*, available scientific and technical information, related processing technology or intended end-uses of products (Annex, Art. 2.2). They should not cause unnecessary barriers to trade and should be applied equally to national and imported products (Art. 2.1).

LEGITIMATE TRADE OBJECTIVES
Include national security, preventing deceptive trade practices, protecting human health or safety, animal or plant life or health, or the environment, consumers' protection and prevention against deceptive practices and other objectives such as quality, technical harmonization or simply trade facilitation, taking account of the risks of non-fulfillment.

It applies where, for example, a country obliges imported products to include in their labels any traces of GMOs. One of its goals is to encourage the harmonization of technical regulations at international level. To this purpose, it recommends that Members use existing international standards for their national regulations, or for parts of them, unless "their use would be ineffective or inappropriate" to fulfill a given policy objective.

Whenever a technical regulation is based on an international standard, and is applied to achieve one of the legitimate objectives listed, it is presumed not to create an unnecessary barrier to trade (Art. 2.5).

Developing country Member States may adopt technical regulations, standards or conformity assessment procedures aimed at preserving indigenous technology and production methods compatible with their development needs. They are, therefore, not expected to use international standards as the basis to develop technical regulations or standards, which are not appropriate to their development, financial or trade needs (Art. 12.4).

2.2.5 Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) (1995)[4]

AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS A broad-ranging agreement aimed at ensuring effective and appropriate protection for trade-related intellectual property rights, taking into account differences in national legal systems, and drawing up a multilateral framework of minimum rules to help combat counterfeiting.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a broad-ranging agreement aimed at ensuring effective and appropriate protection for trade-related intellectual property rights, taking into account differences in national legal systems, and drawing up a multilateral framework of minimum rules to help combat counterfeiting. TRIPS harmonizes all earlier intellectual property conventions and treaties such as the Paris Convention, the Berne Convention, the Rome Convention, the Treaty on Intellectual Property in Respect of Integrated Circuits and to some extent the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. The basic principles include national and most favoured nation treatments, rights of priority and independence of patent. The principle of "independence of patents" is recognized by Article 4bis(1) of the Paris Convention that states that "[p]atents applied for in the various countries... shall be independent of patents obtained for the same invention in other countries...." (Paris Convention).

While TRIPS does not directly relate to biosafety, it interacts with other international agreements on biosafety, notably the ITPGRFA (see section 2.2.8.) and the provisions of the CPB and CBD that address technology transfer, farmers' rights, and access and benefit-sharing (ABS).

PATENT PROTECTION is required to be provided by Member States of the TRIPS Agreement for at least 20 years for inventions, whether products or processes, subject to certain exclusions.

The TRIPS Agreement requires Member States to provide **patent protection** for at least 20 years for inventions, whether products or processes, subject to certain exclusions. It also requires that patents in any field of technology be available without discrimination as to the place of invention and whether products are imported or locally produced (Art. 27.1).

4 Entered into force 1 January 1995 (with the establishment of the World Trade Organization).

There are limited exceptions to the basic rule on patentability. One is to protect human, animal or plant life or health or to avoid serious harm to the environment. Commercial exploitation of an invention in this category must also be prevented and this prevention must be necessary for the protection of *ordre public* or morality, and not simply because exploitation of the invention is prohibited (Art. 27.2).

Another exemption is for plants and animals other than micro-organisms and processes for the production of plants or animals other than non-biological and microbiological processes. However, Member States must still provide either patent protection or an effective *sui generis* system of protection (Art. 27.3[b]). This Article has generated a great deal of debate, and the TRIPS Council continues to discuss how to apply it, and particularly how it relates to the CBD.

2.2.6 The International Plant Protection Convention (IPPC) (1997)[5]

THE INTERNATIONAL PLANT PROTECTION CONVENTION
An international treaty to secure action to prevent the spread and introduction of pests of plants and plant products, and to develop and promote appropriate phytosanitary measures for their control.

The International Plant Protection Convention (IPPC) was originally adopted in 1951. It was subsequently revised in 1997 and came into force in October 2005. It is governed by the Commission on Phytosanitary Measures (CPM), which adopts International Standards for Phytosanitary Measures (ISPMs). The WTO SPS recognizes the IPPC as the organization providing international standards related to plant protection. An SPM that conforms to an international standard established by the IPPC is "deemed to be necessary to protect plant life or health" and "presumed to be consistent" with the SPS Agreement. In this way, government measures to protect plant health are harmonized and are not used as unjustified barriers to trade.

The IPPC is an international treaty to secure action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate

5 Entered into force (latest revision) on 2 October 2005. As of January 2010, 172 contracting parties.

measures for their control. It includes provisions to regulate movements of any organism, object or material capable of harbouring pests or spreading pests that affect plants or plant products (Art. I[4]). The IPPC provides a framework to develop and apply harmonized phytosanitary measures through the elaboration of international standards. It includes an obligation for every member country to designate a national plant protection organization in charge of implementing the Convention at national level and to serve as focal point for other member countries.

PESTS Defined as "any species or biotype of plant, animal or pathogenic agent injurious to plants or plant product". Therefore, the IPPC's scope of application is broad enough to include GMOs, LMOs or products of modern biotechnology that may directly or indirectly damage plants.

"Pests" are defined as *"any species or biotype of plant, animal or pathogenic agent injurious to plants or plant product"* (Art. II[1]). Therefore, the IPPC's scope of application is broad enough to include GMOs or products of modern biotechnology that may directly or indirectly damage plants. Damage to plants is not necessarily limited to cultivated plants. The IPPC can be interpreted to apply to all plants – whether cultivated or wild.

PHYTOSANITARY MEASURES Must meet minimum requirements; they must be non-discriminatory, be necessitated by phytosanitary considerations, proportional and technically justified.

The IPPC provides that phytosanitary measures can be taken for quarantine pests and regulated non-quarantine pests, but not non-regulated pests (Art. VI). **Phytosanitary measures** must meet minimum requirements: they must be non-discriminatory, be necessitated by phytosanitary considerations, proportional and technically justified. They must represent the least trade restrictive measures available and should result in the minimum impediment to the international movement of people, commodities and conveyances (Arts. VI[1] and VII[2][g]). Emergency measures are justified but must be evaluated as soon as possible to justify their continued application (Art. VII[6]). In general, import requirements must comply with minimum stakeholder related requirements between IPPC parties. Some of these include publication and transmission of import requirements, explanation of the rationale for restrictions, promptness of review, and revision of provisions when appropriate (Art. VII[2]).

The Commission on Phytosanitary Measures (CPM) of the IPPC (and previously the Interim Commission on Phytosanitary Measures) has developed a number

of **International Standards for Phytosanitary Measures (ISPM)**. Of special relevance for biotechnology is ISPM No. 11, "Pest risk analysis for quarantine pests, including analysis of environmental risks and LMOs". Annex 2 of ISPM 11 states that phytosanitary risks that may be associated with LMOs are within the scope of the IPPC, and should be considered using pest risk analysis (PRA), as described in the body of the ISPM. Annex 3 gives guidance on determining what factors associated with characteristics or properties related to the genetic modification might create the potential for phytosanitary risks from an LMO.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES (ISPM)
Concerning biotechnology: ISPM 11, stating that phytosanitary risks that may be associated with LMOs are within the scope of the IPPC, and should be considered using pest risk analysis (PRA).

A supplement to ISPM 11 Annex 3 published in 2003 adds definitions and gives further guidance on conducting risk assessments for LMOs, noting that those LMOs will not have the characteristics of a potential pest and will therefore not warrant a complete PRA. It suggests three potential pathways for an LMO to present a pest risk: (1) the organism itself; (2) the combination of genetic material; and (3) the consequences of moving genetic material (Annex III[1]). Section 1.15 provides additional details on assessing the potential of an LMO to become a pest. Additional guidance on assessing economic risks is provided in section 2.3.

2.2.7 The Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Aarhus Convention) (1998)[6]

THE AARHUS CONVENTION
An environmental agreement intended to link environmental and human rights, with a focus on the needs of future generations and a belief that sustainable development requires broad stakeholder involvement.

The Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters is a regional convention developed by Members of the United Nations Economic Commission for Europe (UNECE) and Members with consultative status with the Economic Commission for Europe (ECE). It is more commonly known as the Aarhus Convention.

6 Entered into force (latest revision) on 2 October 2005. As of January 2010, 172 contracting parties.

The Aarhus Convention is an environmental agreement intended to link environmental and human rights, with a focus on the needs of future generations and a belief that sustainable development requires broad stakeholder involvement. It highlights that government transparency and accountability are necessary for environmental protection. To that end, it addresses requirements for governments to create processes and methods for public participation in the negotiation and implementation of international environmental agreements.

The UNECE puts it thus: "The subject of the Aarhus Convention goes to the heart of the relationship between people and governments. The Convention is not only an environmental agreement, it is also a Convention about government accountability, transparency and responsiveness."

The Aarhus Convention grants the public rights and imposes on parties and public authorities obligations regarding access to information and public participation and access to justice (http://www.unece.org/env/pp/).

ACCESS TO ALL INFORMATION must be made available to the public by the competent national authority regarding decision-making processes. The public must be allowed to submit any comments, information, analyses or opinions considered relevant to the proposed activity.

The parties to the Aarhus Convention established a working group on GMOs in 2002 (Decision I/4). This working group prepared the "Guidelines on Access to Information, Public Participation and Access to Justice with respect to Genetically Modified Organisms" adopted in 2003.

The Convention is premised upon the principle that every person of present and future generations has the right to live in an environment adequate to his or her health and wellbeing. To that end, governments should guarantee the rights of access to information, public participation in decision-making and access to justice in environmental matters (Art. 1).

Competent national authorities must give the public **access to all information** relevant to the decision-making, subject to certain exceptions. The public must

be allowed to submit any comments, information, analyses or opinions considered relevant to the proposed activity.

The Convention addresses GMOs in the context of decision-making in Article 6(11). Following the modification introduced by Decision II/1 in 2005, Article 6 introduces a new system of "early and effective information and public participation prior to making decisions on whether to permit the deliberate release into the environment and placing on the market of genetically modified organisms." Per a legal opinion from the UN Office of Legal Affairs (available at http://www.unece.org/env/pp/gmo/Memo_LDJ_draft_9_Jan08.tif), it is likely that the Addendum only applies to Members who have signed it (25 as of January 2010).

The Convention establishes mechanisms for **public participation in decisions** on the deliberate release into the environment and placing on the market of GMOs with an adequate time frame, and requires that these provisions be mutually supportive of national biosafety frameworks and CPB requirements (Article 6).

PUBLIC PARTICIPATION
In decisions on the deliberate release into the environment and placing on the market of genetically modified organisms with an adequate time frame must be ensured.

Exceptions to these requirements are admitted for products already approved or for research use or culture collections approved through national biosafety regulatory frameworks and for which adequate experience exists in comparable ecosystems (Annex 1.bis).

The Aarhus Convention also specifically references the CPB and calls on its Members to ratify or accede to the CPB, but notes that the Aarhus Convention still provides an appropriate framework for public participation regarding GMOs.

2.2.8 The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) (2004)[7]

INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE
The main objectives of the Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture (PGRFA) and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security.

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) applies to all plant genetic resources relevant for food and agriculture. The main objectives of the Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture (PGRFA) and the fair and equitable sharing of the benefits arising out of their use, in harmony with the CBD, for sustainable agriculture and food security (Art. 1).

"**Plant genetic resources for food and agriculture**" are defined as "any genetic material of plant origin of actual or potential value for food and agriculture" (Art. 2). The Treaty's application to GMOs is not direct. The term "modern biotechnologies" is only referred to once in the preamble: "plant genetic resources for food and agriculture are the raw material indispensable for crop genetic improvement, whether by means of farmers' selection, classical plant breeding or modern biotechnologies, and are essential in adapting to unpredictable environmental changes and future human needs."

PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE
Are defined as "any genetic material of plant origin of actual or potential value for food and agriculture."

State parties are obliged to assess, minimize or eliminate any threats to PGRFA and to promote both *in situ* conservation and the compilation of genetic resources for preservation in public collections (Art. 5). State parties should further promote or support, as appropriate, farmers' and local communities' efforts to manage and conserve on-farm their PGRFA. This could include the use of modern biotechnologies. The Treaty mandates that parties develop and maintain measures to advance the sustainable use of plant genetic resources such as extending the genetic base of crops available to farmers and supporting plant breeding efforts that strengthen the capacity to develop varieties adapted to particular ecological conditions.

7 Entered into force 29 June 2004. As of January 2010, 120 parties.

The contracting parties recognize the enormous contribution that the **local and indigenous communities** and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world. To that end, the Treaty confers responsibility on governments to implement farmers' rights which include the protection of traditional knowledge relevant to PGRFA, the right to equitably participate in sharing benefits arising from their utilization and national decision-making about genetic resources (Art. 9). Farmers have the right to save, use, exchange and sell farm-saved seed/propagating material, but this is made subordinate to national law (Art. 9.3).

LOCAL AND INDIGENOUS COMMUNITIES particularly those in the centres of origin and crop diversity, have made and continue to make enormous contributions to the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.

State parties commit to the establishment of an efficient, effective and transparent multilateral system for access to and benefit sharing of PGRFA in a fair and equitable way and on a complementary and mutually reinforcing basis (Art. 10). The multilateral system applies to over sixty-four major crops and forages important for food security listed in Annex I to the Treaty that are under the control of the contracting parties and in the public domain (Art. 11). The contracting parties agree that **benefits arising from the use of PGRFA** that are shared under the multilateral system should flow primarily, directly and indirectly, to farmers in all countries, especially in developing countries and countries with economies in transition, who conserve and sustainably utilize PGRFA.

BENEFITS ARISING FROM THE USE OF PGRFA should flow primarily, directly and indirectly, to farmers in all countries, especially in developing countries and countries with economies in transition, who conserve and sustainably utilize PGRFA.

Article 12 stipulates conditions to the access to plant genetic resources for food and agriculture under the multilateral system. Resources may be obtained solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture, provided that such purpose does not include chemical, pharmaceutical or other non-food/feed industrial uses. The Treaty makes provision for the payment of an equitable share of the monetary benefits where a commercial product is developed using plant genetic resources accessed under the multilateral

system and the product is not available without restriction for further research or breeding. Payment is voluntary if others may use it for further research and breeding. A standard material transfer agreement prepared by the Governing Body sets the terms and conditions for ABS.

2.3 NON-BINDING INSTRUMENTS ON BIOSAFETY

NON-BINDING INSTRUMENTS ON BIOSAFETY
Non-binding agreements have often created the context and formed the basis for later binding agreements on biosafety: on other occasions, they have been "*de facto*" implemented by countries.

As is the case for binding instruments, non-binding international instruments may also address biosafety directly or address provisions related to GMOs within a broader scope. Non-binding agreements have often created the context and formed the basis for later binding agreements on biosafety; on other occasions, they have been "de facto" implemented by countries. This is the case for certain Organisation for Economic Co-operation and Development (OECD) and United Nations Environment Programme (UNEP) recommendations specifically addressing biosafety considerations, such as Agenda 21, Chapter 16. A number of other instruments seek to prevent the establishment of invasive species through guidelines on transportation, import, and release of living organisms. These include the United Nations Industrial Development Organization (UNIDO) Code of Conduct for the Release of Organisms into the Environment, and, with respect to the potential release into the environment of transgenic aquaculture species, the FAO Code of Conduct for Responsible Fisheries.

2.3.1 The Organisation for Economic Co-operation and Development (OECD) Safety Considerations for Biotechnology (1992)

THE OECD SAFETY CONSIDERATIONS FOR BIOTECHNOLOGY
Two issues are addressed: best practices for biotechnological industrial production for fermentation-derived products of biotechnology and Good Developmental Principles (GDPs) for field research with plants and microorganisms with newly introduced traits.

The 1992 Organisation for Economic Co-operation and Development (OECD) Safety Considerations follow earlier OECD work in 1986 that set out the first safety guidelines for biotechnology applications to industry, agriculture and the environment. The 1986 Recombinant-DNA Safety Considerations provided guidance to

be used in assessing field research involving GMOs. The 1992 Safety Considerations address two issues: best practices for biotechnological industrial production for fermentation-derived products of biotechnology and **Good Developmental Principles (GDPs)** for field research with plants and micro-organisms with newly introduced traits.

The Safety Considerations are intended to ensure the environmental safety of small-scale basic and initial applied research involving genetically modified plants and micro-organisms. The GDPs provide guidance to researchers on selecting organisms, choosing the research site and designing appropriate experimental conditions. They recommend step-by-step evaluation of new products, where knowledge is limited, and small-scale experiments before conducting large-scale or commercial growing operations. The Safety Considerations highlight three key factors: (1) characteristics of the organism; (2) characteristics of the research site; and (3) experimental conditions. Annex 1 provides particular scientific considerations for small-scale research with plants, including unintentional spread of plants (with the analogy of invasive species) and plant-produced toxins.

GOOD DEVELOPMENTAL PRINCIPLES (GDPs)
Provide guidance to researchers on selecting organisms, choosing the research site and designing appropriate experimental conditions. They recommend step-by-step evaluation of new products where knowledge is limited, and small-scale experiments before conducting large-scale or commercial growing operations.

BOX 2.5

AGENDA 21 (UNEP GLOSSARY, 2007)

Programme of action on sustainable development adopted [by more than 178 governments] at the UN Conference on Environment and Development [held in Rio de Janeiro, Brazil] in 1992, often referred to as the "Blueprint for Sustainable Development." Agenda 21 has 40 chapters dealing with all aspects of sustainable development, including social and economic dimensions (combating poverty and promoting human health), conservation and resource management, major groups (e.g. women, indigenous people, business and unions), and means of implementation (e.g. financial resources, transfer of technology, public awareness and education).

2.3.2 Agenda 21, Chapter 16 (1992)

AGENDA 21
Sets out a five-point programme: "(a) increasing the availability of food, feed and renewable raw materials; (b) improving human health; (c) enhancing environmental protection; (d) enhancing safety and developing international mechanisms for co-operation; and (e) establishing enabling mechanisms to develop and apply biotechnology in an environmentally sound manner".

Agenda 21 addresses the environmentally sound management of biotechnology in Chapter 16. The programme is to help foster the application of internationally agreed environmentally sound management of biotechnology principles to ensure environmentally sound management; to engender public trust and confidence; to promote development of sustainable biotechnological applications; and establish appropriate enabling mechanisms (Chapter 16.1).

Agenda 21 sets out a five point programme: "(a) increasing the availability of food, feed and renewable raw materials; (b) improving human health; (c) enhancing environmental protection; (d) enhancing safety and developing international mechanisms for co-operation; and (e) establishing enabling mechanisms to develop and apply biotechnology in an environmentally sound manner" (16.1). This programme encourages the development of biotechnology that can assist developing countries as well as industrialized countries, noting that early benefits from biotechnology accrued mainly to the latter. It suggests research into applications that increase food and feed supply and reduce environmental degradation.

At the same time, it notes that food supply questions are also related to food distribution problems, and highlights the importance of taking into account the needs of farmers; the socio-economic, cultural and environmental impacts; the need to promote sustainable social and economic development while paying particular attention to how the use of biotechnology will affect the maintenance of environmental integrity (Chapter 16.4).

The basis for action on programme area "d" includes the need for internationally agreed principles on risk assessment and management; adequate and transparent safety and border-control procedures; the primary consideration of the organism in safety assessment; the application of the principle of familiarity

in a flexible framework considering national requirements, and a step-by-step and case-by-case approach; the evolution to a more comprehensive approach based on the experiences; complementary consideration of risk assessment and risk management; and classification into contained use and release into the environment (Chapter 16.29).

BOX 2.6

PRINCIPLE OF FAMILIARITY (NAP *ET AL.*, 2003)

"[Familiarity] can be considered the ecological counterpart of the concept of 'substantial equivalence', although in some publications these two concepts are also considered separately for environmental release. Familiarity considers whether the GM plant is comparable to its traditionally bred counterpart in environmental safety. Such comparison may assess the relevant issues in a GM crop without direct experience. Familiarity considers the biology of the plant species, the trait introduced, and the agricultural practices and environment used for crop production, in comparison with a suitable counterpart, often the parental non-GM crop; the aim is to establish if the GM change presents any new or greater risks relative to the counterpart. This allows a relative level of safety to be established for the GM crop."

PRINCIPLE OF FAMILIARITY
Familiarity considers whether the GM plant is comparable to its traditionally bred counterpart in environmental safety.

The aim of the programme area is "to ensure safety of biotechnology development, application, exchange and transfer through international agreement on principles to be applied on risk assessment and management, with particular reference to health and environment considerations, including the widest possible public participation and taking into account ethical considerations" (Chapter 16.30). To manage biotechnology, governments should make existing safety procedures widely available and adapt them to local needs; further develop existing safety

procedures; compile a framework of internationally agreed principles as a basis for guidelines on biosafety; and exchange information on safety procedures and assist in emergency situations (Chapter 16.32).

STRENGTHENED ENDOGENOUS CAPACITIES IN DEVELOPING COUNTRIES Are required in order to facilitate accelerated development and application of biotechnology. This includes the need for socio-economic assessment and safety assessment, as well as national mechanisms to allow for informed comment by the public with regard to biotechnology research and application.

Programme area "e" stresses the need for **strengthened endogenous capacities in developing countries** in order to facilitate accelerated development and application of biotechnology. This includes the need for socio-economic assessment and safety assessment, as well as national mechanisms to allow for informed comment by the public with regard to biotechnology research and application. The basis for action also recognizes that biotechnological research and its application could have significant positive and negative socio-economic and cultural impacts and that these should be identified early in the development phase to appropriately manage them. One of the programme area objectives is to raise public awareness on risks and benefits related to biotechnology (16.37-39).

2.3.3 The United Nations Environment Programme (UNEP) Technical Guidelines on Biosafety (1995)

THE UNEP TECHNICAL GUIDELINES ON BIOSAFETY Provide the possibility for states to voluntarily develop mechanisms for evaluating the biosafety of "organisms with novel traits," those whose genetic make-up is unlikely to develop naturally, and to identify, assess and manage the risks associated with the use of biotechnology.

The UNEP Guidelines were adopted in 1995. They were designed and adopted as a contribution to the implementation of Agenda 21, Chapter 16. They provide the possibility for states to voluntarily develop mechanisms for evaluating the biosafety of "organisms with novel traits," those whose genetic make-up is unlikely to develop naturally, and to identify, assess and manage the risks associated with the use of biotechnology. The Guidelines acknowledge the importance of assessing socio-economic and other impacts of new biotechnologies but do not address these issues.

The Guidelines focus on human health and environmental safety for all applications of biotechnology, whether research, development or commercialization. Section II (18-27) addresses general considerations for managing applications of

biotechnology, while Section III (28-32) deals with risk assessment and risk management. The Guidelines suggest a process of hazard identification, risk assessment, and risk management.

Risk assessment and risk management can be based in part on knowledge and experience with an organism (familiarity) with the proviso that familiarity does not imply that an organism is safe, while unfamiliarity does not imply that an organism is necessarily unsafe. **Unfamiliarity** means, however, that organisms should be assessed on a case-by-case basis. With experience and knowledge, a risk assessment may apply to a group of organisms for characteristics functionally equivalent on a physiological level, and monitoring is important to gain this knowledge and experience.

UNFAMILIARITY
Unfamiliarity does not imply that an organism is necessarily unsafe; however, that organisms should be assessed on a case-by-case basis.

The development of generic risk assessment approaches or exemptions in one country does not necessarily mean that other countries will apply similar approaches. The user of the organism has the primary responsibility for the safe use or transfer of organisms with novel traits once adequate risk management strategies have been devised. The introduction of organisms with novel traits into centres of origin must be particularly considered in risk assessment and management.

The Guidelines reflect the principle that risk management should be proportional to the level of risk and the scale of the operation. Risk management measures should be taken until risks have been minimized to acceptable levels. If risk cannot be minimized either the intended operation should not proceed, or a risk/benefit analysis could be used to determine whether the higher level of risk is acceptable.

Risk assessment and management need to be undertaken by the competent authorities at national or regional level. The oversight authorities are responsible for encouraging public participation and access to information on which decisions are based.

Confidential information should be respected. The Guidelines require notification to be made to a potentially affected country where any transboundary impacts occur or where any adverse effects could affect it (Section IV, Paras. 33-39).

2.3.4 The United Nations Industrial Development Organization (UNIDO) Code of Conduct for the Release of Organisms into the Environment (1991)

THE UNIDO CODE OF CONDUCT FOR THE RELEASE OF ORGANISMS INTO THE ENVIRONMENT
Provides general principles governing standards of practice for all parties involved with the introduction of organisms or their products/metabolites into the environment.

The UNIDO Code of Conduct for the Release of Organisms into the Environment provides general principles governing standards of practice for all parties involved with the introduction of organisms or their products/metabolites into the environment (Sec. II[A][1][a]). It covers GMOs in all stages of research, development and disposal while focusing on release into the environment (Sec. I[B]).

The Code is founded upon a number of general principles. For example, Section II(C) addresses regulatory oversight and risk assessment, distinguishing process from product. The Code suggests that risk assessment should be focused on the characteristics of the resulting product rather than the molecular or cellular techniques used to produce it. Furthermore, safety precautions and monitoring procedures should be proportional to the level of assessed risk.

National authorities, industries and researchers have the responsibility to make safety information available to the public. Any unexpected or adverse public health or environmental impacts related to the GMO should be reported to appropriate authorities at national and international levels. Risk assessment should be based on "sound scientific principles" involving the participation of experts from appropriate disciplines. Systems to review proposed applications should remain flexible and adaptable in relation to the latest scientific information. Information on anticipated consequences, which may be transboundary in nature, needs to be provided to those countries that may be affected.

The **actions and responsibilities of governments** include assuring the independence of the assessment process, the use of multi-disciplinary scientific competence and using case-by-case evaluation as the rule unless sufficient experience and an adequate body of knowledge is gathered to allow classifications and general experience on GMO behaviour. Researchers have the general responsibility of evaluating risks at appropriate research and development stages. Approvals should be secured prior to the conduct of any activity involving release and unexpected or adverse impacts on public health or the environment should be notified to the appropriate national authorities. The applicant should notify and suggest alternative review mechanisms to national authorities where a regulatory procedure is not yet in place.

ACTIONS AND RESPONSIBILITIES OF GOVERNMENTS
Include assuring the independence of the assessment process, the use of multi-disciplinary scientific competence and using case-by-case evaluation as the rule unless sufficient experience and an adequate body of knowledge is gathered to allow classifications and general experience on GMO behaviour.

2.3.5 The FAO Code of Conduct for Responsible Fisheries (1995)

The FAO Code of Conduct for Responsible Fisheries is a voluntary set of principles and standards designed to ensure the effective conservation, management and development of all fisheries with due respect for ecosystems and biodiversity. It is global in scope and applies to all governments, fisheries organizations, non-governmental organizations and the private sector (Preface, Art. 1).

THE FAO CODE OF CONDUCT FOR RESPONSIBLE FISHERIES
Is a voluntary set of principles and standards designed to ensure the effective conservation, management and development of all fisheries with due respect for ecosystems and biodiversity.

In its list of general principles (Art. 6), the Code states that conservation and management decisions should be based on the best scientific evidence, taking into account traditional knowledge, as well as environmental, economic and social factors. Furthermore, the precautionary approach is to be applied to the conservation, management and development of living aquatic resources.

The Code's **aquaculture provisions** (addressed in Article 9) address the release of GMOs in the context of aquaculture operations. In accordance with the principle of "responsible development of aquaculture" (Article 9.2) government authorities, aquafarmers and fishery managers have a special obligation to minimize the risks

AQUACULTURE PROVISIONS
Address the release of GMOs in the context of aquaculture operations.

of introducing non-native species or genetically altered stocks used for aquaculture or culture-based fisheries into waters where there is a significant risk of their spreading into the waters of other states.

The use of aquatic genetic resources for the purposes of aquaculture, including culture-based fisheries, is further addressed in Article 9.3, which introduces the duty of the states to conserve genetic diversity and maintain integrity of aquatic communities and ecosystems by appropriate management. States should also conserve genetic diversity and maintain the integrity of aquatic communities and ecosystems. Specifically, states are to minimize the harmful effects of introducing "genetically altered stocks" used in aquaculture, including culture-based fisheries, into waters. This is especially important where there is significant potential for these stocks to spread into the waters of other states.

2.3.6 The Codex Alimentarius (Codex)[8]

THE CODEX ALIMENTARIUS
Is a collection of internationally adopted food standards presented in a uniform manner. The Codex Commission has been recognized as an international standard setting body for purposes of implementing the World Trade Organization's Agreement on Sanitary and Phytosanitary Measures.

The Codex Alimentarius (Codex) is a collection of internationally adopted food standards presented in a uniform manner. The Codex Commission has been recognized as an international standard setting body for purposes of implementing the WTO's Agreement on Sanitary and Phytosanitary Measures (SPS Agreement).

The purpose of the Codex Alimentarius Commission is to protect the health of consumers, to ensure fair practices in food trade, and to promote coordination of all food standards work undertaken by international governmental and non-governmental organizations. The Commission's Medium-term Objectives include *inter alia* "consideration of standards, guidelines or other recommendations as appropriate for foods derived from biotechnology or traits introduced into foods

8 Codex instruments are available for review at the Codex website for current official standards (http://www.codexalimentarius.net/web/standard_list.jsp.)

by biotechnology on the basis of scientific evidence and risk-analysis and having regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and promotion of fair practices in food trade."

The Codex Alimentarius Commission includes an *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology that was created in 1999. In 2003, the Codex Commission adopted three **standards on foods derived from biotechnology**: "Principles for the risk analysis of foods derived from modern biotechnology;" "Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants;" and "Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms."

STANDARDS ON FOODS DERIVED FROM BIOTECHNOLOGY
Adopted by the Codex Commission; includes "Principles for the risk analysis of foods derived from modern biotechnology;" "Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants;" and "Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms."

These standards establish overarching principles for the risk analysis of foods derived from modern biotechnology and the food safety assessment of foods derived from recombinant DNA plants and micro-organisms. The principles dictate a premarket assessment, performed on a case-by-case basis and including an evaluation of both direct effects (from the inserted gene) and unintended effects (that may arise as a consequence of insertion of the new gene).

It should be noted that Codex standards apply to all types of foods and, for this reason, the Codex will need to deal with foods of plant, animal, and fish origin. The impact of feeding GMO plants to animals, and the nature of the resulting foods from these animals will also need to be addressed.

As part of its work, the Codex Commission also keeps under review its relationship with other international intergovernmental organizations such as the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety (CPB).

2.3.7 Office International des Epizooties (OIE) (World Organization for Animal Health) (1924)

OFFICE INTERNATIONAL DES EPIZOOTIES (OIE) is the world organization and standard setting body responsible for animal health.

The OIE, established in 1924, is the world organization and standard setting body responsible for animal health. It has three main objectives: (1) to inform governments of the occurrence and course of animal disease and of ways to control disease outbreaks; (2) to coordinate international scientific research on the surveillance and control of animal disease and (3) to facilitate the harmonization of regulations pertaining to trade in animals and animal products.

Among its activities, the OIE establishes standards that member countries should adopt to protect themselves from diseases, without setting up unjustified sanitary barriers, and to ensure the safety of animals and animal products in transboundary movements and trade. The main normative instruments produced by the OIE are the International Animal Health Code for terrestrial animals, the Manual of Standards for Diagnostic Test and Vaccines, the International Aquatic Animal Health Code and the Diagnostic Manual for Aquatic Animal Diseases.

The OIE cooperates with the Codex Alimentarius Commission and plays an important role in acting "upstream" from other food safety quality standard setting organizations in suggesting norms, guidelines, and recommendations.[9]

In 2005, the International Committee adopted Resolution (XXVIII) on "Applications of Genetic Engineering for Livestock and Biotechnology Products". An *Ad Hoc* Group on Biotechnology was created and, in August 2008, was divided into two new ad hoc groups, one to focus on molecular diagnostics and the other on vaccines related to new and emerging biotechnologies (the *Ad Hoc* Group on Molecular Diagnostics and the *Ad Hoc* Group on Vaccinology, respectively (OIE, 2008)).

9 Resolution No. XXV, recommending that the APFSWG's 2008/2009 work programme guide the OIE's animal production food safety activities

2.4 OTHER AGREEMENTS

A number of agreements with subject matters different from biotechnology address some issues related to biotechnology, such as rules on labelling, certification, threshold levels, monitoring and traceability. These provisions may affect how biosafety agreements are interpreted or give guidance in creating legislation specific to biotechnology. Agreements dealing with animal feed may also have bearing on biosafety frameworks.

Additionally, agreements on avoiding damage from invasive species may also have some bearing on biosafety legislation, as they present means of avoiding negative impacts from introduced species. Examples are the RAMSAR Convention on Wetlands, the ASEAN Agreement and African Convention on the Conservation of Nature and Natural Resources, the FAO Code of Conduct for the Import and Release of Exotic Biological Control Agents, the ICES Code of Practice on the Introductions and Transfers of Marine Organisms and the IUCN Guide to Designing Legal and Institutional Frameworks on Alien Invasive Species.

2.5 POTENTIAL OVERLAPS AND CONFLICTS BETWEEN TREATIES

Specific international agreements may create situations that require additional interpretation and careful implementation in relation to other agreements. Several international instruments are complementary or overlap, and members are trying to establish means of working in harmony rather than duplicating efforts. Harmonization of standards is a driving factor in creating international agreements, and institutions continue to seek improved harmonization in the area of biosafety.

Areas of overlap among international instruments include requirements for risk analysis, monitoring and notification. Areas of conflict that may arise in trade situations include questions of import restrictions, labelling, liability, and ABS. This section reviews interactions among specific agreements relating to biosafety.

OTHER AGREEMENTS
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POTENTIAL OVERLAPS AND CONFLICTS BETWEEN TREATIES
Specific international agreements may create situations that require additional interpretation and careful implementation in relation to other agreements. Several international instruments are complementary or overlap, and members are trying to establish means of working in harmony rather than duplicating efforts.

BOX 2.7

VIENNA CONVENTION ON THE LAW OF TREATIES (1969)**: PRINCIPLES GOVERNING INTERPRETATION OF SUCCESSIVE TREATIES**

PRINCIPLES GOVERNING INTERPRETATION OF SUCCESSIVE TREATIES
These principles guide the application of successive treaties relating to the same subject matter.

Article 30: Application of successive treaties relating to the same subject matter

2. When a treaty specifies that it is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of that other treaty prevail.

3. When all the parties to the earlier treaty are parties also to the later treaty but the earlier treaty is not terminated or suspended in operation under article 59, the earlier treaty applies only to the extent that its provisions are compatible with those of the later treaty.

2.5.1 Potential areas of conflict: trade concerns

TRADE CONCERNS
Include concerns over what are acceptable considerations when directly limiting or restricting trade in GMOs or LMOs, as well as what measures may indirectly limit or restrict trade in ways that fail to comply with international agreements.

The main area of potential conflict in international biosafety issues concerns trade issues broadly. These relate to concern over what are acceptable considerations when directly limiting or restricting trade in GMOs or LMOs, as well as what measures may indirectly limit or restrict trade in ways that fail to comply with international agreements. There are two different potential areas of disagreement. First, there may be conflicts between what constitutes "science-based" decision-making, what are the proper tools to use to assess risks, and what role precautionary policies can play in decisions. Second, there is the question of how institutions can respond to citizen, producer, and consumer concerns that go beyond direct harm to environmental or human health. Questions of labelling and liability legislation fall into this second category.

In fact, international conflicts have already arisen over restrictions on GMO approvals, as with the United States leading a group that challenged the European Commission (EC) de facto moratorium on GMO approvals at the WTO (see Box 2.8 for a discussion of this case). Other debates exist over efforts to harmonize standards for labelling and the related issues of certification, traceability, and monitoring. Liability and redress standards have been an area of contention in CPB COP/MOP meetings. In addition, there are potential conflicts over ABS and intellectual property rights protection.

Where states are party to two or more potentially conflicting agreements, minimizing conflicts requires careful navigation and interpreting agreements in the most mutually supportive fashion possible (Oberthür and Gehring, 2006).

BOX 2.8

THE WTO BIOTECH DISPUTE (EXCERPTED FROM SPREIJ, 2007)

One of the most awaited cases in WTO history has undoubtedly been the *Biotech* dispute. Because of its complexity, the dispute encountered several delays but on 29 September 2006,(...) the Panel Report was issued to the public. It was the lengthiest report in WTO history. Publication of the report was followed by much debate, in particular within the EC, which eventually decided not to appeal the report. On 21 November 2006, as mentioned above, the DSB formally adopted the report.[...]

In the beginning of the 1990s, in accordance with its legislation, the EC authorized a number of GMOs for commercial release into the environment for different uses, some for cultivation, others as food or feed. By the mid-90s, however, several EC Member States started to express concerns. They believed that the existing

THE WTO BIOTECH DISPUTE
Relates to a dispute over trade restrictions between the EC, which had established a de facto moratorium on GMO approvals, and major GMO producers such as the USA, Canada and Argentina.

regulatory framework was not adequate, in particular with regard to issues such as risk assessment, labelling and traceability. As a result of these concerns, and in reaction to rapid scientific developments and the negotiation of the Protocol, no new GMOs were approved under the legislation in force during the period October 1998 until May 2004. By that time, the EC had adopted a new set of rules (...)

However, in August 2003, just a few weeks before the Protocol entered into force, the United States, Canada and Argentina, all major GMO producers and exporters, requested the establishment of a panel under the WTO dispute settlement procedure. In short, the countries claimed that:

- the EC had implemented a general de facto moratorium;
- the EC had failed to approve specific GM products;
- the EC Member States had prohibited products which had been approved by the EC after consideration by its own scientific regulatory approval process;
- the moratoria and the national prohibitions constituted an unjustified barrier to their trade in agricultural and food products, thus violating the SPS Agreement as well as GATT. Some of the complaints also alleged violations of the TBT Agreement.

The panel analysed the scope of the SPS Agreement and found that the EC approval procedures were - in fact - SPS measures.

It also found that the EC had "de facto" established a moratorium, however that this moratorium was not an SPS measure *per se* but rather affected the operation and application of the EC approval procedures. In addition, it found that the EC's failure to complete its approval procedures without "undue delay" was inconsistent with the Agreement's provisions on control, inspection and approval procedures (Article 8 and Annex C).

The panel also ruled on the prohibitions that a number of EC Member States – Austria, France, Germany, Greece, Italy, Luxembourg and the United Kingdom- had imposed on the importation, marketing or sale of a number of biotech products which had already been approved at Community level. The panel found that these prohibitions were also SPS measures and could not be regarded as provisional SPS measures (Article 5.7) - as the EC had argued - because there was sufficient scientific evidence available to conduct a risk assessment. In fact, risk assessments had been conducted under the EC scientific regulatory approval process and resulted in positive opinions. Consequently, the prohibitions were not based on these risk assessments and although some Member States submitted additional reports and studies, the panel considered that the additional documentation did not constitute a proper risk assessment. These prohibitions thus violated the SPS Agreement (Article 5.1).

Of particular interest is that the panel took a wide view of the SPS Agreement and found that a broad range of measures to protect biodiversity fall within its scope, including cross-contamination of plants by GM plants, reduction of the economic value of crops, effects on non-target insects and plants, etc. The panel considerations on the applicability of the SPS Agreement are contained in paragraphs 7.147 to 7.437 of the report.

The panel also addressed the issue of the application of the CBD and the Protocol (paragraphs 7.49 to 7.96). Generally, claims under the WTO dispute settlement mechanism can only be based upon violation of WTO Agreements but - under certain circumstances - other international agreements can be taken into account in the interpretation of WTO Agreements or be used as a defence. For instance, a country can admit to have violated the SPS Agreement but declare that it did so because it had to implement another international

agreement to which it is a party. The panel considered that if a rule of international law is not applicable to one of the parties to the dispute, it is not applicable in the relations between all WTO Members.

Given that the United States was not a party to the CBD, the panel ruled that it was not required to take the CBD into account in interpreting the WTO Agreements at issue in the dispute. Similarly, the panel considered that it was not required to take the Protocol into account since Argentina, Canada and the United States were not parties to it. Moreover, the panel noted that the Protocol had entered into force after the panel was established.

Apart from the panel findings on the applicability of the SPS Agreement, it should be noted that the report in itself is a narrow and specific ruling. The panel did not rule on a number of important questions that remain outstanding.

For instance, it did not examine:

- whether biotech products in general are safe or not;
- whether the biotech products at issue in the dispute are "like" their conventional counterparts; Although this claim was made by the complaining parties in relation to some aspects of their complaints, the panel did not find it necessary to address those aspects of the complaints since the EC and the Member States violated the SPS Agreement; the thorny "like" issue would certainly have come up in considering violations of the TBT Agreement and/or GATT.
- whether the EC has a right to require pre-marketing approval of biotech products;
- whether the EC approval procedures are consistent with the EC's obligations under the WTO Agreements;
- the conclusions of the relevant EC scientific committees regarding the safety evaluation of specific biotech products.

2.5.2 Interactions among specific agreements

The multilateral WTO agreements that form part of international biosafety frameworks – GATT, TBT, and in particular TRIPS and SPS – are the ones that have the most complex interrelationships with other instruments. The WTO is an unusual international instrument in that it has its own dispute resolution mechanism, which sets up a dispute resolution panel to deliver a binding verdict on disputes between or among Members.

INTERACTIONS AMONG SPECIFIC AGREEMENTS
The multilateral WTO agreements that form part of international biosafety frameworks – GATT, TBT, and in particular TRIPS and SPS – are the ones that have the most complex interrelationships with other instruments.

The WTO relies on certain other international instruments to serve as standard-setting instruments. If regulations are in compliance with these other instruments, they are assumed to be in compliance with WTO rules, as well. Codex Alimentarius and the IPPC have this standard-setting relationship with the WTO for food safety and plant health standards, respectively, while the OIE addresses animal health and trade in animals and animal products. OIE also informs the Codex.

Interpretations of the SPS could generate **conflict with interpretations** of other international instruments, particularly the CBD and CPB, as well as national biosafety frameworks. As the SPS is predicated on "science-based" risk assessment and strictly limits precautionary decision-making, it may come into conflict with biosafety instruments based on precautionary approaches. SPS Article 5(7) states that inadequacy of available data for decisions may allow states to adopt provisional SPM, but only if they actively seek the necessary scientific information to support those measures and review the measures within a "reasonable period of time."

CONFLICT WITH INTERPRETATIONS
Regarding the SPS agreement: as the SPS is predicated on "science-based" risk assessment and strictly limits precautionary decision-making, it may come into conflict with biosafety instruments based on precautionary approaches, such as the CBD and CPB.

It was under the SPS agreement of the WTO that the United States (along with Canada and Argentina) challenged the EU de facto moratorium on GMO approvals. Similar challenges could arise for other biosafety legislation if it does not conform to SPS requirements. However, risk assessment standards included in the CPB may minimize future conflicts, given that these standards conform substantially to those foreseen by the SPS (Burgiel, 2002).

2.5.3 Intellectual property rights and access and benefit-sharing (ABS)

INTELLECTUAL PROPERTY RIGHT PROTECTION
TRIPS does not deal specifically with GMOs, but they fall under its purview where developers of a product seek intellectual property right protection (which is the case for nearly all commercialized GMOs). TRIPS requirements have definite potential to come into conflict with access and benefit-sharing (ABS) provisions in the ITPGRFA, the CBD, and the CPB.

TRIPS does not deal specifically with GMOs, but they fall under its purview where developers of a product seek intellectual property right protection (which is the case for nearly all commercialized GMOs). TRIPS requirements have definite potential to come into conflict with ABS provisions in the ITPGRFA, the CBD, and the CPB, all of which attempt to protect farmers' rights and prevent uncompensated use of traditional knowledge systems and biodiversity resources.

Recognizing and seeking to avoid the potential for conflicts, the Doha Ministerial (of the WTO) entrusted the Council for TRIPS a work programme to review, *inter alia*, the relationship between the TRIPS Agreement and the CBD, regarding the protection of traditional knowledge and folklore.

The International Union for the Protection of New Varieties of Plants (UPOV) shares goals with TRIPS and therefore faces similar potential conflicts. These goals are to encourage innovation and investment through protection of intellectual property rights.

ITPGRFA does not conflict with this goal, but seeks additional protection for the original human-biodiversity systems that generated products used in the development of patent-protected varieties, including through ABS provisions. The provisions of the three agreements, however, may be interpreted in mutually-compatible ways (Gerstetter *et al.*, 2007).

The CBD, like the ITPGRFA, seeks to implement ABS provisions that protect farmers and developers/conservers of traditional knowledge and biodiversity systems. The ITPGRFA specifically references the CBD, stating that "The objectives of this Treaty are the conservation and sustainable use of plant genetic resources for food

and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security [and that] These objectives will be attained by closely linking this Treaty to the Food and Agriculture Organization of the United Nations and to the Convention on Biological Diversity" (Part 1, Art. 1.1, 1.2). Again, depending on how TRIPS IPR and CBD ABS provisions are implemented, there may be conflicts over who enjoys intellectual property rights and what the responsibilities are for benefit sharing, but it is possible to interpret the rules to minimize conflict (Gerstetter *et al.*, 2007).

Table 2.1 | **Possible trade scenarios**

Country status *vis-à-vis* international agreements	**Status of trading partner**			
	Signatory to CPB and WTO	CPB, no WTO	WTO, no CPB	No WTO, no CPB
Signatory to CPB and WTO	Follow the norms of the Protocol and of WTO, attempt to minimize incompatibilities	Bilateral or regional accords compatible with the Protocol	Follow WTO norms, adopt bilateral or regional accords compatible with the Protocol	Bilateral or regional accords compatible with Protocol and WTO
CPB, no WTO	Follow WTO norms, adopt bilateral or regional accords compatible with the Protocol	Follow requirements of the Protocol	Bilateral or regional accords compatible with Protocol and WTO	Bilateral or regional accords compatible with the Protocol
WTO, no CPB	Follow WTO norms, adopt bilateral or regional accords compatible with the Protocol	Bilateral or regional accords compatible with Protocol and WTO	Follow WTO norms	Bilateral or regional accords compatible with WTO
No WTO, no CPB	Bilateral or regional accords compatible with Protocol and WTO	Bilateral or regional accords compatible with the Protocol	Bilateral or regional accords compatible with WTO	Compliance with the requirements of the importing country

Adapted from: Sarquis (2004).

POSSIBLE TRADE SCENARIOS
All possible trade scenarios and the country status *vis-à-vis* the discussed international agreements relating to trade are provided.

BOX 2.9

ACCESS AND BENEFIT-SHARING IN THE NAGOYA PROTOCOL

On 29 October, 2010, at its tenth meeting, and after six years of negotiations, the Conference of the Parties to the CBD adopted the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* (Nagoya Protocol). The Nagoya Protocol will enter into force 90 days after it has been ratified by at least 50 Parties.[10]

As noted in section 2.2.1 of this module, the CBD has three main objectives: (1) conservation of biological diversity, (2) the sustainable use of its components, and (3) the fair and equitable sharing of the benefits from the use of genetic resources. The Nagoya Protocol is "the instrument for the implementation of the access and benefit-sharing provisions of the Convention" (Article 4.4), and provides clarification on how to achieve the third objective.

The Nagoya Protocol is intended to provide legal certainty for both providers and users of genetic resources and associated traditional knowledge, and to ensure that providers of genetic resources receive a fair share of the benefits derived from their use (monetary and non-monetary). The Nagoya Protocol defines detailed and specific obligations to develop appropriate national legal frameworks governing access and benefit-sharing, and provides specifications on "prior informed consent" procedures,

10 Article 27(1) of the Nagoya Protocol: This Protocol shall enter into force on the ninetieth day after the date of deposit of the 50th instrument of ratification, acceptance, approval or accession by States or regional economic integrations that are Parties to the Convention.

"mutually agreed terms" and on access and benefit-sharing in relation to genetic resources and associated traditional knowledge held by indigenous and local communities (Articles 5, 6, 7, 8). It introduces a number of obligations to improve domestic legislation including effective dispute resolution and access to justice requirements in access contracts (Article 21), and by developing national model contractual clauses, codes of conduct, guidelines, and best practices (Articles 19, 20).

The Nagoya Protocol furthermore establishes obligations to comply with domestic access and benefit-sharing legislation of the Party that supplies the genetic resources and associated traditional knowledge (Articles 15, 16), including indigenous and local customary laws and procedures, in accordance with domestic law (Article 12).

The Nagoya Protocol lists a number of ways to facilitate its implementation, including through: capacity building, in particular for the least developed countries, small island developing States, transitional economies, and indigenous and local communities and stakeholders (Article 22); an ABS Clearing-House mechanism (Article 14); creation of national focal points and competent national authorities on access and benefit-sharing (Article 13); designation of checkpoints in relation to monitor the utilization of genetic resources (Article 17); technology transfer (Article 23); and awareness raising (Article 21).

2.5.4 Labelling issues related to international agreements

LABELLING ISSUES RELATED TO INTERNATIONAL AGREEMENTS
The main issue related to labelling arises over the different regulatory triggers for GMO regulation.

The main issue related to labelling arises over the different regulatory triggers for GMO regulation. Countries that consider specific, approved GMOs as products that are equivalent to their non-GM counterparts (the "product, not process" view) likewise question the need to label these products. This is particularly pertinent for regulations that require labelling for GM feed and other processed products that no longer contain GM material in the finished product.

Other countries, particularly those that use process as a trigger and take more precautionary positions (notably, the EU), claim that labelling is an important consumer information tool that is justified under the TBT agreement's authorization for non-discriminatory measures to achieve legitimate national objectives. It is possible that these differences will lead to a challenge at the WTO dispute settlement body.

In contrast to the WTO agreements, of which the effects on labelling are still unclear, the CPB has definite labelling requirements, as discussed in section 2.2.2. These do not affect national (or regional) labelling requirements, but do apply to internationally-traded LMOs intended for use as food, feed or for processing (but not processed foods containing GMOs). The CPB requirements originally required only a "may contain" label for shipments that could contain LMO-FFPs; since March 2006, however, any shipment containing LMO-FFPs identified through an identity preservation (IP) system must state the type of LMO and use a "does contain" label. For shipments where the contents are uncertain, the "may contain" label continues to apply (Gruère and Rao, 2007).[11]

11 Further descriptions of these requirements are available at http://www.cbd.int/biosafety/COP/MOP/result.aspx?id=8288, MOP BS-I/6, elaborating on CPB Article 18.

2.6 CONCLUSIONS: CHAPTER 2

Beyond the Cartagena Protocol on Biosafety, other international agreements, conventions and treaties, such as the WTO SPS and TBT Agreements and the Codex Alimentarius on food standards, governed by the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations may impact directly or indirectly on the development of a national biosafety regulatory system. It is important that obligations under these agreements be considered when developing biosafety regulations, particularly for those countries that anticipate exporting GMOs. Where possible, attempts should be made to harmonize with risk assessment criteria and standards that have achieved international acceptance in either practice or principle.

CONCLUSIONS: CHAPTER 2
The discussed agreements may impact directly or indirectly on the development of a national biosafety regulatory system. It is important that obligations under these agreements be considered when developing biosafety regulations, particularly for those countries that anticipate exporting GMOs.

Table 2.2 | **Interactions among selected biosafety-related instruments**

Interactions	SPS	TBT	TRIPS	CBD	CPB	IPPC	Codex	Precautionary*	Product-based*
SPS	=	O	O	C	C	O	O	C	O
TBT	O	=	O	C	C	O	O	C/O	O
TRIPS	O	O	=	C	C	N/A	N/A	C	O
CBD	C	C	C	=	O	O	U	O	O,C
CPB	C	C	C	O	=	O	U	O	O,C
IPPC	O	O	O	O	O	=	U	U	O
Codex	O	O	N/A	U	U	U	=	O	O
Precautionary	C	C/O	C	O	O	U	O	=	C
"Product-based"	O	O	O	O,C	O,C	O	O	C	=

= the agreements are the same or completely compatible
O: the agreements are compatible, overlapping, or complementary
C: the agreements exhibit elements of conflict
U: unclear or not applicable
Some agreements may have both elements of compatibility and conflict. These are discussed further in the text.
* Precautionary refers to national and subnational frameworks that take a precautionary approach; "product-based" refers to those that take a product-based, or "science-based", approach.

INTERACTIONS AMONG SELECTED BIOSAFETY-RELATED INSTRUMENTS
A summary of all interactions between the discussed instruments, i.e. whether they are compatible, complementary or provide areas of conflict, is provided.

CHAPTER 3

CONSIDERATIONS OF LEGAL RELEVANCE TO DRAFTING NATIONAL FRAMEWORKS ON BIOSAFETY

CONSIDERATIONS OF LEGAL RELEVANCE TO DRAFTING NATIONAL FRAMEWORKS ON BIOSAFETY
This section discusses the relationship between international and national legal frameworks on biosafety and biotechnology, then addresses the intent and purpose of adopting national legal frameworks on biosafety.

The relationship between international and national legal frameworks dealing with biosafety and agricultural biotechnology is critical, as in most national legal frameworks it is through adoption into national regulatory frameworks that international agreements are put into practice. This section discusses that relationship, then addresses the intent and purpose of adopting national legal frameworks on biosafety. It next discusses the elements that countries must take into consideration when establishing their national biosafety frameworks, including the principles and approaches that they must consider, regulatory triggers for implementing legislation and approaches to addressing risk. Implementation of risk analysis, an important element of most legal frameworks on biosafety, as well as other available approaches to dealing with potential biosafety and other risks of biotechnology are then discussed.

The importance of transparency, communication, and public participation throughout the process is highlighted, along with monitoring and compliance requirements,

including the issue of liability and redress. Next the section addresses the issue of labelling, which has been an area of contention in international and state institutional relations. Finally, it covers issues of identity preservation, traceability, and monitoring.

3.1 RELATIONSHIP BETWEEN INTERNATIONAL AND NATIONAL BIOSAFETY FRAMEWORKS

RELATIONSHIP BETWEEN INTERNATIONAL AND NATIONAL BIOSAFETY FRAMEWORKS
Provisions of international instruments are most often not self-executing. International and national legal systems may require ratification by the parliament, and/or implementation through national legal instruments. This means that national legislation and regulations may be necessary to make agreements operational in national legal systems.

Provisions of international instruments are most often not self-executing. International and national legal systems may require ratification by the parliament, and/or implementation through national legal instruments. This means that national legislation and regulations may be necessary to make agreements operational in national legal systems. When existing national measures are insufficient, this may be done by amending existing measures or adopting new ones. Such measures should include all necessary elements to ensure appropriate implementation, including an administrative framework with appropriate decision-making powers.

States that are party to any international treaty are bound by that treaty and must comply with its obligations under the treaty. The party may itself decide on the legal, institutional and other means through which to achieve implementation. The tools generally used by states for this purpose are a national legal framework setting out rights and obligations for persons under its jurisdiction which aim at ensuring the implementation of the international instruments and an institutional framework to apply and enforce the national legislation (MacKenzie *et al.*, 2003).

Whether measures should be implemented through national laws or through regulations will depend on the internal law of the state concerned. Certain matters usually have to be dealt with by law, notably the establishment of offences and penalties. Others can be dealt with at the level of regulations issued by the relevant ministry or department that can be updated and amended more easily.

3.2 PURPOSES OF BIOSAFETY AND BIOTECHNOLOGY LEGISLATION

PURPOSES OF BIOSAFETY AND BIOTECHNOLOGY LEGISLATION
International and national biosafety frameworks, instruments, guidelines and regulatory systems reflect the need to protect human health and the environment from possible adverse effects of the products of modern (bio)technology.

International and national biosafety frameworks, instruments, guidelines and regulatory systems reflect the need to protect human health and the environment from possible adverse effects of the products of modern (bio)technology. Complex scientific, legal, social, environmental, health and economic issues have to be taken into account when developing or strengthening legal or regulatory frameworks for biosafety.

To understand the challenges of legal frameworks on biosafety, it is important to identify the interests and potential conflicts behind the areas that need to be covered. Institutions pass biosafety legislation to address biosafety specifically. They also pass biosafety and other biotechnology legislation to address a range of socio-economic issues that are important to their citizens. These include issues related to consumer protection, consumer information, labelling, trade, development, intellectual property rights, patenting, liability, ethical questions and food sovereignty. Some instruments attempt to address two or more of these issues (see Annex 2 for a chart listing the main issue areas addressed by different international agreements).

ISSUES ADDRESSED BY DIFFERENT INTERNATIONAL INSTRUMENTS
In relation to biosafety include environmental protection, human health and food safety, and consumer protection. Agreements also deal with public information, participation, and access to information and technologies.

Issues addressed by different international instruments which may relate to biosafety include environmental protection, human health and food safety and consumer protection. They also deal with public information, participation and access.

Many instruments serve more than one of these functions:

» **Environmental health and biodiversity:**
Instruments directly addressing these issues include IPPC, CBD, CPB, ITPGRFA. Indirectly affecting issues of environmental health and biodiversity are the Aarhus Convention, SPS, TBT.

» **Health and food safety:**
Codex Alimentarius, CPB, SPS, and TBT all directly address issues of human health and food safety.
The Aarhus Convention and CPD can be indirectly related to these and connected areas.

» **Consumer and citizen information and participation:**
Codex, the TBT, and the Aarhus Convention directly address consumer and citizen issues, while CBD, CPB and Aarhus all attempt to improve citizen information and participation provisions.

3.3 NATIONAL LEGISLATIVE FRAMEWORKS TO ADDRESS BIOSAFETY

Any biosafety regulatory system is based on the enabling legislation (acts, laws, decrees, and government orders) governing biosafety. At the national level, this derives from the authority to promulgate regulations, preempt subnational authorities, intercede in trade or domestic movements, and create enforcement agencies. The establishment of regulations (or executive orders) is necessary for enacting prohibitions, restrictions, permits and requirements under the authority of national legislation.

National regulatory frameworks also include guidelines and administrative procedures such as notification or information requirements. These policy instruments may be **mandatory or voluntary**. Voluntary instruments are generally easier and faster to adopt, and can be quite effective. However, in the absence of a binding legal instrument, the public may not have confidence that the government is adequately regulating products of biotechnology, or that developers are complying with voluntary guidelines.

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MANDATORY OR VOLUNTARY INSTRUMENTS
Voluntary instruments are generally easier and faster to adopt, and can be quite effective. However, in the absence of a binding legal instrument, the public may not have confidence that the government is adequately regulating products of biotechnology, or that developers are complying with voluntary guidelines.

National regulatory frameworks also need to address how notifications are handled. The CPB AIA requirements (see section 2.2.2; chart 1) should guide signatories to the CPB. Handling of notifications should, in any case, address information required in the notification (for example, name of the GMO/LMO), risk assessment (and determination of party or parties responsible for conducting the risk assessment), time frame for making decision, procedures for communicating decision and means for provision of public information and participation.

ELEMENTS OF NATIONAL BIOSAFETY LEGISLATION
Should include, as proposed by the UNEP Biosafety Toolkit: (1) biosafety policy providing an overarching framework and clear principles; (2) a regulatory regime; (3) means to address notifications or requests for authorizations; (4) means for enforcement and monitoring; and (5) public information, education and participation mechanisms.

Countries electing to develop national legislation on biosafety have different choices: (1) they can develop a framework act and implementing regulations to specifically address GMOs; or (2) they can review existing legal instruments, potentially introducing new provisions to regulate GMOs. The advantages of the former are specificity, flexibility and transparency. The disadvantages are the political difficulty and time required to adopt new legislation.

3.4 ELEMENTS OF NATIONAL BIOSAFETY LEGISLATION

Biosafety legislation at the national level should cover a number of elements. First, it should serve to implement the international binding agreements to which the country is signatory, and those elements of the non-binding agreements that the country has decided to implement. Countries choosing to regulate GMOs under the auspices of existing legal instruments should likewise determine that their existing legislation is in compliance with any international agreements to which they are signatories. Again, for most countries adopting legislation, the main agreements of interest will be the CBD/CPB and the WTO SPS and TBT agreements. Second, it must include all the national provisions necessary to foster or ensure implementation at national level.[1]

1 For a full discussion of national biosafety legislation implementation in accordance with the Cartagena Protocol, including case studies, see the United Nations Environment Programme's web site on biosafety at http://www.unep.org/biosafety/Default.aspx

The UNEP biosafety toolkit identifies five core components that every national biosafety framework should address: (1) biosafety policy providing an overarching framework and clear principles; (2) a regulatory regime; (3) means to address notifications or requests for authorizations; (4) means for enforcement and monitoring; and (5) public information, education and participation mechanisms.[2]

General operational principles to consider when creating biosafety frameworks include making the approach (1) preventative of harm; (2) responsive to unexpected events; (3) effective and efficient; (4) equitable; and (5) inclusive. Policies should be coherent and transparent. The remainder of this section addresses policies, principles, and components of biosafety frameworks, with a particular view to how national and international agreements relate and interact.

GENERAL OPERATIONAL PRINCIPLES
To consider when creating biosafety frameworks include making the approach
(1) preventative of harm;
(2) responsive to unexpected events;
(3) effective and efficient;
(4) equitable; and
(5) inclusive.

3.5 REGULATORY TRIGGERS

Determination of exactly what and how to regulate depends on the national policy on GMOs. Governments can consider GMOs as intrinsically novel, due to the techniques and process of their transformation, or as similar to other products of animal and plant breeding. Therefore, regulatory triggers can include either the product or the process by which it is developed.

REGULATORY TRIGGERS
Determination of exactly what and how to regulate depends on the national policy on GMOs; regulatory triggers can include either the product or the process by which it is developed.

It is generally acknowledged that product attributes define the associated risks, but many states and biosafety instruments utilize the process of genetic engineering as the de facto trigger for regulatory oversight. For example, the CPB addresses biosafety concerns that may be associated with the products of modern biotechnology, irrespective of the trait or traits that a GMO may express. Even some national frameworks based on the idea of "product, not process", such as the United States, include some elements of process-based regulation.

2 UNEP proposed format for preparation of a draft national biosafety framework, http://www.unep.org/biosafety/Toolkit.aspx

In the area of research on GMOs, where the final product attributes remain uncertain, international instruments and national biosafety frameworks include guidelines specifying levels of physical containment and health and safety procedures to be followed when undertaking research involving genetic manipulation. These usually include a system of mandatory notification and/or environmental risk assessment prior to the approval of experimental field trials, and standards for reproductive isolation and monitoring in order to minimize any impact on the environment or accidental release of genetically modified material.

3.6 RISK ANALYSIS

RISK ANALYSIS
Risk analysis is generally defined as a process comprising risk assessment, risk management and risk communication. Please refer to Module C for a detailed discussion of the process.

Risk analysis is generally defined as a process comprising risk assessment, risk management, and risk communication. Scientific risk assessment is the cornerstone of biosafety regulatory systems and public-policy decisions related to the safety and acceptability of GMOs. A strong scientific capacity and knowledge base is viewed as key to identifying hazards and assessing their impacts and likelihood of occurring. Nearly all of the international biosafety agreements discussed earlier highlight the importance of risk analysis; science-based risk assessment is recommended in the UNIDO Voluntary Code of Conduct, the WTO SPS, the Codex Statements of Principle Concerning the Role of Science in the Codex Decision-making Process, the CPB, and several FAO draft Codes of Conduct, among other agreements.

Risk assessment often addresses only biosafety issues strictly related to environmental and human health, leaving socio-economic, ethical and cultural issues to be addressed through other mechanisms. There may be cases where other factors are essential for making final decisions; these considerations are generally separated from the scientific risk assessment process, but may be considered during the risk management phase of risk analysis. This is the approach taken by the CPB, where socio-economic considerations are discussed in Article 26, separate from the articles addressing risk assessment.

BOX 3.1

STANDARDS FOR RISK ASSESSMENT

International agreements describe characteristics required for risk assessments to be considered adequate. Two important descriptions for standards for risk assessment are found in the WTO SPS and the Cartagena Protocol.

In the **SPS Agreement**, Article 5 specifies elements for consideration in risk assessment:

(2) In the assessment of risks, Members shall take 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.

(3) In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

The **Cartagena Protocol on Biosafety**, Article 15(1) states: Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on

STANDARDS FOR RISK ASSESSMENT International agreements describe characteristics required for risk assessments to be considered adequate. Two important descriptions for standards for risk assessment are found in the WTO SPS and the Cartagena Protocol.

information provided in accordance with Article 8 [on notification] and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Annex III outlines the factors to be considered in risk assessments, and notes the following general principles:

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.
4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.
5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.
6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

While risk evaluation is based on the available scientific data, risk management may also address other considerations such as social concerns or quantifiable economic impacts. Some international agreements, such as the CPB and the SPS, note economic concerns. In such cases, many institutions have attempted the creation of a regulatory structure that allows separation of the scientific risk assessment and regulatory decision-making processes to the extent possible. Such a **tiered approach** provides a system in which the regulatory decision is "informed," both by the scientific risk assessment and by other considerations.

TIERED APPROACH describes attempts to create a regulatory structure that allows separation of the scientific risk assessment and regulatory decision-making processes to the extent possible; the regulatory decision is "informed," both by the scientific risk assessment and by other considerations.

The drawback of this approach concerns the extent to which decisions may be subject to "political interference" or impinge on existing international trade agreements. Questions also remain about the possibility of separation of science and politics in practice. Adequate transparency, openness, and objectivity are key to the successful implementation of such an approach. Most biosafety frameworks do not attempt to include broader **socio-economic considerations** (excluding economic consequences) into the process for individual product approvals. These important considerations are instead dealt with by establishing expert bodies responsible for providing governments with policy advice on ethical, legal, or social issues related to the adoption of new technologies. The exploration of these issues can serve both to develop a public consensus on the acceptability of various technologies and to guide the evolution of a policy framework for regulation.

SOCIO-ECONOMIC CONSIDERATIONS are excluded from most biosafety frameworks; instead, these important considerations are dealt with by establishing expert bodies responsible for providing governments with policy advice on ethical, legal, or social issues related to the adoption of new technologies.

In tiered systems, it is generally the risk management phase of risk analysis that provides an opportunity to consider some of these issues. The underlying principle of risk management is to identify and take steps to eliminate or minimize to an acceptable level any risks identified in the risk assessment. Risk management strategies vary with circumstances and can embrace a number of techniques ranging from an outright ban to softer approaches that might include educating users of the proper application of an end product. In particular, post-approval monitoring, labelling and traceability can be used within risk management strategies and are described below.

As is the case with risk assessment, additional principles have been recognized by the international community that provide a framework for the application of risk management, especially as it relates to international trade. The need for risk management measures to be "necessary" and where implemented, "proportional" to the risks identified are two principles that share the widest recognition at the international level. Calls for necessity and proportionality are common to both biosafety and food safety instruments (Glowka, 2003). Among others, the WTO SPS and TBT Agreements require that risk management measures be non-discriminatory, necessary, proportional, and justified.

Risk communication has developed from a one-way, post-decision process to a multi-party, iterative process that occurs throughout the stages of risk analysis. It is closely related to efforts to increase public awareness and knowledge and to enhance public participation. Several international agreements related to biosafety contain specific references to risk communication as part of the risk analysis process (Box 3.2).

3.6.1 Approaches to risk analysis

APPROACHES TO RISK ANALYSIS
Different frameworks on biosafety approach the question from different perspectives; please also refer to *Module C for further information.

Different frameworks on biosafety approach the question from different perspectives. Some take the position that there is no special novelty associated with GMOs, particularly in cases where there is *familiarity* with the host and recipient organisms. In such cases, they hold that there should be an assumption of *substantial equivalence* unless the product itself exhibits unexpected characteristics, and that, concomitantly, no additional information provision is warranted unless there are questions related to allergenicity or public health (as with crops or animals altered to produce pharmaceutical products, for example).

BOX 3.2

RISK COMMUNICATION

From **Codex Alimentarius**, Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003) (amended 2008, www.codexalimentarius.net/download/standards/10007/CXG_044e.pdf):

22. Effective risk communication is essential at all phases of risk assessment and risk management. It is an interactive process involving all interested parties, including government, industry, academia, media and consumers.

23. Risk communication should include transparent safety assessment and risk management decision-making processes. These processes should be fully documented at all stages and open to public scrutiny, whilst respecting legitimate concerns to safeguard the confidentiality of commercial and industrial information. In particular, reports prepared on the safety assessments and other aspects of the decision-making process should be made available to all interested parties.

24. Effective risk communication should include responsive consultation processes. Consultation processes should be interactive. The views of all interested parties should be sought and relevant food safety and nutritional issues that are raised during consultation should be addressed during the risk analysis process.

RISK COMMUNICATION
According to the Codex Alimentarius: Effective risk communication is essential at all phases of risk assessment and risk management. It is an interactive process involving all interested parties, including government, industry, academia, media and consumers.

This position is generally associated with an approach that follows conventional risk assessment, with scientific risk assessment addressing biosafety issues exclusively, followed by risk management to determine how to address issues raised during risk assessment. This approach leads to the view that there is no reason to restrict trade in GMOs unless particular risk characteristics have been identified.

By contrast, other institutions base their approach on the novelty of the process of genetic modification, and use the concept of "substantial equivalence," if at all, as a tool in the risk analysis process. Instead, they prioritize *precaution* and *prevention* of risk. Many seek to incorporate concerns beyond those that could be defined strictly as biosafety (that is, risks to human and environmental health). Economic concerns include not only those about trade restriction, but also concerns about potential economic damage. Other socio-economic concerns are also considered, including traditional livelihoods, food security and food sovereignty.

3.6.1.1 Familiarity

FAMILIARITY
Most genetically modified organisms to date have been developed from organisms that are "familiar", i.e. there is substantial available information about the organism's attributes, and long history and experience of its safe use.

Risk assessment of GMOs requires information on the identity, characteristics and history of safe use of the organism that is subjected to genetic modification. Most GMOs to date have been developed from organisms that are "familiar", i.e. there is substantial available information about the organism's attributes, and long history and experience of its safe use. Both Agenda 21, Chapter 16 and the UNEP Guidelines use familiarity as a basis for conducting risk assessments.

The concept of familiarity provides a way to recognize the potential risks by using already available information on the attributes of the organisms involved in the transformation. Familiarity can help devise effective methods to avoid or manage the risks to acceptable levels. For example, it may be possible to determine the potential for invasiveness of the GM crop based on knowledge of its ecological characteristics (e.g. presence of traits that are associated with invasiveness) and

the presence of wild compatible relatives. Likewise, it may be possible to identify the potential allergenicity of the GMO if knowledge and history of safe use of the origin/source of the gene used in genetic modification is available. In this context, the concept of familiarity is not a risk assessment by itself but can be a useful tool for identifying, evaluating and managing risks.

Familiarity, however, has its drawbacks as a risk analysis tool. Many ecologists question its usefulness, believe that it is an intrinsically subjective concept, and caution that it can lead to false reliance on previous knowledge that may not apply in a given situation (e.g. Marvier and Kareiva, 1999; Antonovics, 1999). Furthermore, the depth of familiarity with a crop is often more geared to its agronomic performance than to potential environmental impacts (Gaugitsch, 2002). While its usefulness as evidence is contested, the concept of familiarity may be more useful as a benchmark or comparator, and in identifying areas where there is inadequate knowledge of the characteristics of the organism involved (see e.g. Kareiva and Marvier, 2000; Kapuscinski & Hallerman, 1995). Critiques of the principle of familiarity highlight the importance of post-commercial monitoring to confirm pre-planting assumptions based on familiarity.

SUBSTANTIAL EQUIVALENCE
Recognized as one of the principles for environmental risk assessment. According to CBD: Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

3.6.1.2 Substantial Equivalence

Internationally, the concept of substantial equivalence is recognized as one of the principles for environmental risk assessment by the CPB, and in food safety assessment by the Codex Alimentarius Commission. The relevant texts (italics provided) are as follows:

Cartagena Protocol on Biosafety (2000)

Annex III 5 – Risk Assessment

Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing

detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, *should be considered in the context of the risks posed by the non-modified recipients or parental organisms* in the likely potential receiving environment.

Codex Alimentarius Commission Principles and Guidelines on Foods Derived from Biotechnology (2003)

Section 3, Principles, Article10 – Risk Assessment

Risk assessment includes a safety assessment (…) The safety assessment *should include a comparison between the food derived from modern biotechnology and its conventional counterpart focusing on determination of similarities and differences*. If a new or altered hazard, nutritional or other safety concern is identified by the safety assessment, the risk associated with it should be characterized to determine its relevance to human health.

As an approach, it should be noted that the concept of substantial equivalence is considered a *starting* point for the safety assessment to structure the safety assessment procedure, and focus on the identified differences that may require further testing. Its application is limited by the choice of an appropriate comparator and availability of sufficient scientific information relevant to the risk assessment.

These points are illustrated in the three cases presented below.

- *GMOs that are shown to be substantially equivalent to the conventional counterparts* may be regarded as being "as safe as" their counterpart. No further safety considerations other than those for the counterpart are necessary.
- *GMOs that are substantially equivalent to the conventional counterpart except for defined differences* need further safety assessment that should focus only on the defined differences. Typically, the defined differences will result from the intended effect of the genetic modification that may, or may not, change the endogenous traits, or produce new traits in the host organism.

» *GMOs that are not substantially equivalent to the conventional counterpart*. In these cases, the concept of substantial equivalency cannot be applied.

The proper application of familiarity and substantial equivalence, in particular the assumptions upon which both principles are founded and applied, is an outstanding issue that may determine the extent to which the risks of GMOs can be accurately identified and subsequently minimized or eliminated. In particular, some uses of substantial equivalence are becoming increasingly criticized.

The concept of substantial equivalence has undergone major reassessment. Initially, it was thought that if a genetically modified food was "substantially equivalent" to its traditional counterpart, a risk assessment would not be necessary. Comparisons focused on attributes such as protein, carbohydrate and fatty acid levels between the novel food and its traditional counterpart. However, there were no clear and universal guidelines stipulating what to test and how similar the items in question should be. It has been said that the amount of comparative data required to establish "substantial equivalence" involved "a somewhat subjective judgment" (Royal Society, 2002).

The approach proved immensely controversial. Consumer organizations, environmental groups and a few leading scientists criticized "substantial equivalence" for helping to play down the novelty of genetic engineering and facilitating its commercialization. Over the years, the approach has come to mean something very different and it has ultimately been demoted in the regulatory framework - albeit implicitly (Royal Society, 2002).

Applying the concept of substantial equivalence requires that sufficient analytical data be available in the literature, or be generated through experimentation, to allow effective comparison between the novel plant and its traditional counterpart. A problem arises in that risk factors have generally not been established for traditionally bred plant varieties and so there is very little baseline information

about the environmental risks associated with their introduction. This suggests a **basic limitation of the substantial equivalence concept**: dependence on a comparator (base product), and on the information that is available or can be generated for the comparator, means safety assurance is relative to the components assessed for the particular comparator. The choice of comparator is therefore crucial to effective application of the concept of substantial equivalence.

BASIC LIMITATION OF THE SUBSTANTIAL EQUIVALENCE CONCEPT
Applying the concept of substantial equivalence requires that sufficient analytical data be available in the literature, or be generated through experimentation, to allow effective comparison between the novel plant and its traditional counterpart. A problem arises in that risk factors have generally not been established for traditionally bred plant varieties and so there is very little baseline information about the environmental risks associated with their introduction.

3.6.1.3 Precaution

Precaution is an approach related to decision-making in situations of scientific uncertainty. Precaution is particularly relevant to GMO issues because of the inherent scientific uncertainty and difficulties of predicting potential impacts. The precautionary approach allows decision-makers to take account of scientific uncertainty and to make judgments based on limited scientific evidence and available knowledge as to the level of acceptable uncertainty in a given context. Environmental measures based on precaution should be proportionate to the anticipated risk and non-discriminatory.

Principle 15 of the Rio Declaration (Agenda 21) states that "lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation."

The CPB reaffirms in its preamble the **precautionary approach** contained in Principle 15 of the Rio Declaration on Environment and Development, stating lack of certainty "shall not be used as a reason to postpone measures to avoid or minimize a threat of significant reduction or loss of biodiversity." The precautionary approach is also referred to in Article 10.

Under the Protocol, decisions of the contracting party importing a GMO destined for first-time release into the environment (and where necessary for GMOs intended for direct use as food or feed, or for processing) must be according to a risk assessment.

BOX 3.3

PRECAUTIONARY APPROACHES

Definitions of precaution, or descriptions of precautionary approaches, exist in several international agreements.

Principle 15 of the 1992 **Rio Declaration** on Environment and Development defines the precautionary approach as follows: "*In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*"

In the **Convention on Biological Diversity**, the Preamble does not specifically refer to "precaution," but states that "*...where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.*"

The **Cartagena Protocol**, in turn, specifically references Principle 15 of the Rio Declaration in its preamble and refers to precaution in several other sections, such as: Article 1, indicating that the objective of the Protocol is "*in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on environment and Development*"; Article 10.6 and 11.8, stating: "*Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an LMO on biodiversity, taking into account risks to human health, shall not prevent a Party of import from taking a decision, as appropriate, with regard to the import of the LMO in question, in order to avoid or minimize such potential adverse effects*"; and Annex III on risk assessment, stating: "*Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a*

PRECAUTION
Precaution is an approach related to decision-making in situations of scientific uncertainty. Precaution is particularly relevant to GMO issues because of the inherent scientific uncertainty and difficulties of predicting potential impacts.

THE PRECAUTIONARY APPROACH
According to the Rio Declaration: "lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation."

particular level of risk, an absence of risk, or an acceptable risk" (http://www.cbd.int/biosafety/articles.shtml?lg=0&a=cpb-10).

The **SPS** agreement Article 5(7) permits the taking of provisional measures when there is insufficient scientific evidence to permit a final decision on the safety of a product of process:
"*In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or 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 or phytosanitary measure accordingly within a reasonable period of time.*"

Regional agreements, too, make mention of precaution. Notable among them is the **European Union**'s description of the precautionary principle, as mentioned in the EC Treaty (article 174) and presented in the European Commission's Communication on the Precautionary Principle, COM (2000)1, available at: http://ec.europa.eu/environment/docum/20001_en.htm. The Communication specifies that:

"*Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty. The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty.*"

In the framework of food safety, the precautionary principle has been recognized in Article 7 of Regulation 178/2002 on the principles of food safety legislation (OJL 31 of 1.2.2002).

However, lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects should not prevent the contracting party of import from taking a decision, as appropriate, in order to avoid or minimize potential adverse effects. Parties may take into account the precautionary approach in reaching decisions on imports of LMO-FFPs (Art. 11[8]).

In the food safety area, it appears the Codex Commission is embracing a precautionary approach, even if the term is not explicitly referred to in the Codex itself. For example, the Codex Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology state that risk managers are to account for the uncertainties identified in the risk assessment and manage the uncertainties (Sec.3 [18]).

In the area of trade, the WTO SPS Article 5.7 of the SPS Agreement permits the taking of provisional measures when there is insufficient scientific evidence to permit a final decision on the safety of a product or process. In such cases, measures can be adopted on the basis of the available pertinent information about the health risk(s) of a product or process. However, when taking such a provisional measure, a Member must seek the additional information necessary for a more objective assessment of the risk(s), and review the SPS measure within a reasonable period of time. It should be emphasized that Article 5.7 is a "qualified exemption" in that the following four conditions must all be met for the provision to be legitimately invoked: (i) an Article 5.7 SPS measure may be imposed only in a situation where relevant scientific information is insufficient; (ii) the provisional measure must be adopted on the basis of available pertinent information; (iii) the Member adopting the measure must seek to obtain the additional information necessary for a more objective assessment of risk; and (iv) the Member must review the SPS measure within a reasonable period of time.

BOX 3.4

WTO DS26, THE BEEF HORMONES DISPUTE

The "beef hormone case" is a good example of potential conflicts between precautionary policies and trade agreements. The EU in 1985 adopted policies against using growth hormones in cattle production (EC Directives 81/602, 85/358, 96/22), on the basis of health and consumer concerns. The directives also led to the EU banning imports of meat produced using growth hormones. In 1997, the United States and Canada filed a WTO complaint against the EU for its import ban, saying that it had no scientific basis. While the SPS Agreement allows for Members to adopt more stringent policies than the agreed international standards, it has the concomitant requirement that any such policies be justified by risk assessment.

As discussed in sections 2.2.3 and 3.6, the risk assessment process is meant to avoid, insofar as possible, the inclusion of concerns beyond direct human and environmental health hazards. Therefore, consumer opinion, along with other socio-economic and/or ethical concerns, is excluded from consideration. In this case, the EU had in fact conducted a risk assessment that did not back a ban, as it showed no significant impact on human health from growth hormones in beef.

While some supporters of the ban argued that the scientific studies were inadequate, the EU itself did not argue the case on the basis of the risk assessment they had conducted, and instead marshalled arguments based on consumer perception and trust. They claimed that, due to a series of public health scandals (primary among them BSE ["mad cow" disease]), the ban was necessary to respond to public concerns.

While this position may have had policy merit, it did not convince the arbiters, who were constrained to deciding the case on the basis of the risk assessment *per se*, as

foreseen in the SPS agreement. The WTO trade dispute resolution panel, and subsequently the WTO's appellate body, found that the EU's basis for the ban was not justifiable. The trade dispute panel noted three main problems: (1) other international standards did not back up the ban; (2) the policy was not consistent; and (3) the EU's decision was not based on findings of a risk assessment, as required by the SPS agreement. The appellate decision demurred from the panel's decision in the areas of harmonization and discrimination, but noted, in particular, that the risk assessment was too broad and did not adequately show that the EU's policies achieved additional health protection.

While this decision seems to indicate an anti-precautionary stance, it is not definite what effect it will have on future decisions. Precautionary policies rarely call for "absolute certainty" of no harm, and the WTO's decision in this case is more tied to the fact that the EU was unable to persuade the appellate body that their standards did a better job of protecting human health than the Codex standards. Furthermore, the appellate body's decision can be read (and, indeed, has been read thus by the EU) as confirming that the EU did have the right to set more stringent standards than the Codex.

Adapted from: Giandomenico, 2002 and Holmes, 2006.

3.6.1.4 Prevention

PREVENTION
The duty to take preventive measures is laid down by most international environmental instruments. Prevention is more cost effective and environmentally desirable than remedial measures taken after damage to the environment and human and animal life.

The duty to take preventive measures is laid down by most international environmental instruments. Prevention is more cost effective and environmentally desirable than remedial measures taken after damage to the environment and human and animal life. At times destruction, eradication or other control measures may be impossible and the ecological damage irreversible (Shine, Williams and Gundling, 2000).

In general terms, prevention applies to activities that may have serious adverse effects on the environment. It does not impose an absolute duty on states to prevent all harm but requires them to exercise due diligence and act reasonably and in good faith in prohibiting or regulating activities that could have such results. Governments should also put measures in place to prevent or minimize damaging consequences of activities that are permitted.

Many international and national instruments establish a threshold above which preventive measures should be taken. This is true for biosafety measures, as well. Preventive actions must be different for intentional and unintentional movement of GMOs or their release into the environment. For intentional unauthorized movements or release, prevention may take the form of total prohibition or partial prohibition usually under a permit to which conditions may be attached. For unintentional release, the likelihood of GMOs escaping should be prevented.

The CPB in Article 2 states as its objective "to ensure that the development, handling, transport, use, transfer and release of any LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health." It emphasizes that legal rules should be designed to prevent damage from occurring rather than attempting to remedy damage after it has occurred. Article 2(2) provides that parties should be guided by the preventive approach in relation to the following activities involving LMOs: development, handling, transport, use, transfer and release.

ADAPTIVE MANAGEMENT Is a technique that can augment traditional risk management by taking into account new information.

3.6.1.5 Adaptive management

Adaptive management is a technique that can augment traditional risk management by taking into account new information. It involves adjusting management in light of experience and additional data, and essentially means "learning by doing." It

is an especially valuable technique for new technologies and new applications of existing technology, as these often involve uncertainties and issues that require reassessment based on experience. As such, it can be a valuable tool in biosafety management. Indeed, it is a principle that is being incorporated into biosafety capacity development training on the CBD by UNEP (see, for example, http://www.cbd.int/doc/meetings/nbsap/nbsapcbw-pac-01/official/nbsapcbw-pac-01-01-add1-en.pdf).

3.7 PUBLIC PARTICIPATION AND ACCESS TO INFORMATION

PUBLIC PARTICIPATION AND ACCESS TO INFORMATION
Many international instruments mandate public participation in environmental planning and decision-making, which is increasingly reflected in national legal systems and administrative procedures.

Many international instruments mandate public participation in environmental planning and decision-making, which is increasingly reflected in national legal systems and administrative procedures. Participatory approaches need to be complemented by judicial review procedures to guarantee individual rights. Affected parties should be given the right to appeal decisions for the refusal of permits. On the other hand, there should be judicial remedies available for interested individuals or groups to challenge administrative decisions on GMO imports, exports or activities that are considered to be unlawful or inconsistent with the protection or conservation objectives of relevant legislation.

One of the most useful legal tools for realizing the potential and avoiding the risks of modern biotechnology may be legally requiring public participation in the policy-making and regulatory decision-making processes. Opening decision-making processes up to the public helps to ensure that decision-makers have the best information at their disposal in order to evaluate the benefits and risks that modern biotechnology could present. Public participation can also help to ensure better transparency and accountability in decision-making (see Box 3.5: Public participation mechanisms).

Access to accurate information related to biotechnology in general and GMOs in particular is a cornerstone of any system to realize modern biotechnology's benefits and avoid its risks. The accessible information can include permit applications, environmental and other assessment results, the results of consultations with the public, as well as information on approvals and denials (Glowka, 2003). Access to information is especially important because GMO releases generally take place on a case-by-case basis.

A sub-area of access to information is the extent to which a permit applicant may withhold confidential information and prevent its dissemination to the public during the regulatory review and decision-making process. The possibility to withhold commercially sensitive information is an established principle at international and national levels (Glowka, 2003). The issue of CBI is also discussed in Section 2.5.3 on the relationship between IPR and access and benefit-sharing..

PUBLIC PARTICIPATION MECHANISMS
Apart from new rules to increase openness, transparency, and information sharing with the public, governments worldwide have also sought to improve governance by making the process of decision-making itself more democratic.

BOX 3.5

PUBLIC PARTICIPATION MECHANISMS

Public participation in environmental policy-making has been an increasingly important concern for governments. Apart from new rules to increase openness, transparency and information sharing with the public, governments worldwide have also sought to improve governance by making the process of decision-making itself more democratic.

Several new institutions and techniques form part of this scheme to solicit information and public input. Initially used principally in Northern Europe and the United States (citizen juries, for example, originated in Germany and the United States, while consensus conferences were first promoted in Denmark), these techniques are spreading globally.

Mechanisms include citizen juries, expert committees (with or without public or lay members), public oversight boards, polls, consensus conferences, focus groups, participatory foresight exercises and public hearings. Many of these techniques are focused on gaining the viewpoint of non-specialists (as opposed to expert committees).

These techniques aim for inclusiveness and representativeness as well as to provide mechanisms for information provision, discussion and debate. They are intended to give policy-makers a sense of the will of the citizenry, as well as an understanding of the factors citizens consider when reaching decisions.

Governments are also exploring improving access to upstream decision-making by including civil society organizations and citizen representatives on science panels (for example, the European Union has several initiatives exploring the role of civil society in science policy).

Citizen juries and consensus conferences have been used to solicit public input in a number of areas of environmental decision-making, from park management to water resources to food and agriculture, and in particular, in areas that have engendered substantial controversy, such as agricultural biotechnology. The techniques have been used in the United States, Europe, and developing countries, such as India and Brazil. One of the most recent high-profile examples was as part of a broad-based effort by the British Government to involve the public in policy decisions on genetically modified (GM) organisms, GM Nation, in 2003. Other examples include citizen juries in Brazil (2001) and consensus conferences in Belgium (2003), Japan (2000), Australia (1999), Argentina (2000), and India (2001).

3.8 TRANSPARENCY OF DECISIONS AND PUBLIC ENGAGEMENT

TRANSPARENCY OF DECISIONS AND PUBLIC ENGAGEMENT
Transparency refers to the amount and level of information that governments provide on why and how certain products are regulated, on how risk assessments are performed and decisions made, and on what conclusions are reached.

The twin issues of public information and participation relate to the degree of transparency in a regulatory system and to the extent to which the public can provide input to the formulation either of a regulatory policy, or of specific regulatory decisions. In this context, transparency refers to the amount and level of information that governments provide on why and how certain products are regulated, on how risk assessments are performed and decisions made, and on what conclusions are reached. Transparency can also relate to the perceived independence and objectivity of the regulatory decision-makers. Although closely related, public information and participation have some mutual exclusivity, as it is certainly possible to have an open and transparent process that, however, does not involve public input. Greater transparency concerning both the risks and benefits of biotechnology products and government decision-making is an essential component of building public trust in new technologies. The dissemination of more and better information on agricultural biotechnology is a stabilizing force because, while the public may not generally read scientific studies, risk assessments, or government decision documents, opinion leaders, members of special interest groups, or others who hope to shape public opinion, do (McLean *et al.*, 2002).

GOVERNMENT POLICY ON TRANSPARENCY
Will determine the extent to which the public and special interest groups will contribute to the development of a national biosafety policy; the opportunities for public participation in the risk-assessment and decision-making process; and the degree to which the public will have ready access to information about the biosafety system.

Government policy on transparency will determine the extent to which the public and special interest groups will contribute to the development of a national biosafety policy; the opportunities for public participation in the risk-assessment and decision-making process; and the degree to which the public will have ready access to information about the biosafety system. Ideally, the process used to develop a national biosafety system should be transparent and the level of involvement of the public and/or stakeholder or special interest groups as legislation, regulations, or guidelines are being developed, as well as after they have been adopted, ought to be considered.

As a minimum, the process and criteria for risk assessment and risk management should be widely published so that developers, stakeholders and the public can trust the biosafety system to be both credible and predictable. Some jurisdictions have surpassed this level: they additionally notify the public when applications for the environmental safety assessment of a GMO are received by the competent authorities, and also when a regulatory decision is made. Within the context of implementing a biosafety system, opportunities for public engagement may be provided through formalized requests for public input. Most commonly, the public is provided with an opportunity to evaluate summary information about the GMO under review and to submit comments in this regard.

3.9 MONITORING[3] AND COMPLIANCE

MONITORING AND COMPLIANCE
Two types of monitoring are considered: monitoring of obligations under different international agreements and related compliance, and post-release monitoring, namely a systematic process of monitoring or surveillance of GMOs after release into the market or the receiving environment.

There are two types of monitoring that are important for biosafety. First, there is monitoring of obligations under different international agreements and related compliance. The CPB, notably, has a monitoring and reporting requirement. Article 33 of the CPB addresses monitoring and reporting of obligations under the Protocol, requiring reporting of what steps Members have taken to implement the Protocol.

Second, there is post-release monitoring, namely a systematic process of monitoring or surveillance of GMOs after release into the market or the receiving environment. Many countries recognize the need for a long-term monitoring of the cumulative effects of GMOs but to date few have implemented such a system.

With respect to monitoring and compliance, the Biosafety Clearing-House (BCH), a mechanism set up by the CPB, facilitates exchange of information about transboundary movements of GMOs. Other international and national organizations also disseminate information from research on GMOs that can be useful in developing

3 See Module D of this Compendium for a more detailed discussion of pre- and post-release monitoring.

monitoring plans; these include the International Centre for Genetic Engineering and Biotechnology (ICGEB), FAO, WHO, Codex, the OECD, and national agencies such as the United States Department of Agriculture (USDA). There remain practical, technical and economic limitations to monitoring for GMOs to ensure that national and international rules and regulations are respected. Given these difficulties, ensuring compliance remains difficult. Several environmental non-governmental organizations (NGOs) have focused their efforts in this area, alerting their Members and national governments to contamination incidents. Effective monitoring could assist in minimizing these events.

3.10 LIABILITY AND REDRESS

LIABILITY AND REDRESS
Another aspect of biosafety regulation that is related to monitoring and compliance is liability. International agreements mention the issue of liability, but as of March 2009, none contain binding provisions.

Another aspect of biosafety regulation that is related to monitoring and compliance is liability. Initial CBD discussions raised the issue, but the parties did not agree on a set of requirements for liability and redress. Other international agreements mention the issue of liability, but do not contain binding provisions. As a result, Article 27 directed the COP to "adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movement of LMOs, analyzing and taking due account of the ongoing process in international law on these matters, and shall endeavour to complete this process within four years."

On 15 October, 2010, at its fifth meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP, the governing body of the Cartagena Protocol on Biosafety to the CBD) adopted the *Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety* (N-KL Supplementary Protocol). The N-KL Supplementary Protocol will enter into force 90 days after it has been ratified by at least 40 Parties.[4]

4 Article 18.1 of the Nagoya-Kuala Lumpur Supplementary Protocol: This Supplementary Protocol shall enter into force on the ninetieth day after the date of deposit of the fortieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Protocol.

As noted in section 2.2.1 of this module, the CBD has three main objectives: (1) conservation of biological diversity, (2) the sustainable use of its components, and (3) the fair and equitable sharing of the benefits from the use of genetic resources. The N-KL Supplementary Protocol addresses issues relating to conservation of biological diversity, the first objective – many Parties to the Cartagena Protocol felt that the Protocol needed specific rules addressing liability and redress. In response, the N-KL Supplementary Protocol elaborates international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms.

DAMAGE
Defining damage is important for liability approaches; a proposed definition is "adverse or negative effect on biological diversity" that must be measurable and significant.

In particular, the N-KL Supplementary Protocol defines what constitutes "damage to biodiversity" (traditional damage, such as personal injury, loss or damage to property or economic interests, is not covered by the N-KL Supplementary Protocol). "**Damage**" is defined as a measurable and significant "adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health..." (Articles 2.2[b] and 2.3).

Once a determination is made that measurable and significant damage resulting from transboundary movement of LMOs exists (and, per Article 4, a causal link is made between the LMO in question and the damage) the N-KL Supplementary Protocol has adopted an administrative approach for addressing such damage. Signatories to the Supplementary Protocol are required to adopt response measures in the case of damage (and implement them through domestic law [Article 12]), including (1) identification of the operator who caused the damage; (2) evaluation of the damage; and (3) response measures to be taken by the operator (Article 5.2). In case of failure by the operator to respond in a timely fashion, the competent authority itself may take action (Article 5.4) and recover costs of appropriate response from the operator (Article 5.5). Response measures include actions to (1) prevent, minimize, contain, mitigate, or otherwise avoid damage, as appropriate; and (2) restore biological diversity (Article 2.2[d]).

As noted in the Nagoya-Kuala Lumpur Supplemental Protocol, liability and redress provisions require showing a causal link between damage and the activity. Further considerations are valuation of damage; means of assigning liability to the parties involved; compensation; and finally, response measures in the case of damage could include minimization, containment, restoration, and/ or replacement of biodiversity losses. Additional considerations for liability and redress legislation would include compensation, cases for exemptions or mitigating factors, and the idea of insurance coverage for operators.

DOMESTIC LIABILITY AND REDRESS REGIMES
An example being Article 14 of the African Model Law on Safety in Biotechnology, which suggests an extensive list of elements for a liability and redress regime that should be incorporated into domestic biosafety legislation.

In addition to action via international instruments such as the CBD, countries may develop **domestic liability and redress regimes** or use existing civil law remedies where these are appropriate and adequate. Some models for this exist, including Article 14 of the African Model Law on Safety in Biotechnology, which suggests an extensive list of elements for a liability and redress regime that should be incorporated into domestic biosafety legislation. It makes any person who imports, arranges transit, makes contained use of, releases or places on the market a GMO or GMO product strictly liable for any harm caused by the GMO or product. The harm must be fully compensated.

COMPENSATION
In the case of harm to the environment, or biological diversity, compensation should include the costs of reinstatement, rehabilitation or clean up measures incurred as well as the costs of preventive measures.

Liability also extends to the person responsible for any activity that results in damage, injury or loss, as well as to the provider, supplier or developer of the GMO or GMO product. Liability can be joint or several (Art. 14 [2] and [3]. Where harm occurs to the environment or biological diversity, **compensation** should include the costs of reinstatement, rehabilitation or clean up measures incurred as well as the costs of preventive measures (14[4]). In case of harm to human health, compensation should include costs of seeking and obtaining treatment, compensation for disability or diminished quality of life, and costs of reinstating quality of life, and compensation for loss of life and related expenses (14[5]).

Liability further extends to harm or damage caused directly or indirectly by the GMO or GMO product to economic, social or cultural conditions, including negative impacts on the livelihood or indigenous knowledge systems or technologies of a local community. Liability also extends to any damage or destruction arising from incidence of public disorder triggered by the GMO or GMO product, any disruption or damage to production or agricultural systems, reduction in yields, soil contamination, damage to biological diversity, the economy of an area or community and any other consequential damage (14[6]).

3.11 BASIC ASPECTS OF LABELLING[5]

BASIC ASPECTS OF LABELLING
The labelling of GMOs or products derived from GMOs is a sub-area of access to information with three main uses of labelling in consumer protection and consumer and environmental safety: (1) consumer right-to-know concerns; (2) protection from misleading claims; and (3) consumer education on issues related to human and environmental health.

The labelling of GMOs or products derived from GMOs is a sub-area of access to information. Glowka (2003) provides a good overview of three main uses of labelling in consumer protection and consumer and environmental safety: (1) consumer right-to-know concerns; (2) protection from misleading claims; and (3) consumer education on issues related to human and environmental health. Labelling is being considered, and in some cases is already being used, in the biosafety and food safety areas in order to provide consumers with information on the GMO or GMO-derived product that they are either considering purchasing or are already using.

One aspect of labelling is premised on the principle that the consumer has a right to know what he or she is purchasing and subsequently using. This principle has its origins in consumer protection. With the information that labels provide, consumers may make better, more informed choices about the products that they are thinking of buying. Furthermore, when products are properly labelled consumers can exercise their right to choose products that meet their particular economic,

5 A more detailed discussion of traceability, monitoring and labelling of GMOs can be found in Module 4 of this compendium.

health, religious, ethical, moral or other needs. For these reasons, labels can become a market-based mechanism that can contribute to the marketplace's acceptance of a product or the technology upon which the product is based.

A second aspect of labelling, related to the right to know, is protecting the consumer from false, misleading or deceptive practices. Labelling may be able to provide consumers enough information and to ensure that the claims made about a product are indeed true.

A third aspect of labelling is premised on consumer education. Consumer safety and environmental protection can be promoted when labels supply the appropriate information to consumers. For example, a label's information may warn the consumer of product attributes that could endanger his or her health or threaten the environment if the product is used in a certain way or is not kept or maintained adequately. In this way, labels can be viewed as a risk management tool.

When labels can or should be applied to products that may or not contain GMOs is a major issue that is being addressed at international and national levels. Labelling in the area of GMOs exists as both positive and negative information – that is, for claims that foods contain GMOs or that foods are GMO-free. Labelling can be voluntary or mandatory.

At the international level, the CPB sets out the obligations of parties concerning the identification of LMOs. Different obligations exist for LMOs intended for direct use as food or feed or for processing, LMOs destined for contained use and LMOs intended for intentional introduction into the environment (Art. 18). The TBT Agreement applies to all labelling requirements, including labelling of GMOs. The Codex Alimentarius Commission is preparing reference standards for the labelling of GMOs.

Table 3.1 | **Labelling requirements**

Examples of labelling requirements	Voluntary	Mandatory
GMO-free	Allowed for organic products in some jurisdictions such as the United States	No jurisdictions
Contains GMOs	All jurisdictions	European Union Transboundary movement of LMOs under CPB

LABELLING REQUIREMENTS
When labels can or should be applied to products that may or not contain GMOs is a major issue that is being addressed at international and national levels; different regulations in different jurisdictions exist.

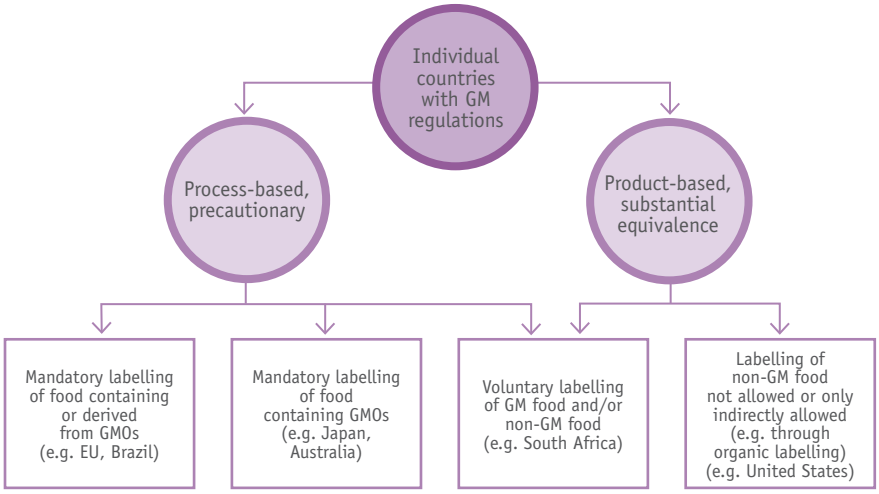
Labelling has been a particularly contentious area in international fora on biosafety. The main issues of contention return to the different risk approaches. Under strict theories of substantial equivalence with product-based approaches, there is no logical reason for requiring labels. States that hold this position fear that labelling requirements may be used as a protectionist measure to restrict trade.

Under process-based approaches, by contrast, and precautionary approaches that seek to accommodate uncertainty, labelling can be a public information and risk management tool. To date, these two approaches have been incompatible, although a majority of states have some labelling requirements, as required by the CPB, or in addition to CPB requirements.

Benefits of labelling can be summarized as protecting, informing, and educating consumers. Labelling can also serve as a compromise policy solution where political or regulatory consensus on risk regulation is not possible. Drawbacks include additional costs to producers and manufacturers, which will likely be passed on in turn to consumers. These costs arise from the requirement that labelling be accurate and useful, which in turn necessitates effective segregation, traceability and monitoring systems.

CLASSIFICATION OF LABELLING REGULATIONS
Regulations can be mainly grouped into process-based versus product-based approaches and according to the resulting mandatory/ voluntary labelling requirements.

Figure 3.1 | **Classification of labelling regulations**
(*Adapted from*: Gruère, 2006)



SEGREGATION, IDENTITY PRESERVATION, AND TRACEABILITY
Ensure that there is no unintentional admixture of GMO and non-GMO products that could lead to unintentional releases of LMOs or adventitious presence of GMOs in food, feed or processed products.

3.12 SEGREGATION, IDENTITY PRESERVATION, AND TRACEABILITY

Segregation, identity preservation and traceability ensure that there is no unintentional admixture of GMO and non-GMO products that could lead to unintentional releases of LMOs or adventitious presence of GMOs in food, feed or processed products. They are also critical elements of any effective labelling regime.

Segregation or ensuring that GMO and non-GMO products are kept separate and that there is no unintentional admixture, can be achieved by either specializing in biotech or non-biotech (both on the farm and the subsequent processing steps), establishing separate facilities for biotech and non-biotech, or taking precautions to separate biotech and non-biotech production (including a thorough

cleaning of equipment and storage facilities after each biotech variety). As an alternative to segregation, processors can choose to reformulate their products to use ingredients from crops that are exclusively non-biotech, thus minimizing the risk of inadvertently using a biotech variety.

The cost of any of these options varies greatly depending on the flexibility of the production and marketing systems, the tolerance level for biotech content, the volume of biotech and non-biotech commodities and products processed by the system, and the likelihood of achieving economies of scale.

Another set of costs arises in convincing manufacturers and consumers that the product is truly non-biotech. One way to achieve this is to test for biotech content, and a number of private firms have begun to market biotech-testing products.

Another method of monitoring the integrity of the non-biotech label is to establish a system of IP for both GMO and non-GMO products (see Box 3.5) in which producers track each stage of the marketing chain and can thus attest to the integrity of their non-biotech products. Such a system relies on strict segregation and product tracking more than on continual testing.

The costs of non-compliance can also be high, as is evident from the case of adventitious presence of non-approved GMO rice in commercial rice exports (see Box 3.7).

In addition, it may be difficult for individual firms and farmers to establish a credible non-biotech label. Consumers may be sceptical of producers' claims. Such scepticism could be fuelled by the observation that biotech tests are not completely reliable or consistent, and that it is difficult to ensure the integrity of an IP system. To this end, standards, traceability, testing, certification and enforcement could all facilitate the development of a market for non-biotech foods.

BOX 3.6

IDENTITY PRESERVATION (IP)

Identity preservation (IP) is an important measure for traceability: every product which is a genetically modified organism, or which contains genetically modified ingredients, must be accompanied by documents detailing the identity of this GMO during the whole production chain. For this purpose, the OECD introduced a naming system called Unique Identifiers. Should a GMO have to be withdrawn from the market, IP allows authorities to trace all shipments up to the food stores (emphasis in original)

From: EU Co-extra glossary, http://www.coextra.eu/glossary/word694.html

IDENTITY PRESERVATION
Identity preservation is an important measure for traceability: every product which is a genetically modified organism, or which contains genetically modified ingredients, must be accompanied by documents detailing the identity of this GMO during the whole production chain.

Biotech standards or tolerance levels would determine the maximum amount of biotech ingredients allowable in a "non-biotech" commodity or food. Consistent enforcement of standards, testing and certification would also decrease transaction costs and increase market efficiency. This, along with added public trust, makes it an important policy goal.

3.13 ISSUES OF INTEREST FOR COUNTRIES THAT HAVE NOT YET ADOPTED BIOSAFETY LEGISLATION

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Countries that have not yet adopted biosafety regulations must take into consideration the above-mentioned international agreements.

Countries that have not yet adopted biosafety regulations must take into consideration the above-mentioned international agreements. Import regulations in particular will require compliance with the standards of any international agreements to which the country is (or hopes to become) a signatory. Additionally, a country's regulations on issues such as notification, commercial approvals, identity preservation, traceability, labelling and monitoring may affect its ability to export to countries with different requirements.

BOX 3.7

UNAPPROVED RICE CONTAMINATION EVENTS

An example of how the issues of identity preservation, traceability and monitoring arise in international trade comes from the 2006-2007 case of adventitious presence of unapproved varieties of genetically modified rice in rice crops in the southern United States.

The unapproved variety was found in commercial rice seeds and entered the food and feed system in the United States. While the USDA later determined that the genetically modified variety posed no safety concerns for food or feed use, and subsequently granted it approval for commercialization, the contamination incidents had broad-ranging and serious trade effects.

The genetically modified rice was also found in rice imports from the United States to a number of countries in Europe, the Middle East and Asia (another unapproved genetically modified variety was also discovered in rice exported from China).

After the discovery of the adventitious presence of Bayer LL Rice 601, Japan suspended imports of long-grain rice from the United States. The European Commission adopted a decision banning all consignments of United States long-grain rice except those tested by an accredited laboratory and certified as free from the genetically modified variety.

United States rice farmers have filed several lawsuits against USDA and Bayer for losses due to the contamination; there are claims of up to USD 1.2 billion in losses due to lost exports and closed markets. The litigation, as of July 2010, is still ongoing, but juries have already held Bayer liable for over USD 50 million to compensate farmers for their losses, and is indicative of the high stakes involved in ensuring compliance with biosafety regulations.

The case also shows the importance of meeting IP, traceability and containment standards. It demonstrates the role of testing and monitoring in ensuring a successful trade regime, especially in an environment where different countries may have different import standards and requirements.

UNAPPROVED RICE CONTAMINATION EVENTS
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Most developing countries do not export GMOs, but many do export conventional products, and therefore "…find themselves in a particularly difficult situation: in order to preserve their export opportunities, especially towards markets that are skeptical about bioengineered products, they may need to be 'GM-free' countries. This means not only that they should not be exporters of GMOs, but also that they should not be producers of GMOs for domestic consumption and not even importers of GMOs. Losing 'GM-free' status is perceived by some countries as having negative repercussions for their export opportunities for all agricultural products" (Zarrilli, 2005). This perception has the potential to limit choice for developing countries. At the same time, developing countries may feel pressured by GMO-exporting countries to make regulatory decisions based on the ideas of substantial equivalence and "product, not process."

As Zarrilli (2005) writes, "While developed countries have established their national frameworks… focusing primarily on domestic priorities and strategies, most developing countries are doing so under less flexible circumstances…. …[D]eveloping countries increasingly seem to be expected to set up their national regulatory schemes based on the requests and expectations of their main trade partners."

Indeed, all countries need to address both constraints, in terms of requirements of international agreements to which they or their trading partners are signatories, and expectations, in terms of goals and legal frameworks of their trading partners. While several issues remain open and unresolved, international agreements generally seek to harmonize and streamline regulations and requirements.

3.14 CONCLUSIONS: CHAPTER 3

Implementation of (national) biosafety legal instruments involves the establishment of appropriate mechanisms for implementing international agreements, conducting risk analysis, including public participation, notifying trading partners and the public, and ensuring compliance through monitoring, management, and mechanisms for addressing non-compliance.

Other concerns to address include opportunities for international cooperation at a technical level (sharing human and scientific resources and expertise), establishing a scheduled phasing-in of regulations (for example, initial voluntary guidelines entrenched in legislation over time), and creating a means for revising the framework in response to new data and/or requirements of international agreements.

CONCLUSIONS: CHAPTER 3
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ANNEX 1

INTERNATIONAL LEGAL INSTRUMENTS ADDRESSING BIOTECHNOLOGY AND BIOSAFETY

Year	Treaty, agreement, or law	Decision-making body	Parties (as of January 2010)	Focus	Binding	Direct or indirect application to biotechnology	Web site
1963	Codex Alimentarius	WHO, FAO	183	Food safety	No	Direct	http://www.codexalimentarius.net/web/index_en.jsp
1982	Convention on Law of the Sea	UN	157	Fisheries and oceans	Yes	Indirect	http://www.un.org/Depts/los/convention_agreements/convention_overview_convention.htm
1985	Guidelines for Consumer Protection	UN		Consumer protection	No	Indirect	http://www.un.org/esa/sustdev/publications/consumption_en.pdf
1987	World Conservation Union (IUCN) Position Statement on Translocation of Living Organisms	IUCN	Government and NGO Members at various levels	Biosafety	No	Direct	http://www.iucnsscrsg.org/download/IUCNPositionStatement.pdf
1991	Code of Conduct for the Release of Organisms into the Environment	UNIDO		Biosafety	No	Direct	http://www.biosafety.gov.cn/image20010518/5079.pdf
1992	Agenda 21, Chapter 16	UN	Over 178 signatories	Sustainable development, "Environmentally sound management of biotechnology"	No	Direct	http://www.unep.org/Documents.Multilingual/Default.asp?DocumentID=52&ArticleID=64
1992	Convention on Biological Diversity	CBD	193	Biosafety	Yes	Direct	http://www.cbd.int/convention/convention.shtml
1992	Safety Considerations for Biotechnology	OECD		Biosafety	No	Direct	http://dbtbiosafety.nic.in/guideline/OACD/Safety_Considerations_for_Biotechnology_1992.pdf
1993 (reviewed 2001, 2004, 2006)	Code of Conduct on Plant Biotechnology as it Relates to Plant Genetic Resources for Food and Agriculture	FAO		Biosafety	No	Direct	ftp://ftp.fao.org/ag/cgrfa/cgrfa9/r9w18ae.pdf

Year	Treaty, agreement, or law	Decision-making body	Parties (as of January 2010)	Focus	Binding	Direct or indirect application to biotechnology	Web site
1994	Agreement on Application of Sanitary and Phytosanitary Measures (SPS)	WTO	153 WTO Members	Trade and human health	Yes	Direct	http://www.wto.org/english/tratop_e/sps_e/sps_e.htm
1994	Agreement on Technical Barriers to Trade (TBT)	WTO	153 WTO Members	Trade	Yes	Direct	http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm
1994	Trade Related Aspects of Intellectual Property Rights (TRIPs)	WTO	153 WTO Members	Trade and IPRs	Yes	Indirect	http://www.wto.org/english/tratop_e/trips_e/trips_e.htm
1995	Code of Conduct on Responsible Fisheries	FAO		Fisheries	No	Indirect	http://www.fao.org/DOCREP/005/v9878e/v9878e00.htm
1995	Technical Guidelines on Biosafety	UNEP	58 Members chosen from UN General Assembly Members	Biosafety	No	Direct	http://www.unep.org/biosafety/Documents/Techguidelines.pdf
1996	Code of Conduct for the Import and Release of Exotic Biological Control Agents	FAO		Biosafety, biocontrol	No	Indirect	http://www.fao.org/docrep/x5585E/x5585e0i.htm
1997	International Plant Protection Convention (IPPC)	IPPC/ FAO	172 Members	Biodiversity, agriculture, biosafety	Yes	Direct	https://www.ippc.int/servlet/CDSServlet?status=ND0xMzI5MiY2PWVuJjMzPSomMzc9a29z
1998 with 2005 (addendum on GMOs)	Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention)	UNECE	44	Public participation, democracy, environmental rights, human rights	Yes	Direct	http://www.unece.org/env/pp/treatytext.htm
2000	Cartagena Protocol on Biosafety	CPB	157	Biosafety	Yes	Direct	http://www.cbd.int/biosafety/
2004	International Treaty on Plant Genetic Resources for Food and Agriculture	FAO	120	Biosafety, Agriculture	Yes	Indirect	http://www.planttreaty.org/

ANNEX 2

AREAS COVERED BY INTERNATIONAL TREATIES THAT INCLUDE PROVISIONS ON BIOSAFETY

International agreement	Environmental health/biodiversity	Human health	Trade	IPR	Access and benefit-sharing (for genetic resources)	Liability	Consumer protection/ information	Participation and democracy	Standard-setting
Codex Alimentarius		x	x				x		x
IPPC	x		x						x
CBD	x	x	x		x			x	
Cartagena Protocol	x	x	x		x			x	
SPS	y	x	x						y
TBT	y	y	x		y				y
TRIPS			x	x	y				
Law of the Sea	x		x						
Aarhus Convention	y	y	y		y		x	x	
ITPGRFA	x		x	x	x				

X = directly concerned with; Y = interacts with or indirectly affects

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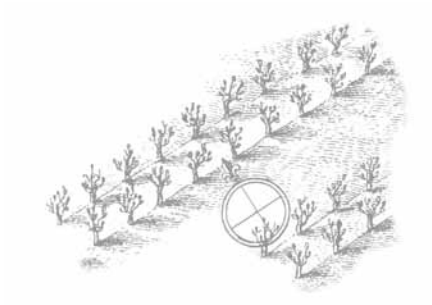

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Biosafety Resource Book

MODULE E

LEGAL ASPECTS

provides an overview of the existing legal tools and frameworks on biotechnology and biosafety, and offers a thorough description of the international instruments that regulate biosafety and their interactions.

For additional information please consult
www.fao.org/biotech
or contact
biotech-admin@fao.org