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LEGAL
ASPECTS

Biosafety Resource Book



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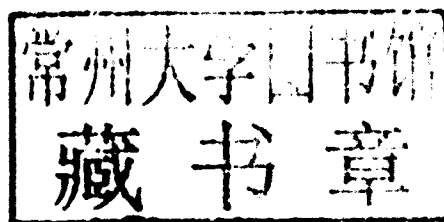
Biosafety Resource Book

LEGAL ASPECTS

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LIST OF ABBREVIATIONS

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

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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.

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 Members¹, 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.

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.

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 AND REGIONAL INSTRUMENTS

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

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.

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.

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).

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	<p>(1) Generic term for an international legally binding instrument. In this sense, encompasses several instruments, such as treaties, conventions, protocols or oral agreements.</p> <p>(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.</p>	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.