



**CONVENTION ON
BIOLOGICAL DIVERSITY**

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CONFERENCE OF THE PARTIES TO THE
CONVENTION ON BIOLOGICAL DIVERSITY
Second meeting
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SURVEY OF NATIONAL LEGISLATION/REGULATIONS ON BIOSAFETY

1. Pursuant to Decision I/9 of the Conference of the Parties at its first meeting, the Open-ended *ad hoc* Group of Experts on Biosafety met in Madrid from 24 to 27 July 1995. While considering, under item 4 of its agenda, existing knowledge, experience and legislation in the field of biosafety, including the views of the Parties, subregional, regional and international organizations, the meeting noted that only a limited number of countries had responded to the Secretariat's survey of national legislation/regulations on biosafety. Therefore, the meeting invited Governments that did not provide information to do so.
2. In order to facilitate a more comprehensive overview of national legislation/regulations on biosafety, the Secretariat sent out, in August and September 1995, to all Parties and other Signatories to the Convention a new form based on the questionnaire used for the survey carried out in preparation for the meeting of the Panel of Experts on Biosafety held in Cairo from 1 to 5 May 1995, but including the items to be considered in an international framework on biosafety suggested by the Open-ended *ad hoc* Group of Experts on Biosafety.
3. Information received to date is contained in Annex I of this note.
4. With a view to facilitating the response from those Governments that have not provided the information, the Secretariat has attached to this information note a copy of the updated form sent out in August and September 1995, contained in Annex II.
5. The Secretariat is merging the information from this and the former survey. The result will be disseminated in response to the wish of some participants in the meeting of the Open-ended *ad hoc* Group of Experts on Biosafety who stated that the publication by the Secretariat of that survey would be useful.

ANNEX I*

STATUS AND COVERAGE OF NATIONAL REGULATIONS/LEGISLATION ON THE SAFE TRANSFER, HANDLING AND USE OF LIVING MODIFIED ORGANISMS (LMOs) RESULTING FROM BIOTECHNOLOGY

Part I

COUNTRY	NATURE OF REGULATION		LMOs COVERED		DOMESTIC TRANSPORT	TRANSBOUNDARY MOVEMENTS		CONTAINED USE	SMALL- AND LARGE-SCALE RELEASE (including for disposal)	COMMERCIALIZATION
	Legally-binding	Non- legally binding	LMOs (from modern biotechnology)	Others		Unintended	Deliberate			
Albania	NR ¹									
Australia		✓	✓		✓	✓	✓	✓	✓	✓
Barbados	NR									
Belarus		✓	✓	✓	✓	✓	✓	✓	✓	✓
Brazil	✓		✓	✓ ²	✓	✓	✓	✓	✓	✓
Cameroon	NR									
Chad	✓			✓	✓	✓			✓	✓
China	✓		✓		✓	✓				✓
Czech Republic	✓		✓ (Plant)				✓ (Plant)			

¹ No existing regulations on safety in biotechnology, to date.

² The Brazilian legislation on living non-modified organisms is a resolution of the Brazilian National Council of Health and it is different from legislation on LMOs. This resolution has been recently reviewed by the Ministry of Health.

COUNTRY	NATURE OF REGULATION		LMOs COVERED		DOMESTIC TRANSPORT	TRANSBOUNDARY MOVEMENTS		CONTAINED USE	SMALL- AND LARGE-SCALE RELEASE (including for disposal)	COMMERCIALIZATION
	Legally-binding	Non- legally binding	LMOs (from modern biotechnology)	Others		Unintended	Deliberate			
Denmark	EC-based ³		✓		✓		within EU	✓	✓	✓
Dominican Republic	NR									
Ecuador	NR									
Egypt	To be soon implemented	✓	✓		✓			✓	✓	✓
Equatorial Guinea	NR									
European Community ⁴	✓		✓	✓	✓	✓	✓	✓	✓	✓
Finland	✓		✓			✓	✓	✓	✓	✓
Germany	EC-based		✓		✓ ⁵	✓ ⁶	✓ ⁷	✓	✓	✓
India	✓		✓	✓	✓	✓	✓	✓	✓	

³ Regulations based on Council Directives 90/219/EEC and 90/220/EEC. The scope of these Directives covers contained use, small- and large-scale releases, use of LMOs referred to as genetically modified organisms, and protection of environment and human health.

⁴ Information provided are based on the following: Council Directives 91/414/EEC concerning the placing of plant protection products on the market, 93/114/EC amending Directive 70/524 concerning additives in feeding stuff, 94/55/EC on the transport of dangerous goods by road, 90/219/EEC on the contained use of genetically modified microorganisms, 90/220/EEC on the deliberate release of genetically modified organisms into the environment; Council Regulations 2309/93 on the procedures for the authorization and supervision of medicinal products for human and veterinary use, 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work; Commission Directive 90/40/EC amending Council Directive 87/153/EEC fixing guidelines for the assessment of additives in animal nutrition. Individual documents listed above include one or more of the elements in the headings, but not all the elements.

⁵ This is being regulated through the implementation of the UN Recommendations on the Transport of Dangerous Goods.

⁶ Information in case of accidents in installations need to be provided if they may affect other member states of the European Union.

⁷ Limited to transport, see footnote No. 5.

COUNTRY	NATURE OF REGULATION		LMOs COVERED		DOMESTIC TRANSPORT	TRANSBOUNDARY MOVEMENTS		CONTAINED USE	SMALL- AND LARGE-SCALE RELEASE (including for disposal)	COMMERCIALIZATION
	Legally-binding	Non- legally binding	LMOs (from modern biotechnology)	Others		Unintended	Deliberate			
Israel	✓		✓	✓	✓		✓		✓	✓
Italy	EC-based		✓		✓	✓	✓	✓	✓	✓
Jamaica	NR									
Japan		✓	✓				✓	✓	✓	✓
Mexico	✓		✓		✓		✓		✓	
Myanmar ⁸	NR									
Morocco	NR									
Nepal	NR									
Norway	✓		✓				✓	✓		
Oman	NR									
Portugal	✓		✓					✓	✓	✓
Republic of Korea	NR									
Romania	✓		✓	✓	✓	✓	✓	✓		✓
Russian Federation	NR									
Saint Lucia	NR									
Samoa	NR									

⁸ In Myanmar, quarantine regulations are used for some living or dead specimens; a phyto-certification is made by the Forest Research Institute for the transfer, within and outside the country, of living or dead forest materials. In 1994, the Government promulgated the Environmental Protection Act and the Fauna and Flora Protection Act .

⁹ Microorganisms.

COUNTRY	NATURE OF REGULATION		LMOs COVERED		DOMESTIC TRANSPORT	TRANSBOUNDARY MOVEMENTS		CONTAINED USE	SMALL- AND LARGE-SCALE RELEASE (including for disposal)	COMMERCIALIZATION
	Legally-binding	Non- legally binding	LMOs (from modern biotechnology)	Others		Unintended	Deliberate			
Sao Tome and Principe	✓		✓		✓		✓		✓	✓
Spain	EC-based		✓		✓		✓	✓	✓	✓
Sweden	EC-based		✓		✓	✓ ¹⁰	✓	✓	✓	
Ukraine	✓	✓	✓		✓	✓	✓	✓	✓	✓
United Kingdom of Great Britain	EC-based		✓		✓	✓ ¹¹	within EU	✓	✓	✓
Venezuela ¹²	✓		✓	✓	✓	✓	✓			
Zambia	NR									

¹⁰ No sanctions. Risk assessments always need to consider risk for any unintended (domestic as well as transboundary) spread/movement.

¹¹ If relevant, within the EU, information taken into account in environmental risk assessments.

¹² More precise information on contained use, small- and large-scale release and commercialization of LMOs will be made available at a later date by the Government of Venezuela.

PART II

COUNTRY	BILATERAL AND/OR MULTILATERAL ARRANGEMENTS	ADVANCE-INFORMED- AGREEMENT-LIKE PROCEDURE	RESEARCH AND DEVELOPMENT	TARGET		SOCIO- ECONOMIC ASPECTS	LIABILITY AND COMPENSATION
				To ensure conservation of biological diversity and sustainable use of its components	To protect human health		
Albania							
Australia	✓		✓	✓	✓		
Barbados							
Belarus	✓	✓	✓	✓	✓	✓	✓
Brazil	✓	✓	✓	✓	✓		✓
Cameroon							
Chad	✓		✓	✓	✓	✓	✓
China			✓	✓			
Czech Republic				✓	✓	✓	
Denmark			✓	✓	✓	*13	
Dominican Republic							
Ecuador							
Egypt	✓		✓	✓	Under consideration	✓	

¹³ In Denmark, there is no specific mention of liability in biosafety regulations. If questions on liability and compensation arise, Danish Courts will deal with them in accordance with the general legal provisions on liability and compensation.

COUNTRY	BILATERAL AND/OR MULTILATERAL ARRANGEMENTS	ADVANCE-INFORMED- AGREEMENT-LIKE PROCEDURE	RESEARCH AND DEVELOPMENT	TARGET		SOCIO- ECONOMIC ASPECTS	LIABILITY AND COMPENSATION
				To ensure conservation of biological diversity and sustainable use of its components	To protect human health		
Equatorial Guinea							
European Community		✓	✓	✓	✓		
Finland	within the EU	✓		✓	✓		✓
Germany	✓		✓	✓	✓		✓
India			✓	✓	✓		
Israel			✓				
Italy	✓	✓	✓	✓	✓	✓	✓
Jamaica							
Japan			✓	✓	✓		
Mexico			✓	✓			
Myanmar							
Morocco							
Nepal							
Norway	within the EU	✓		✓	✓	✓	
Oman							
Portugal	✓	✓	✓		✓		✓
Republic of Korea							
Romania	✓		✓	✓	✓	✓	
Russian Federation							
Saint Lucia							

COUNTRY	BILATERAL AND/OR MULTILATERAL ARRANGEMENTS	ADVANCE-INFORMED- AGREEMENT-LIKE PROCEDURE	RESEARCH AND DEVELOPMENT	TARGET		SOCIO- ECONOMIC ASPECTS	LIABILITY AND COMPENSATION
				To ensure conservation of biological diversity and sustainable use of its components	To protect human health		
Samoa							
Sao Tome and Principe		✓	✓	✓	✓	✓	✓
Spain			✓	✓	✓		✓
Sweden	✓		✓	✓	✓		*14
Ukraine	✓	✓	✓	✓	✓	✓	✓
United kingdom of Great Britain	✓	✓ ¹⁵	✓	✓	✓	✓	✓
Venezuela ¹⁶							
Zambia							

* The Table includes only information received from countries that responded to the Secretariat questionnaire sent out to all Parties and other Signatories to the Convention on Biological Diversity in August and September 1995.

¹⁴ An infringement constitutes a criminal offense (or crime) and can be penalized in accordance with the Gene Technology Act or Criminal Law.

¹⁵ Consents required for all deliberate releases. Notifications plus consents required for some contained uses

¹⁶ More precise information on advance-informed-agreement-like procedure and on research and development will be made available at a later date by the Government of Venezuela

ANNEX II

TO: Calestous Juma

Executive Secretary

CBD Secretariat

15, Chemin des Anémones

1219 Chatelaine, Geneva, Switzerland

FAX 41 22 797 2512

FROM: **Country:**

INFORMATION ON NATIONAL REGULATIONS/LEGISLATION ON BIOSAFETY

Please tick in column 3 if the elements in columns 1 and/or 2 characterize or are included in your national regulations/legislation on biosafety, and return this page to the Secretariat of the Convention on Biological Diversity preferably before 30 January 1996. In addition, please send to the Secretariat copies of any national legal text or proposals on biosafety regulation, if they are not listed in document CBD/Biosafety Expert Group/Inf. 1 distributed as part of the background documents for the meeting of the Open-ended ad hoc Group of Experts on Biosafety in Madrid.

Nature of regulation	Legally-binding	
	Non-legally-binding	
Living modified organisms (LMOs) covered	LMOs resulting from modern biotechnology	
	Others	
Domestic transport		
Transboundary movements	Unintended	
	Deliberate	
Bilateral and/or multilateral arrangements		
Advance-informed-agreement like procedure		
Research and development		
Contained use		
Small- and large-scale release including disposal		
Commercialization		
Target	Conservation of biological diversity and sustainable use of its components	
	Human health	
Socio-economic aspects		
Liability and compensation		

Please tick here ☐ if your country does not have regulations/legislation for the safe transfer, handling and use of LMOs resulting from biotechnology that may have adverse effect on the conservation of biological diversity and sustainable use of its components, and on human health.