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INTERGOVERNMENTAL COMMITTEE FOR THE
CARTAGENA PROTOCOL ON BIOSAFETY
First meeting
Montpellier, France, 11-15 December 2000
Item 3 of the provisional agenda*

REPORT OF THE EXECUTIVE SECRETARY ON INTER-SESSIONAL WORK REQUESTED BY THE CONFERENCE OF THE PARTIES AT ITS FIRST EXTRAORDINARY MEETING (DECISION EM-I/3, PARAS. 11, 12, 13, 14) AND AT ITS FIFTH REGULAR MEETING (DECISION V/1, PARA. 3)

Note by the Executive Secretary

INTRODUCTION

1. To date, the Conference of the Parties to the Convention on Biological Diversity has adopted two decisions related to the Cartagena Protocol on Biosafety, namely, decision EM-I/3 adopted at its first extraordinary meeting, and decision V/1, adopted at its fifth regular meeting. Both decisions contained, *inter alia*, provisions addressed to Parties and other States and provisions addressed to the Executive Secretary concerning certain activities to be carried during the interim period pending the entry into force of the Protocol.

2. The present note contains the report by the Executive Secretary on the following matters:

(a) Designation of focal points for the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) by Parties to the Convention, other States and regional economic integration organizations (decision EM-I/3, para. 11);

(b) Information submitted by Parties, States and regional economic integration organizations on their existing programmes for regulating living modified organisms and related technical assistance, including training, to interested Parties and States (decision EM-I/3, para. 12);

(c) Progress on the preparatory work on the functioning of the Biosafety Clearing-House (decision EM-I/3, para. 13) and the related Meeting of Technical Experts on the Biosafety Clearing-House convened from 11 to 13 September 2000 pursuant to paragraph 3 of decision V/1; and

(d) The establishment of the roster of government-nominated experts in fields relevant to risk assessment and risk management related to the Protocol (decision EM-I/3, para. 14).

3. In addition to matters arising from the provisions of the two above-mentioned decisions of the Conference of the Parties, the note also provides information on other matters identified by the Bureau of the ICCP as being relevant for the ICCP in its preparatory work for the first meeting of the Parties to the

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Protocol, such as the status of signature of the Protocol and the designation of competent national authorities and national focal points pursuant to paragraph 1 of Article 19 of the Protocol.

4. With regard to matters arising out of the provisions of decisions EM-I/3 and V/1, the Executive Secretary sent two letters to all national focal points for the Convention on Biological Diversity, on 27 March 2000 and on 26 May 2000, transmitting decisions EM-I/3 and V/1, respectively, and requesting Governments to provide the relevant information to the Secretariat. The following sections present the current state of affairs on the basis of information provided to the Secretariat as of 30 September 2000.

I. DESIGNATION OF FOCAL POINTS FOR THE ICCP

5. As of 30 September 2000, the following Parties, States and regional economic integration organizations had designated a focal point for the ICCP: Armenia, Australia, Austria, Bahrain, Barbados, Belarus, Benin, Bolivia, Canada, Central African Republic, Chile, China, Comoros, Congo, Cuba, Czech Republic, Denmark, Estonia, European Community, Fiji, France, India, Iran (Islamic Republic of), Italy, Japan, Jordan, Kenya, Kiribati, Lao People's Democratic Republic, Lebanon, Malta, Mexico, Morocco, Namibia, New Zealand, Niger, Norway, Poland, Portugal, Republic of Korea, Saudi Arabia, Seychelles, Slovenia, Sri Lanka, Sweden, Switzerland, Tunisia, Turkey, Uganda, Ukraine, Venezuela, Viet Nam.

II. EXISTING PROGRAMMES FOR REGULATING LIVING MODIFIED ORGANISMS AND RELATED TECHNICAL ASSISTANCE, INCLUDING TRAINING

6. A summary of the information received by the Secretariat as at 30 September 2000 pursuant to paragraph 12 of decision EM-I/3 is contained in the annex to this note. It should be noted that some Governments provided the Secretariat with copies of their guidelines or other legal documents applying to biosafety such as decrees and laws. Such cases are indicated in the summary.

III. PREPARATORY WORK ON THE FUNCTIONING OF THE BIOSAFETY CLEARING-HOUSE AND THE RELATED MEETING OF TECHNICAL EXPERTS ON THE BIOSAFETY CLEARING-HOUSE

7. As stated above, in paragraph 13 of decision EM-I/3, the Conference of the Parties requested the Executive Secretary to commence preparatory work on the functioning of the Biosafety Clearing-House referred to in Article 20 of the Protocol. In decision V/1, the Conference of the Parties re-emphasized the priority of launching the Biosafety Clearing-House no later than the entry into force of the Protocol, and requested the Executive Secretary to convene, prior to the first meeting of the ICCP, a meeting of technical experts on the Biosafety Clearing-House to consider issues relevant to information–sharing and the Biosafety Clearing-House as reflected in the work plan of the ICCP adopted by the Conference of the Parties.

8. After consultation with the Bureau of the ICCP, the Executive Secretary, by letter dated 26 May 2000, conveyed the modalities of the process and the criteria for the selection of the technical experts to all national focal points for the Convention. A reminder was sent on 4 July. The outcome of the selection was also communicated to all Parties and States through a notification of 25 August 2000.

9. The Meeting of Technical Experts was held at the seat of the Secretariat from 11 to 13 September 2000. It was attended by 26 experts drawn from a roster of government-nominated experts, the Chairman and members of the Bureau of the ICCP, representatives of a number of intergovernmental organizations active in biosafety and/or information-exchange issues, and representatives of the Global Industry Coalition and the NGO community.

10. The outcome of the meeting and its conclusions and recommendations with regard to the preparatory work on the functioning of the Biosafety Clearing-House will be before the ICCP for consideration under item 4.1 of the provisional agenda and are contained in annex I to the note by the Executive Secretary on information-sharing prepared for the first meeting of the ICCP (UNEP/CBD/ICCP/1/3).

IV. ESTABLISHMENT OF THE ROSTER OF GOVERNMENT-NOMINATED EXPERTS IN FIELDS RELEVANT FOR RISK ASSESSMENT AND RISK MANAGEMENT RELATED TO THE PROTOCOL.

11. In accordance with paragraph 14 of decision EM-I/3, the mandate of the regionally balanced of government-nominated experts in fields relevant for risk assessment and risk management related to the Protocol is to provide advice and other support, as appropriate and upon request, to developing country Parties and Parties with economies in transition, to conduct risk assessments, make informed decisions, develop national human resources and promote institutional strengthening associated with transboundary movements of living modified organisms. As of 30 September 2000, a total of 185 expert nominations from 33 Governments had been received by the Secretariat for inclusion in the roster.

V. OTHER MATTERS OF RELEVANCE TO THE WORK OF THE ICCP

A. Status of signature of the Protocol

12. In paragraph 3 of decision EM-I/3, the Conference of the Parties called upon Parties to the Convention on Biological Diversity to sign the Protocol from 15 May 2000 or at the earliest opportunity thereafter and to deposit instruments of ratification, acceptance or approval or instruments of accession, as appropriate, as soon as possible. In paragraph 4 of the same decision, the Conference of the Parties further called upon States that are not Parties to the Convention to ratify, accept, approve or accede to it, as appropriate, without delay, thereby enabling them also to become Parties to the Protocol. At its fifth meeting, the Conference of the Parties welcomed the signatures that had already taken place and reiterated those calls. As at 30 September 2000, a total of 74 Parties to the Convention had signed the Protocol. A list of the signatories is attached as annex II to the present note.

13. No Party has as yet ratified the Protocol.

B. Designation of national focal point and competent national authorities

14. Under the provisions of Article 19 of the Protocol, each Party is expected to designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party is also required to designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by the Protocol and which shall be authorized to act on its behalf with respect to those functions.

15. Paragraph 2 of Article 19 of the Protocol requires each Party, no later than the date of entry into force of the Protocol for it, to notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities.

16. Under paragraph 3 of Article 19, the Secretariat is required to inform forthwith the Parties of the notifications it receives under paragraph 2 of Article 19, and to also make such information available through the Biosafety Clearing-House.

17. Notwithstanding the notifications submitted by Parties and other States in response to the requirements of paragraph 11 of decision EM-I/3 with respect to national focal points for the ICCP

reported in paragraph 6 above, the Secretariat has not yet received any notification concerning national focal points and competent national authorities pursuant to paragraphs 1 and 2 of Article 19 of the Protocol.

VI. OPTIONS FOR RECOMMENDATIONS BY THE ICCP

18. With respect to matters covered by this report in the preceding sections, the ICCP may wish to consider the following options for recommendations:

Designation of focal points for the ICCP

(a) Call on Parties and other States and regional economic integration organizations that have not yet designated a focal point for the ICCP to do so as soon as possible and inform the Executive Secretary accordingly, pursuant to paragraph 11 of decision EM-I/3.

Existing programmes for regulating living modified organisms and related technical assistance

(b) Invite Parties, States and regional economic integration organizations that have not yet submitted to the ICCP the information pursuant to paragraph 12 of decision EM-I/3 to do so as soon as possible, through the Executive Secretary.

Preparatory work on the functioning of the Biosafety Clearing-House

(c) Consider the conclusions and recommendations of the meeting of Technical Experts on the Biosafety Clearing-House contained in the addendum to the note by the Executive Secretary on information-sharing (UNEP/CBD/ICCP/1/3/Add.1) and make recommendations for the launching of the Biosafety Clearing-House, taking into account the priority accorded to this activity by the Conference of the Parties (decision EM-I/3, para. 13 and decision V/1, ninth preambular paragraph).

(d) Consider the estimate of resources that would be required to establish the pilot phase of the Biosafety Clearing-House to be presented by the Executive Secretary in the addendum to document UNEP/CBD/ICCP/1/3, and invite Parties and other States to make voluntary contributions to support the preparatory work on the functioning of the Biosafety Clearing-House.

Roster of government-nominated experts in fields relevant for risk assessment and risk management related to the Protocol

(e) In order to make effective full use of the roster, give further consideration to the provisions of paragraph 14 of decision EM-I/3 with a view to making recommendations for the operationalization of the roster of experts. This point is highlighted in paragraph 15 of the annotated agenda (UNEP/CBD/ICCP/1/1/Add.1), which suggests that the ICCP might wish to address the issue under agenda item 4.3 (Capacity-building), taking into account that the work plan for the ICCP approved by the Conference of the Parties at its fifth meeting (decision V/1, annex) identified “establishment and role of the roster of experts” as one of the issues for consideration by the ICCP under the item 4.2 of the provisional agenda, on capacity-building.

Signature and ratification of the Protocol

(f) Reiterate the call of the Conference of the Parties to Parties to the Convention and other States that have not yet signed the Protocol to do so at the earliest opportunity, and thereafter to deposit instruments of ratification, acceptance or approval or instruments of accession, as appropriate, as soon as possible;

(g) Reiterate also the call of the Conference of the Parties to States that are not Parties to the Convention to ratify, accept, approve or accede to it, as appropriate, without delay, thereby enabling them also to become Parties to the Protocol;

Designation of national focal points and competent national authorities

(h) Invite Parties to the Convention and other States to submit to the Secretariat information on national focal points and national competent authorities as soon as possible, pursuant to Article 19, paragraph 1, of the Protocol;

(i) Since it could be assumed that the information provided so far to the Secretariat with respect to national focal points for the ICCP (as reported in paragraph 5 above) may or may not apply to the requirements of Article 19, paragraph 1, subject to further confirmation by each Party, further invite Parties to clarify this matter for the Secretariat, no later than the date of entry into force of the Protocol for each Party, in line with the provisions of paragraph 2 of Article 19 of the Protocol;

(j) Invite the Executive Secretary to make available the above information through the Biosafety Clearing-House, in line with paragraph 3 of Article 19 of the Protocol.

Annex I

SUMMARY OF INFORMATION SUBMITTED BY GOVERNMENTS ON EXISTING NATIONAL PROGRAMMES FOR REGULATING LMOS AND PROVISION OF RELATED TECHNICAL ASSISTANCE TO INTERESTED COUNTRIES (DECISION EM-I/3, PARA. 12)

ARMENIA [*12 April 2000*]

[ORIGINAL: ENGLISH]

Armenia does not have ongoing programmes for regulating LMOs and has submitted to UNEP a project proposal entitled "Preparation of Armenian Biosafety Framework".

AUSTRALIA [*30 June 2000*]

[ORIGINAL: ENGLISH]

Overview of current arrangements for controlling LMOs in Australia

Current regulatory systems for controlling LMOs

In Australia, genetically modified organisms (GMOs) and genetically modified (GM) products are currently subject to control under five main regulatory systems:

1. Foods (including GM foods) are regulated under State and Territory Food Acts with the role of developing food Standards resting with the Australia New Zealand Food Authority (ANZFA) under the *Australia New Zealand Food Authority Act 1991* (Cth);

2. Therapeutic goods (including GM therapeutic goods) are regulated under the *Therapeutic Goods Act 1989* (Cth) which is administered by the Therapeutic Goods Administration (TGA) at the Commonwealth level. Unlike ANZFA, TGA approves individual products, and retains responsibility for enforcement and compliance with this framework, as well as for the pre-market approval of these goods. GMOs used in human gene therapy are also regulated by the TGA;

3. Agricultural and veterinary (agvet) chemicals (including GM agvet chemicals) are regulated through a national scheme administered by the National Registration Authority (NRA). Regulation centres around the Agvet Code which was established under the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth). This scheme is similar to the ANZFA model, where State and Territory agriculture authorities retain responsibility for control-of-use activities, such as licensing of pest control operators and aerial spraying;

4. Industrial chemicals are regulated through the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cth), administered by the National Occupational Health and Safety Commission (NOHSC) and accompanying State/Territory legislation. The scope of the legislation is limited to industrial chemicals as defined in the Act. This definition explicitly excludes whole animals or whole plants, and therefore NOHSC is limited to regulating industrial chemicals produced by GMOs, rather than living GMOs;

5. Imports/exports are regulated under the *Quarantine Act 1908* (Cth), the *Imported Food Control Act 1992* (Cth) and the *Export Control Act 1982* (Cth) administered by the Australian Quarantine and Inspection Service (AQIS). AQIS, under the *Quarantine Act*, ensures that products imported

into Australia do not lead to the introduction, establishment or spread of pests and diseases that may endanger plant, animal and human life or health. Environment Australia also regulates the export and import of certain organisms under the *Wildlife Protection (Regulation of Exports and Imports) Act 1982* (Cth).

Current administrative arrangements for controlling LMOs

The Genetic Manipulation Advisory Committee (GMAC) is an expert scientific advisory body now within the Commonwealth Department of Health and Aged Care (specifically within the Interim Office of the Gene Technology Regulator). GMAC's membership includes a wide range of experts in fields such as molecular biology, ecology, plant genetics, agriculture and biosafety engineering.

Since 1975, GMAC (and its predecessors) has underpinned the application of the regulatory systems described above. Any work in Australia involving the use of GMOs or genetic modification techniques (including field trials and general releases of GMOs) is overseen by this Committee, and it provides advice to the regulators described above on the risks associated with GMOs.

GMAC assesses whether GMOs pose potential hazards to the community or to the environment, and recommends appropriate safety procedures (including containment of organisms). However, GMAC's recommendations are advisory only.

GMAC has been effective in overseeing the safe development and use of innovative genetic manipulation techniques in Australia. There have been no instances of harm to research workers, public health or to the environment during the 25 years this technology has been in use in Australia, and compliance with GMAC requirements has been very high.

The need for change

While the existing regulatory systems and GMAC have done an excellent job to date in overseeing research and other activities involving GMOs, the Federal Government has been keen to ensure that any existing regulatory gaps are filled, and that the current voluntary GMAC processes are placed on the same footing as the other regulatory systems described above.

The current system, like any system dealing with a "cutting edge" technology, has to change from time to time to remain relevant not only to the science that it oversees, but also to the industry it regulates and the community it protects.

Three key developments have necessitated the current review of Australia's regulatory system for GMOs:

1. *The emergence of "gap" GMOs*. Today, a number of GMOs are being developed which do not fall within the mandate of existing regulators. Some examples are herbicide-resistant crops, certain microorganisms designed to decompose toxic substances (bioremediation); and ornamental plants modified to enhance particular characteristics;

2. *A move toward general (commercial) releases of GMOs*. To date in Australia only three general releases of GMOs have been approved. However, GMO research has progressed significantly in the last few years and a number of GMOs are nearing a stage of development when proponents may seek approval for general release; and

3. *Community and industry expectations of regulatory systems*. Over the past decade, consumers have become increasingly interested in the way in which businesses and services are regulated.

Community expectations of transparency and fairness, as well as a desire to be involved in the development and review of regulatory systems, have increased across the board.

The proposed new system

The Commonwealth and State and Territory governments have been working together for some time to develop a national scheme for regulating GMOs and GM products in Australia. The new system has also been the subject of an extensive consultation process. The result of this work, the *Gene Technology Bill 2000*, was introduced into Federal Parliament on 22 June 2000.

The legislation establishes an Office of the Gene Technology Regulator, which will regulate all activities or dealings involving GMOs that are not currently under the control of the existing national regulatory schemes described earlier. The legislation predominantly focuses on living and viable GMOs, however there is also a capacity under the Bill to prescribe certain GM products (for example, stockfeed) if necessary. Genetic manipulation with humans is exempted.

The legislation introduces a licensing scheme for any proposed releases of GMOs into the environment, and requires the Gene Technology Regulator to undertake an extensive public health and environmental risk assessment in relation to all such proposals. Public consultation is also required where such releases may present significant risks to public health and to the environment. The Bill also prescribes substantial enforcement powers, as well as significant penalties for non-compliance. A copy of the Bill can be obtained at www.aph.gov.au/legis.htm.

It is anticipated that the Bill will be debated in Australia's Parliament, and its final form is therefore still to be settled. However, the Government expects the Office of the Gene Technology Regulator to be fully functional from 3 January 2001.

Contact information

IOGTR website: www.health.gov.au/tga/genetech.htm
Email: iogtr@health.gov.au
Fax: 61 2 6270 4310

AUSTRIA [*27 June 2000*]

[ORIGINAL: ENGLISH]

Information on existing programmes in Austria

The European Union directives 90/219/EEC and 90/220/EEC have been implemented by the Austrian Law on Genetic Engineering (in force since 1 January 1995 and amended on 22 May 1998). The following additional regulations (ordinances) complement the framework law:

- March 1996: Ordinance on the Safety of Contained Uses of GMOs;
- February 1997: Ordinance on Deliberate Release;
- February 1997: Ordinance Prohibiting the Use and Sale of the Bt-Maize 176;
- November 1997: Ordinance on the Limitation of GMO Emissions with Liquid Effluents;
- February 1998: Ordinance on Labelling of Products which Contain or Consist of GMOs;
- July 1998: Ordinance on Biological Agents at Work;
- March 1999: Ordinance on Labelling of Genetically Modified Plant Varieties and Seeds of Genetically Modified Plant Varieties;

- June 1999: Ordinance Prohibiting In Particular the Cultivation of Bt-Maize MON810;
- April 2000: Ordinance prohibiting the Placing on the Market of Herbicide Tolerant Maize T 25.

In April 1998, the Austrian Codex Alimentarius Commission adopted a guideline on criteria for labelling food as "gene-technology-free".

Possibilities of providing related technical assistance

The Austrian Federal Environment Agency offers technical support and know-how in following fields:

- Development of regulatory mechanisms in the area of modern biotechnology;
- Risk assessment of GMOs;
- Analytical detection and identification of genetically modified substances in various samples (food, feed, environment);
- Development of monitoring concepts and plans for GMO releases and placing on the market.

The Federal Environment Agency is currently involved (together with the Netherlands Ministry of Environment) in a multi-year project of technical assistance, of the pre-accession countries of Central and Eastern Europe, in the area of biosafety.

BELARUS [*8 and 21 June 2000*]

[ORIGINAL: ENGLISH]

Information on existing programmes and technical assistance required will be transmitted to the Secretariat in the nearest future.

Special programmes on controlling living modified organisms are not available in Belarus. However, in the context of the national biodiversity programme, research work on developing the principles for the biosafety system in Belarus has been under way for the period 1999-2000. Special activities for developing a normative-legal basis for State control over the release of genetically engineered organisms into the environment will be undertaken in order to implement the CBD provisions on biosafety.

Belarus does not have technical and financial capacities to train specialists from countries Parties to the Cartagena Protocol in biosafety issues.

BOLIVIA [*13 June 2000*]

[ORIGINAL: SPANISH]

With regard to programmes for regulating living genetically modified organisms, Bolivia has in force the Regulation on Biosafety for the Convention on Biological Diversity, approved by part two of Supreme Decree No. 24676 of 21 June 1997. A copy has been sent to Secretariat.

Bolivia has also sent to the Secretariat a document entitled "Diagnostic Study on the Status of Biosafety and Biotechnology in Bolivia", prepared with the support of the Ministry of Sustainable Development and Planning and the Ministry of Environment and Natural Resources and Forestry under project GEF/1200-98-71, entitled "Support for the establishment of a national biosafety framework", with funding from the Global Environment Facility and the United Nations Environment Programme.

CAMEROON [*21 September 2000*]

[ORIGINAL: ENGLISH/FRENCH]

Cameroon has transmitted to the Secretariat its draft Bill Regulating Safety in Modern Biotechnology in Cameroon. The draft Bill (available with the Secretariat) has 96 articles that cover different fields as follows:

- Development and management of LMOs;
- Biosafety aspects linked to biodiversity (agrobiodiversity, forest and animal biodiversity);
- Biosafety aspects linked to the protection of human health;
- Creation of a national authority in charge of supervising and coordinating safety in the development, movement and use of LMOs so as to coordinate the work of the various ministries under which LMOs would be regulated;
- Penalties for non-compliance with the law.

The draft legislation also contains four annexes that explain certain concepts contained in it.

CENTRAL AFRICAN REPUBLIC [*28 June 2000*]

[ORIGINAL: FRENCH]

In November 1999, the Central African Republic submitted a budget for a project entitled "Support to the national biosafety framework" to the Global Environment Facility through the United Nations Environment Programme.

CHILE [*20 July 2000*]

[ORIGINAL: SPANISH]

Existing programmes in Chile to regulate LMOs are the responsibility of the Advisory Committee for the Release of Transgenics (CALT) in the agriculture and livestock ministry. The following other departments are also maintain and design of programmes to monitor and regulate the management of LMOs: CONAMA (National Corporation for the Environment); ODEPA (Office for Agricultural Planning): INTA (the Institute for Nutrition and Food Technology of the University of Chile); the Department of Fisheries in the Ministry of Fisheries. For this reason, the Republic of Chile is in a position to offer technical assistance through the above-mentioned bodies.

CHINA [*17 July 2000*]

[ORIGINAL: ENGLISH]

China has completed the UNEP/GEF project for formulating the national biosafety framework. China is currently preparing a further project in this field for GEF assistance. This project aims to strengthen legislative and administrative measures for biosafety management and human resources management and training in this field.

CUBA [*2 June 2000*]

[ORIGINAL: ENGLISH AND SPANISH]

The Coordination Centre

In Cuba, Resolution 67/96 of the Ministry of Science, Technology and Environment established that the National Centre for Biosafety has as its objective to organize, manage and control measures towards the fulfilment of the obligations of the Republic of Cuba with regard to legal international instruments related with biosafety.

Coordinates of the National Centre for Biosafety:

Director: Jose Rodriguez Duenas
Address: Calle 28 No. 502 as. And 7a. Playa
Havana, Cuba
Tel: 537 223 281/238/040

Existing programmes to regulate LMOs

In Cuba, LMOs are regulated in accordance to the following legal documents:

(a) Law 81 on the Environment:

- Identify the processes and categories of activities that might have adverse effects that would affect the conservation and utilization of biological diversity and follow-up on their effects;
- Regulate and control the risks derived from the utilization and release of LMOs by biotechnology or other substances or products, which can affect the sustainable conservation and utilization of biological diversity.

(b) Decree Law 190 on Public Safety:

- Evaluate and assess the risks and approve the research and investigation regarding the release of biological agents and products, organisms and fragments into the environment;
- Authorize, suspend and revoke authorizations for the realization of activities related to the use, research and rehearsal, production, liberation as well as import and export of biological agents and its products, organisms and fragments of these with genetic information;
- Establish guidelines for the study, evaluation and management of the risks of releasing biological agents and products into the environment, as well as organisms and fragments with this genetic information, and the procedures for the control, mitigation and treatment of dangerous biological discharges;
- The entity, which releases waste into the environment or carries out exports and imports will have to have a technical file of the release, which it will make with the pertinent recommendations for the protection of the worker and the environment to avoid any negative outcome.

Other legal instruments are in the process of being developed. These will be developed in accordance with biological safety resolutions in institutions and establish a methodology and procedures for the evaluation and management of biological risks arising from the release of organisms into the environment for the approval of licences for biosafety.

Possibilities of technical assistance

Cuba has a National Centre for Biosafety as a vortex for a national system which, since 1996, has been carrying activities related to the evaluation of biological risk due to the release of LMOs.

This Centre has structured three national courses annually about biological safety, which includes all the elements for evaluation and management of risks arising from modern biotechnology. Two of these courses have an international profile wherein different specialists from different Spanish-speaking countries have been trained. The Centre has also coordinated and given courses on biosafety on a regional scale. It has planned to offer a masters degree in biosafety with three specializations: human health, plant health and veterinary medicine. It also promotes courses in territories and institutions.

The Centre has collaborated with other countries in carrying out evaluation of risks arising from the release into the environment of transgenic plants. The Centre has a group of highly qualified specialists, doctorates in science, masters and researchers in different categories.

The technical assessment group has free access to the Biosafety Centre to evaluate risks and manage the risks identified, to offer courses in biosafety in Cuba as well as in other countries, with the only condition being that the international or national entity covers the expense of these courses.

DENMARK [*28 June 2000*]

[ORIGINAL: ENGLISH]

The Danish regulatory framework in the area of deliberate release and contained use of LMOs is based on an implementation of the European Union directives 90/220/EEC and 98/81/EC amending 90/219/EEC on the contained use of genetically modified microorganisms (GMMs). The framework consists of Act No. 356 of June 6, 1991 on the Environment and Genetic Engineering with connected Statutory Orders*. The amended statutory orders that implement directive 98/81/EC entered into force on 5 June 2000 and are in the process of being translated.

Denmark has several windows for assistance to training and capacity-building in Parties and States. Within the framework of the Environment, Peace and Stability Facility, support can be provided to specific countries and regions.

DANIDA, through the Ministry of Foreign Affairs, provides support to low-income developing countries in Africa, South-East Asia and Latin America, in particular to twenty selected programme cooperation countries. In each country, particular sectors receive support. The contact details of DANIDA are:

DANIDA
Ministry of Foreign Affairs
Asiatisk Plads 2
1448 Copenhagen K
Denmark
Tel: + 45-33-92-00-00
Fax: + 45-31-54-05-33

The Ministry of Environment and Energy provides support to middle-income countries in southern Africa (Botswana, Lesotho, Namibia, South Africa and Swaziland) and South-East Asia (Malaysia and Thailand) through Danced. The Ministry also provides support to countries with economies in transition (in particular, Estonia, Latvia, Lithuania, Poland and Russia) through Dancee.

* *Note*: Pieces of legislation available at present in English, totalling 33 pages, have been submitted to the Secretariat.

Currently, Dancee is working on expanding the range of countries in Central and Eastern Europe receiving support from the Facility, especially Slovakia and Ukraine among others. Contact details of Danced and Dancee are given below:

Ministry of Environment and Energy
Environmental Protection Agency
Strandgade 29
1401 Copenhagen K
Denmark
Tel: + 45-32-66-01-00
Fax: + 45-32-66-04-79

ESTONIA [*15 June 2000*]

[ORIGINAL: ENGLISH]

Estonia has adopted the Act on Deliberate Release of LMOs into the Environment, but no licences have been issued as of now. The Ministry of Social Affairs is currently preparing a draft Act on Contained Use of LMOs, and the Ministry of Agriculture is preparing a draft Act on Experimental Use of LMOs Other Than Genetically Modified Microorganisms (GMMs). Estonia has therefore no practical experience in regulating LMOs although LMOs have been widely used in science for a long time.

ITALY [*6 July 2000*]

[ORIGINAL: ENGLISH]

Legislative Decree No. 92 of 1993 is the current regulation for the deliberate release of LMOs into the environment. This decree adopts the European Union directive 90/220/EEC, which is now being revised. A new directive is awaited before the end of the year 2000 and will be adopted by Italy within two years. Following this new regulation(s) and following the entry into force of the Cartagena Protocol on Biosafety, Italy plans to activate international initiatives for training and capacity-building on the issues of biosafety. For the moment, such initiatives are limited at a national level.

JAPAN [*29 June 2000*]

[ORIGINAL: ENGLISH]

Japan has the following three guidelines related to agro-industries, industries and experiments, as well as a ministerial ordinance and announcements based on the Food Sanitation Law:

(a) Guidelines for Application of Recombinant DNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries;

(b) Guidelines for Industrial Application of Recombinant DNA Technology;

(c) Guidelines for Recombinant DNA Experiments;

(d) Ministry of Health and Welfare Ordinance No. 95 regulates standards for composition and manufacturing process of milk and dairy products produced by recombinant DNA techniques;

(e) Ministry of Health and Welfare Announcement No. 232 regulates standards for composition and manufacturing process of foods produced by recombinant DNA techniques;

(f) Ministry of Health and Welfare Announcement No. 233 regulates procedures of application for safety assessments of foods defined in he above-mentioned Announcement No. 232;

(g) Ministry of Health and Welfare Announcement No. 234 regulates standards for manufacturing methods of foods defined in the above-mentioned Announcement 232.

Regarding the possibilities of providing technical assistance, Japan would like to respond to requests from developing countries on a case-by-case basis through the use of available mechanisms.

KIRIBATI [*28 July 2000*]

[ORIGINAL: ENGLISH]

Under the Environment Act 1999 (December 1999), genetically engineered organisms are one of the prescribed developments that require to go through the national development consent procedures. In relation to compliance with the Environment Act, changes to the Customs Regulation and Ordinance are under way. Unfortunately, limited technical expertise within the country is a major constraint to efficient continuity of the process.

The Secretariat for the Community of the South Pacific had been liaising with the Quarantine Department in Kiribati for a possible in-country workshop in the year 2000 on LMOs and invasive species. The Environment and Conservation Division within the Ministry of Environment and Social Development undertook very limited coverage for public awareness of LMOs on radio only.

A major obstacle in managing LMOs, despite being controlled under the new environmental legislation, are the enforcement procedures especially in terms of risk assessment risk management and other related actions required to control, handle and manage LMOs well because of the limited qualified technical experts in the country.

Kiribati welcomes technical assistance from Parties willing to offer appropriate assistance in the area of handling, controlling, managing and regulating LMOs well.

MALTA [*26 July 2000*]

[ORIGINAL: ENGLISH]

Malta is in the process of commissioning a report to identify the state of the use of LMOs in Malta. There is a lack of expertise in biosafety and Malta would like financial and other assistance to implement the Protocol in the Maltese Islands.

NAMIBIA [*12 July 2000*]

[ORIGINAL: ENGLISH]

Namibia's national biosafety framework prepared with the assistance of the UNEP/GEF biosafety pilot project includes the following:

- Country study of the status quo of biotechnology and biosafety activities, institutional structures and capacity, safety protocols, legislation and operational guidelines;
- Technical guidelines for the safe use in laboratory contained uses, field trials, filed releases and commercial use of biotechnology and risk assessment procedures and risk management principles;
- A Cabinet-approved national policy, "Enabling the safe use of biotechnology in Namibia";
- Draft legislation currently in a stage of technical review.

The national biosafety framework is almost complete, with the draft biosafety legislation due to be enacted by the end of the year 2000.

NEW ZEALAND [*4 July 2000*]

[ORIGINAL: ENGLISH]

Information on how New Zealand regulates LMOs is on the website (http://www.ermanz.govt.nz) of the Environmental Risk Management Authority (ERMA, New Zealand).

Possibilities of providing technical assistance. New Zealand is currently exploring with the South Pacific Regional Environment Programme (SPREP) the possibility of holding a regional workshop on biosafety in the year 2000 specifically targeted at Pacific island countries and territories. Given its limited expert resources, it is unlikely that New Zealand will be able to extend assistance beyond its region at this stage.

NORWAY [*28 July 2000*]

[ORIGINAL: ENGLISH]

Norway has no programmes *per se* for regulating LMOs. A comprehensive legislation is established for regulating the field, *inter alia* risk assessments for releasing LMOs into the environment and procedures for evaluating products before marketing. All applications for marketing new LMOs are evaluated separately; so far, 32 applications have been evaluated. The Norwegian Research Council (NFR) has several programmes for analysing different aspects of biotechnology, *inter alia*, development of new LMO-products, medical research, research on social and environmental effects from LMOs.

LMO- and biotechnology-related funding receives about US$ 17 million a year of which about US$ 0.25 million goes directly to evaluation of unintended dispersal of LMOs in the environment. Competent authorities have broad experience in building legal framework for regulation and management of biotechnology in 18 developing countries. This experience is in the following areas:

- Institutional capacity-building for institutions working with biotechnology management sectors and at different levels
- Developing:
    - Legislation and guidelines
    - Systems for risk assessments, management and control of LMOs, import/export and release into the environment, facilitating national / international information flow and cooperation between consumers, industry and authorities.

POLAND [*21 September 2000*]

[ORIGINAL: ENGLISH]

There is only one programme existing in Poland. It is a project entitled “Implementation of national biosafety framework in pre-accession countries of central and Eastern Europe” conducted by the Netherlands Ministry of Environment. More information on this project can be found on the website http://www.biosafety.hu/CEE/.

SAUDI ARABIA [*6 July 2000*]

[ORIGINAL: ENGLISH]

Committees and regulations are being established for regulating LMOs, but facilities for providing technical assistance and training are not available as yet.

SEYCHELLES [*8 May 2000*]

[ORIGINAL: ENGLISH]

Seychelles has established a task force to oversee the development of the national biosafety framework, and a submission for funding is being processed.

TURKEY [*4 July 2000*]

[ORIGINAL: ENGLISH]

As yet, Turkey has no programmes except studies on a legal framework. The Ministry of Agriculture and Rural Affairs, General Directorate of Agriculture Research, Department of Field Crop Research is undertaking preparation of regulations and technical infrastructure. The Ministry of Environment, General Directorate of Environment Protection has initiated a public awareness study.

VIET NAM [*6 July 2000*]

[ORIGINAL: ENGLISH]

The regulations on safety management of LMOs and their products have been prepared and submitted to the Office of the Prime Minister for approval. Vietnam requests the Secretariat to provide technical assistance for enforcing the regulations, focusing on the priority of training experts in fields relevant to risk assessment and risk management.

Annex II

LIST OF SIGNATORIES OF THE CARTAGENA PROTOCOL ON BIOSAFETY*

	Participant	*Date of signature*
1.	Algeria	25 May 2000
2.	Antigua and Barbuda	24 May 2000
3.	Argentina	24 May 2000
4.	Austria	24 May 2000
5.	Bahamas	24 May 2000
6.	Bangladesh	24 May 2000
7.	Belgium	24 May 2000
8.	Benin	24 May 2000
9.	Bolivia	24 May 2000
10.	Bulgaria	24 May 2000
11.	Burkina Faso	24 May 2000
12.	Central African Republic	24 May 2000
13.	Chad	24 May 2000
14.	Chile	24 May 2000
15.	China	8 August 2000
16.	Colombia	24 May 2000
17.	Costa Rica	24 May 2000
18.	Croatia	8 September 2000
19.	Cuba	24 May 2000
20.	Czech Republic	24 May 2000
21.	Denmark	24 May 2000
22.	Ecuador	24 May 2000
23.	El Salvador	24 May 2000
24.	Estonia	6 September 2000
25.	Ethiopia	24 May 2000
26.	European Community	24 May 2000
27.	Finland	24 May 2000
28.	France	24 May 2000
29.	Gambia	24 May 2000

* As of 15 September 2000.

Participant		*Date of signature*
30.	Germany	24 May 2000
31.	Greece	24 May 2000
32.	Grenada	24 May 2000
33.	Guinea	24 May 2000
34.	Haiti	24 May 2000
35.	Honduras	24 May 2000
36.	Hungary	24 May 2000
37.	Indonesia	24 May 2000
38.	Ireland	24 May 2000
39.	Italy	24 May 2000
40.	Kenya	15 May 2000
41.	Kiribati	7 September 2000
42.	Lithuania	24 May 2000
43.	Luxembourg	11 July 2000
44.	Madagascar	14 September 2000
45.	Malawi	24 May 2000
46.	Malaysia	24 May 2000
47.	Mexico	24 May 2000
48.	Monaco	24 May 2000
49.	Morocco	25 May 2000
50.	Mozambique	24 May 2000
51.	Namibia	24 May 2000
52.	Netherlands	24 May 2000
53.	New Zealand	24 May 2000
54.	Nicaragua	26 May 2000
55.	Niger	24 May 2000
56.	Norway	24 May 2000
57.	Peru	24 May 2000
58.	Philippines	24 May 2000
59.	Poland	24 May 2000
60.	Portugal	24 May 2000
61.	Republic of Korea	6 September 2000
62.	Rwanda	24 May 2000
63.	Samoa	24 May 2000

Participant		*Date of signature*
64.	Slovakia	24 May 2000
65.	Slovenia	24 May 2000
66.	Spain	24 May 2000
67.	Sri Lanka	24 May 2000
68.	Sweden	24 May 2000
69.	Switzerland	24 May 2000
70.	The former Yugoslav Republic of Macedonia	26 July 2000
71.	Togo	24 May 2000
72.	Turkey	24 May 2000
73.	Uganda	24 May 2000
74.	United Kingdom	24 May 2000
75.	Venezuela	24 May 2000
