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ADDENDUM TO THE BIODIVERSITY CONSERVATION IN SRI LANKA

A Framework for Action

CHAPTER REPORT - 08

BIOSAFETY

Biodiversity Secretariat
Ministry of Environment

Addendum to the Biodiversity Conservation in Sri Lanka
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CHAPTER REPORT ON BIOSAFETY
(TASK FORCE NO-07)

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BIOSAFETY

I. INTRODUCTION

Biosafety is a concept that refers to the need to protect, biodiversity, human health and the environment from the possible adverse effects of the products of modern biotechnology (Cartagena Protocol on Biosafety). Biosafety is one of the many issues addressed by the CBD which entered into force on 29 December 1993.

Biotechnology refers to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use (Convention on Biological Diversity). "Old" biotechnology generally refers to tissue culture and traditional fermentation methods while modern biotechnology refers to, among many techniques, the use of recombinant DNA technology (rDNA technology) to produce novel plants, animals, microbes and products from them.

A "Living Modified Organism" (LMO) means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (Cartagena Protocol on Biosafety). For the purpose of the protocol, the same definition holds for "Genetically Modified Organisms" (GMO) as well. The products from LMOs/GMOs are used as food (Genetically Modified Food, GMF), feed (Genetically Modified Feed, GMF) and as processed products, together designated as GMO/FFPs.

"Modern biotechnology" means the application of:

(a) *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
(b) Fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.
(Cartagena Protocol)

The Convention very clearly recognizes the two important aspects of modern biotechnology i.e. its advantages as well as the risks and concerns. While Article 16,
paragraph 1, and Article 19, paragraphs 1 and 2, provides for the access to and transfer of technologies, including biotechnology, that are relevant to the conservation and sustainable use of biological diversity, Articles 8(g) and 19, paragraph3, refers to the development of appropriate procedures to enhance the safety of biotechnology in the context of the Convention's overall goal of reducing all potential threats to biological diversity, taking also into account the risks to human health. Article 8(g) deals with steps that Parties should adopt at national level, whilst Article 19, paragraph 3, seeks the development of an international legal instrument.

After many years of negotiations, the Working Group on Biosafety established by the Conference of the Parties to the Convention, developed the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. It was finalized and adopted in Montreal on 29 January 2000. Sri Lanka is a signatory to this Protocol. It is an international regulatory framework, an enabling environment for the environmentally sound application of biotechnology, so that countries can harness the immense potential of this powerful technology whilst making sure that possible risks to biodiversitry, environment and to human health are minimized.

Recombinant DNA Technology

(I) Production of a GMO using rDNA technology can be summarized as follows:

Isolating a gene of interest from the DNA of an organism.

- Inserting the gene into the DNA of another plant/animal cell using a vector system.
- Producing the whole plant/animal and checking for the presence of the foreign gene.
- Checking the gene for proper expression in the new environment.
- Checking the offspring of GM plant/animal for proper inheritance of inserted gene.

(ii) Benefits of modern biotechnology

Many end products of rDNA technology have been reported such as plants carrying herbicide tolerant genes, genes conferring resistance to pests, as well as biotic and abiotic stress factors. Others include products with higher nutritional value, biofertilizer, biopesticides, bioherbicides, novel flowers and improved microbes for conversion of waste and break down of pollutants and for use in industries such as brewery, confectionary, detergent and leather. This technology also has wide application in animal improvement and in medicine such as in gene therapy, production of pharmaceuticals, nutraceuticals, monoclonal antibodies and vaccines.

(iii) Concerns and risks

Although many benefits of GMOs have been reported, many risks and concerns regarding their use have also been aired and questioned at many international fora.

- The product of the new gene can be toxic or allergenic

- The transgene can move to other organisms through natural systems and thus create new undesirable organisms such as super weeds
- The product of the transgene, such as the Bt toxin, can affect non-target organisms
- The antibiotic resistant marker gene can transfer to human pathogenic microbes and result in them being resistant to antibiotic treatment
- The transgenic organisms can be invasive and affect our biodiversity
- Can a few organizations be allowed to "own" through patenting, the myriad of genes available in our country?
- Ethical and moral issues such as "owning" life and the inclusion of animal genes in vegetables and other products.

The Precautionary principle

At present there is a lack of scientific certainty of the potential adverse effects of GMOs on the conservation and sustainable use of biological diversity, on the environment and human health. This may be due to insufficient relevant scientific information and knowledge. This shall not prevent a country from taking appropriate steps/precautions with regards to the import of GMOs, in order to avoid or minimize such potential adverse effects.

II. The Convention on Biological Diversity

The CBD addresses biodiversity issues including the conservation of biological diversity, sustainable use of natural resources, fair & equitable sharing of benefits derived from the use of genetic resources and biosafety.

Sri Lanka has been named as one of the 25 biodiversity hotspots of the world .The CBD was finalized in Nairobi in May 1992 and opened for signature at the UN conference in Rio de Janeiro in June 1992. It entered into force on 29 December1993.

CBD – Article 19, Para 1 & 2

- Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties

- Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

CBD - Article 8 (g) – National Level

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

CBD - Article 19, para 3

The Parties shall consider the need for and modalities of a protocol 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.

The Conference of the Parties to the Convention met in November 1995 and established Working Group on Biosafety to develop a draft protocol on **biosafety**, especially on Transboundary Movement of any LMO resulting from modern biotechnology that may have adverse effects on conservation and sustainable use of biological diversity.

The Protocol was finalized and adopted in Montreal in Jan. 2000 as the Cartagena Protocol on Biosafety to the CBD.

III. The Cartagena Protocol

Provides an international regulatory framework to ensure an adequate level of protection in the field of the safe transfer, handling and use of LMO 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 movement.

It is an enabling environment for environmentally sound application of modern biotechnology so as to derive maximum benefits while minimizing the possible risks to the environment and human health.

Some important features of The Protocol:

- Reaffirms precautionary approach (Principle 15 of Rio Declaration on Envt. & Development)
- Aware of rapid expansion of modern biotechnology and growing public concern over its potential adverse effects on the environment and human health
- Recognizes that modern biotechnology has great potential for human well being if used with adequate safety measures
- Recognizes the crucial importance of centres of origin and centres of genetic diversity
- Takes into account limited capabilities of developing countries to cope with the nature and scale of known and potential risks associated with LMO
- Recognizes that trade and environment agreements should be mutually supportive

Sri Lanka signed the Biosafety Protocol on 24 May 2000 and therefore, as a signatory is obliged to set up a national regulatory framework in accordance with the articles of the protocol.

The Ministry of Environment & Natural Resources is the National Executing Agency and National Focal Point for biosafety. It has embarked on establishing the National Biosafety Framework (NBF) in line with the Cartagena Protocol on Biosafety.

IV. A Framework for Action (BCAP) – Review and Gap analysis

There is no separate chapter for biosafety in the above document. Following are some of the few occasions where biotechnology and Biosafety are indicated in the document.

- Legal Measures

Recommended Action:

3. Establish a legal framework and regulatory mechanism for controlling research in, and the release of, genetically modified organisms. (p76)
5. Clarify legal issues relating to the import of all organisms, including microorganisms and living modified organisms. (p76)

- Integrating National Efforts for Biodiversity Conservation

The Role of private sector:

Prepare (or amend), in consultation with national experts, regulations and guidelines for controlling and regulating (iii) use of biotechnology in developing genetically engineered organisms (iv) import and distribution of transgenic biological material (including viruses, bacteria and other microorganisms) (p84)

- Biodiversity Secretariat: Develop modalities for effective participation in biotechnological research including establishment of national guidelines and regulations for safe transfer, handling and use of LMOs (p86)

- Time frames for achievement of results

Regulating the import & export of GMOs, LMOs and their products (p87)

➢ Resource Needs

Manpower training:

Specialized training of selected personnel will be necessary in certain areas such as underwater and marine research, modern biotechnology, biosafety procedures etc.

V. Status of Biotechnology and Biosafety in Some Asian Countries

Many Asian countries have adopted modern biotechnology, especially in its application to agriculture (Table 1) (ADB report, 2000).

The Peoples Republic of China leads the way, particularly in the production of GMOs. Field tests have been carried out in rice, wheat, maize, cotton, tomato, pepper, potato, cucumber, papaya and tobacco. The traits include resistance to diseases, pests and herbicides and quality traits. More than 50 GM varieties have been approved for environmental release and also a few for large-scale commercial production, the most common being the pest-resistant cotton. The Ministry of Agriculture of China is responsible for all matters concerning agricultural GMOs. The ministry has approved 59 GMOs for commercial production during 1997-2001 and 12 items were issued with biosafety certificates in 2002. The GMOs include insect-resistant cotton, delayed ripening tomato, colour-altered petunia and disease resistant sweet pepper. In 1993, the State Science & Technology Commission issued the Safety Administration regulation on Genetic Engineering, which was the first law on biosafety in China. Three years later, the Safety Administration Implementation Regulation on Agricultural Genetic Engineering was issued and entered into effect in July 1996. The Office of Genetic Engineering Safety Administration was also established in 1996 to regulate field tests, environment release and commercialization of transgenic organisms in China. In May 2001, the State Council issued the Regulation on Biosafety Administration of Agricultural GMOs.

The Department of Biotechnology of the Government of India, Established in the early 1980s, was instrumental in promoting modern

Biotechnology in industry, medicine and agriculture including bioremediation and bioinformatics (Sharma, 2000). India has already approved the commercial production of Bt cotton and carries out extensive research on producing other GM products such as potatoes, edible vaccines, animal vaccines etc. There is a significant interaction with the private sector especially in the seed sector, veterinary products sector and bioinformatics which is linked with the rapidly developing information technology sector (Dhawan, 2001). The MS Swaminathan Research Foundation of India is introducing the novel concept of Biovillage programme which concentrates on introducing new technology to the villages with active participation of the people, especially the womenfolk, using the resources of the village itself.

The Indonesian government has designated three National Biotechnology Centres to coordinate research and development in agriculture, medicine and industrial microbiology. The Agency for Agricultural Research and Development is the decision making body for applications of biotechnology to agriculture. The National Committee on Biotechnology is the apex advisory body on policy. Several GM crops such as Bt cotton, RR soybean, Bt rice etc. are being developed and / or commercially planted. As a signatory to the Cartagena Protocol, Indonesia is at present preparing the biosafety regulations in the form of a government regulation.

The Philippine government has established a National Committee on Biosafety of the Philippines in 1990 as an agency of the office of the President of the Philippines. The biosafety guidelines were formulated in 1991. Furthermore, guidelines on planned release of GMOs and potentially harmful exotic species were formulated and implemented. Bt Corn is being field-tested in the Philippines.

Bhutan is taking an initiative to develop its biosafety framework, although GMOs are not being developed nor field-tested at present.

The Maldives is at the initial stages of developing its National Biosafety Framework.

The Biosafety Sub-Committee of Thailand was established by the

Centre for Genetic Engineering and Biotechnology in 1990 to be responsible for biosafety issues including the drafting of the biosafety guidelines. The guidelines were completed in June 1992 followed by the establishment of the National Biosafety Committee in 1993. Since Thailand has not yet ratified the Convention on Biological Diversity, it has no obligation to adhere to the Cartagena Protocol on Biosafety. The Biosafety Law to cover GMOs is being proposed to the parliament. Other regulations such as the Plant Quarantine Act and Plant Variety Protection Act prohibit the import of 40 plant species known to undergo transgenesis as well as 37 other transgenic plant species. Introduction of GM plants into Thailand can only be for research purposes and has to be granted permission by the Department of Agriculture and the Ministry of Agriculture and Cooperatives after receiving technical reviews and advice from the National Biosafety Committee in accordance with Thailand's biosafety guidelines. The first transgenic plant permitted for field trials was Flavr Savr tomato. Since then, 16 permits have been given to introduce GMOs into the country such as Bt cotton and Bt corn for research purposes and field trials but none for commercial production. The Ministry of Public Health has established requirements for labelling of GM food since May 2003.

There is no evidence of importation of GMOs or their products to Vietnam. No genetically modified crops have been released locally, although much research in this area is going on in crops such as rice, papaya, potato, sugarcane, tomato, cotton, maize etc. Vietnam is currently engaged in initiating the establishment of the national biosafety framework.

Bangladesh, Malaysia, Nepal, Pakistan and Singapore are actively engaged in establishing biosafety measures in their biotechnology programs.

VI. Strategies and Recommendations:

National Biosafety Framework of Sri Lanka

As a country which has ratified the convention on Biological Diversity, Sri Lanka is obliged to implement the articles of the protocol and develop its national regulatory framework for the safe transfer, handling, use and release of any GMOs resulting from the use of modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, specifically focusing on transboundary movement of GMOs.

The Ministry of Environment and Natural Resources, being the National Focal Point and the National Executing Agency for biosafety has to develop a National Biosafety Framework of Sri Lanka with regional and international interaction.

The National Biosafety Framework is a system of legal, technical and administrative mechanisms set in place to address safety in the field of modern biotechnology.

The main elements of the framework will consist of the following.

1. A regulatory system set in place to address safety in the field of modern biotechnology. It should be a legally binding system whose main elements should include general provisions, operational provisions and other relevant elements, with reference to ICCP Implementation Toolkit and UNEP-GEF Implementation Manual. It should also consider international and national obligations and what is already covered by existing legislation. The operational provisions must consider contained use, release, placing on the market, import/export/transit, institutional procedures etc. The other elements to be considered must include enforcement, transparency, accountability, information & public participation, monitoring, confidentiality, emergency measures etc. As the country's choice it could include knowledge management, offences and penalties, appeal

system, transition period, liabilities & redress, new information, revision of decision, labelling & traceability, ethical issues etc.

2. An administrative system to handle requests for permits for importation or for field release of GMOs. It should be linked to the regulatory regime. The system should include the administration tasks (initial & future), legal requirements &/or undertakings and procedural requirements (AIA & Article 11). The administrative system should identify the Focal Point and the respective Competent Authorities for risk assessment and management, the mechanism for public participation in the decision making process and a means for appeal.

3. A decision-making system that includes risk assessment and management for the release of GMOs. Risk assessment should be carried out according to Article 15 of the protocol and risk management according to Article 16 of the protocol.

4. Mechanism for public participation and information should be established according to Article 23 of the Protocol.

5. National Biosafety Policy

See Appendix I & II

The programme to establish the NBF-SL should be conducted in 4 phases as given below. A National Coordinating Committee (NCC) should be set up to provide guidance and advice. A Project Management Committee (PMC) should be set up to manage the financial and other day-to-day matters of the programme and to implement the action plans of the programme. Coordinators from the relevant institutions and ministries can be appointed to coordinate and assist in all activities of the project.

I. Carry out an island-wide survey on biotechnology and biosafety.

The objective of this exercise is to establish a national database on biotechnology and biosafety. The information therein can be used to identify the resources available in these fields in terms of expertise,

centres, laboratories, equipment, knowledge, services, library facilities, funds etc. as well as assist in formulating the national policies in biotechnology & biosafety, the evaluation of existing relevant legal documents, identifying industrial requirements etc. Therefore the relevant questionnaires should be prepared to obtain this information. requirements etc. Therefore the relevant questionnaires should be prepared to obtain this information.

II. Carry out awareness programmes on GMO/GMF & relevant issues

This should be carried out in all provinces for various categories of stakeholders such as NGOs, farmer organizations, consumer organizations, the scientific community, private sector, banks, lecturers, teachers and students, media and legislators.

III. Carry out training programmes on Risk Assessment & Management

This should be carried out for selected stakeholders such as Institutional Coordinators and the members of the National Coordinating Committee as they will be most likely involved with risk assessment & management on implementing the NBF-SL.

IV. Drafting of the National Biosafety Framework of Sri Lanka.

This will be done after analyzing the data from the survey and on completion of the training programmes. It will be carried out in consultation with the NCC.

VII. Highlights:

PROGRESS OF NATIONAL BIOSAFETY RAMEWORK DEVELOPMENT PROJECT OF SRI LANKA

01. Office Set up

The office was set up in May 2003 with the appointment of the NPC and the PA. The NPC, PA and seven (7) Graduate Assistants (appointed in June/July 2003) together with a Computer Assistant, 2 Office Assistants and the Computer Programmer all work as a single team in a

be appointed in November 2003. Telephone, e-mail and Internet facilities were established in July 2003.

02. Institutional Coordinators (ICs)

On a suggestion made by the NPC, all relevant institutions in Sri Lanka were requested to appoint Institutional Coordinators to assist in developing the NBF-SL at various stages. A total of 55 ICs have been appointed. The first meeting of the ICs was held on 31 st July 2003, where the objectives of the project and the expected assistance of the ICs were explained.

03. Survey

The office staff was trained in survey methodology by the Academic Staff of the Dept. of Agricultural Extension, Faculty of Agriculture, University of Peradeniya. Drafts of questionnaires were checked on several occasions at Peradeniya. Questionnaires from similar surveys carried out by USA, New Zealand and Seychelles were examined, studied and relevant portions adopted in the questionnaires. The questionnaires of several categories were prepared as given below.

1. Policy issues
2. Expertise
3. Physical resources
4. Industry
5. Media
6. Libraries
7. Export / Import
8. Technology / techniques / knowledge
9 Service sector
10. Frameworks for import
11. Health

Samples of questionnaires from each category were pre-tested by sending them to appropriate personnel/institutes. It is proposed to obtain the assistance of the Institutional Coordinators to get back, if not all, as many filled questionnaires as possible. It is also proposed to

insert an advertisement in the newspapers requesting anyone who had not received a questionnaire and who wishes to have one (or several) to contact the biosafety unit. Telephone and e-mail resources will also be used to carry out mini-surveys if necessary. The filled questionnaires are being received now.

It should be noted that the National Biotechnology Committees of NSF and CARP have assured their support in this endeavour, as they will be also looking forward to using the database in the future for various purposes.

04. Awareness Programmes

Following awareness programmes were conducted by the NBFSL upto 31 st January 2004.

1. Awareness workshop for Media, at Colombo
2. Awareness workshop for NGOs, Farmer and Consumer Organizations in Western province, Colombo
3. Awareness workshop for NGOs, Farmer and Consumer Organizations in Central province at Kandy
4. Awareness workshop for NGOs, Farmer and Consumer Organizations in the North Central province at Anuradhapura
5. Awareness workshop on GMOs/GMFs and biosafety for Scientists in the Western province at Colombo
6 Awareness workshop for NGOs, Farmer and Consumer Organizations in Southern province at Mathara
7 Awareness workshop for NGOs, Farmer and Consumer Organizations in North Western province at Kurunegala

05. Training Programmes on Risk Assessment & Management

Several training programmes on risk assessment & management will be conducted in 2004 including a regional programme for SAARC countries.

06. The National Coordinating Committee (NCC)

The NCC consisting of 22 members was appointed by the BD secretariat and its first meeting was held on 18th September 2003. Following are the appointed members.

1. Mr. Thosapala Hewage, Secretary, Ministry of Environment and Natural Resources
2. Mr. Jayantha Dissanayake, Addl. Secretary, Ministry of Environment and Natural Resources
3. Prof. A.L.T. Perera, National Project Coordinator
4. Mr. Sarath Fenando, Conservator General of Forests, FD
5. Mr. Rohan Pethiyagoda, Advisor to the Hon. Minister of Environment and Natural Resources
6. Mr. Gamini Gamage, Director (Biodiversity) ME &NR
7. Dr. C.K. Shanmugarajah, Director(E & OH), Dept. of Health
8. Mrs. R. W. M. P. Senevirathne, Deputy Legal Draftsman, Legal Draftsman Department
9. Mr. Samantha Gunasekara, Superintendent of Customs (Biodiversity Protection Unit), Dept. of Customs
10. Mr. H. M. B. C. Herath, Diretor General, Dept. of Wildlife Conservation
11. Dr. Thamara F. Dias, Scientific Officer, National Science Foundation
12. Mr. N. J. Liyanage, Research Officer and OIC, Plant Quarantine Unit, Ministry of Agriculture and Livestock
13. Mr. Hemantha Withanage, Director, Environmental Foundation Ltd
14. Mr. Jagath Gunawardena , Representative, Society for Environment Education
15. Mr. A.S. Premasundera, Assistant Director, Dept. of Animal Production and Health
16. Mr. D. S. Nandasena, Asst. Director (Actg.), Dept. of Fisheries and Aquatic Resources
17. Mr. S. R. Balachandran, Financial Director, National Chamber of Commerce (private sector)
18. Mr. Ajith Silva, Dy. Director (Biodiversity), ME &NR

19. Ms. Manel Jayamanna, Director General, Central Environment Authority
20. Ms. L. P. Batuwitage, Director (Environment)
21. Mr. Ravindranatha Dabarre, Environmental Foundation Ltd
22 Ms. Pomoda Rujzkeey, Environmental Foundation Ltd

07. The Management Committee (Steering Committee)

The management committee consisting of the Additional Secretary, NPC, Director BD, Deputy Director, BD, Senior Accountant and the PA meet regularly to discuss various aspects of the project, especially the use of the budget allocations.

08. Publications

It is proposed to purchase relevant books, journals, videos and CDs for a library. Wallpapers, posters, booklets, key-tags, models etc. for extension purposes are being prepared. It is also proposed to carry out TV programmes, debates etc. concurrently with the awareness programmes. The TV programme "Kamatha" included a discussion on the biosafety programme.

The following have been published

1. Newsletters (2 publications in Sinhala & English medium)
2. Brochures (English & Sinhala medium)
3. Translations (Cartagena Protocol into Sinhala medium)
4. Poster depicting genetic engineering and its concerns
5. 2004 Calendar
6. Docket for participants in awareness programmes

09. National sub-committees

The following National sub-committees were appointed to provide recommendations in the relevant areas.

1. Policy on Biotechnology & Biosafety

The committee was to recommend the national policy on biotechnology and biosafety.

2. Legal Framework

The committee was appointed to consider the national, regional and international legal issues related to biosafety and to identify and propose the nature of the national legal document relating to biosafety.

3. Techniques & Technology

The committee was to recommend the necessary technologies for biosafety related matters.

4. Administrative Structure

The committee was to recommend an administrative structure for receiving applications and for risk assessment and management

APPENDIX 1

SUMMARY OF SOME OF THE BASIC REQUIRMENTS OF THE BIOSAFETY PROTOCOL AND THOSE RELATED ACTIONS HIGHLIGHTED IN THE PRESENT NOTE

Requirements	*Article*	*Actions*
Designating competent national authorities and national focal point	Article 19	(1) Designate and communicate to the Secretariat, no later than the date of entry into force of the Protocol, the name and addresses of one national focal point and one or more competent national authorities; (2) In case more than one competent national authority has been designated, notify the Secretariat about their respective responsibilities.
Identifying a point of contact for notifications on unintentional transboundary movements and emergency measures	Article 17	(1) Make available to the Biosafety Clearing-House (BCH), no later than the date of entry into force of the protocol, details of a point of contact for the purpose of receiving notifications concerning any occurrence that leads or may lead to unintentional transboundary movement of LMO.
Making available information to the Biosafety Clearing House (BCH)	Articles 20(3), 11(1), 11(5), 11(6), 12(1), 13, 14(4), 17(1), 17(2), 25(3)	(1) Put in place the necessary infrastructure and personnel at domestic level for the purpose of collecting, classifying, making available, use, access and disseminate relevant information to and from the BCH; (2) Ensure, through the Biosafety protocol national focal point or a BCH focal point, as appropriate, that Information flow to and from the BCH is done in a timely manner.
Implementing the advanced informed agreement procedure	Articles 7,8 to 10 and 12	(1) Establish or maintain a procedure for the notifications of exports, on the one hand, and for talking decision on imports on the other, of living modified organisms destined for intentional introduction into the environment of the party of import; (2) Ensure that any domestic regulatory framework used in place of the decision procedure of the Protocol's AIA is consistent with the Protocol; (3) Where adequate capacity to handle the transboundary movement of an LMO exists, a Party of import may wish to specify in advance to the BCH cases where transboundary movement could takeplace simultaneously with the notification, and imports exempted from the AIA procedure.
Communicating decisions regarding LMOs intended for direct use as food or feed, or for processing (LMOs-FFP)		(1) Make sure to inform the other parties through the BCH of any final decision regarding any domestic use, including placing on the market of a LMO that may be subject to transboundary movement for direct use as food or feed, or for processing within fifteen days of making that decision; (2) Make available to the BCH copies of any national laws, regulations and guidelines applicable to the import of LMOs-FFP; (3) For a developing country Party or Party with an economy in transition without a domestic regulatory framework, declare, through the BCH, that decision with regard to the first import of LMOs-FFP will be taken within a predictable timeframe, not exceeding 270 days, in accordance with a risk assessment undertaken in accordance with Annex III of the Protocol.

Carrying out risk assessment for decision taking	Article 15 and Articles 5, 6(2) and 11.6, as appropriate	(1) Ensure that risk assessments are carried out in a scientifically sound manner and taking into account recognized risk assessment techniques; (2) Ensure that risk assess ments are undertaken for decisions taken under the AIA procedure of the Protocol as regards the import o LMOs for intentional introduction into the environment
Undertaking risk management measures	Article 16	(1) Ensure that appropriate mechanisms, measures, and strategies to regulate, manage and control risks associated with the use, handling and transboundary movement of LMOs as identified in the risk assessment, are established and maintained
Identification of LMOs in accompanying documentation	Article 18	(1) Take measures to require the appropriate persons to clearly identify transboundary movements of LMOs-FFP in accompanying documentation, that they "may contain" LMOs and are not intended for intentional introduction into the environment and also to specify a contact point; (2) Take measures to require the appropriate persons to clearly identify, in accompanying documentation, transboundary movements of LMOs for contained use as living modified organisms, and to specify any safety requirements, contact point for further information, including the name and address of the person to whom the LMOs are consigned; and (3) Take measures to require the appropriate persons to clearly identify, in accompanying documentation, LMos for intentional introduction into the environment and any other LMOs within the sc0e of the Protocol, as living modified organisms; to specify the identity and relevant trait and/or characteristics; to specify and safety requirem ents, contact point for further information, the name and address of the importer and exporter, as appropriate; and to declare that the movement is in conformity with the requirements of the Protocol.
Protecting confidential information	Article 21	(1) Establish or maintain procedure to protect information submitted under the procedures of the Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential information.
Promoting public awareness and participation	Article 23	(1) Take appropriate measures that would allow or demand all relevant bodies to inform the public as regards the safe transfer, handling and use of living modified organisms that are of interest to the Protocol, including a mean of public access to the Biosafety Clearing House.
How transboundary movements of LMOs between parties and non-parties must be conducted	Article 24, and 14	(1) Ensure that and transboundary movements of LMOs with non - Party, taking place either under domestic regulatory framework or bilateral, regional and multilateral agreements and arrangements, is consistent with the objective of the Protocol;
Assessment of capacity building needs		(1) Assess and communicate through the BCH broader capacity - building needs.
Developing or maintaining capacity to the BCH		(1) Put in place some level of capacity at the national level that would allow access to and use of the BCH
Preparing for the first meeting of the COP-MOP		(1) Undertake the necessary preparation, both at national and regional level, as appropriate, to participate a nd take decisions during the first meeting of COP-MOP.

APPENDIX II

Annex III, Recommendation 3/5, third meeting of the ICCP
IMPLEMENTATION TOOL KIT

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

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

I. ADMINISTRATIVE TASKS

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

II. LEGAL REQUIRMENTS AND/OR UNDERTAKINGS

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

	Tasks	Article
19.	Endeavour to ensure that public awareness and education encompass access to information on LMOs identified in accordance with the protocol that may be imported.	23(1)(b)
20.	In accordance with relevant domestic laws, consult with the public in decision making under the protocol, while respecting confidential information.	23(2)
21.	Endeavour to inform the public about the means of public access to the Biosafety Clearing -House.	23(3)
22.	Adopt appropriate measures aimed a preventing and, if appropriate, penalizing transboundary movements in contravention of domestic measures to implement the Protocol.	23(1)
23.	Dispose, at its expense, LMOs that have been the subject of an illegal transboudary movement through repatriation or destruction, as appropriate, upon request by an affected Party.	23(2)

III. PROCEDURAL REQUIREMENTS: ADVANDCED INFORMED AGREEMNET

	Tasks	Article
1.	Provide written acknowledgement of receipt of notification to notifier within 90 days, including:	
	- Date of receipt o notification	9(2)(a)
	- Whether notification meets requirements of Annex I	9(2)(b)
	- That the import may proceed only with written consent and whether to proceed in accordance with the domestic regulatory framework or in accordance with Article 10; Or - Whether the import may proceed after 90 days without farther written consent	10(2)(a) 9(2)(c) 10(2)(b)
2.	Communicate in writing to the notifier, within 270 days of receipt of notification: - Approval of the import, with or without conditions; - Prohibition of the import; - A request for additional relevant information in accordance with domestic regulat ory framework or Annex I; or - Extension of the 270 days period by a defined period of time; AND	10(3)(a)-(b)
	Except where the approval is conditional, reason for the decision, including the reasons for the request for additional information or for an extension of time.	10(4)
3	Provide in writing to the Biosafety Clearing House the decision communicates to the notifier.	10(3)
4	Respond in writing within 90 days to a request by an exporting Party for a review of a decision under Article 10 where there has been a change in circumstances or additional relevant scientific or technical information has been made available, providing the reasons for the decision upon review.	12(2), (30)

Procedural Requirements; Living Modified Organisms For Direct Use As Food, Feed Or For Processing

	Tasks	Article
1	Upon making a final decision regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing, inform the Biosafety Clearing - House within 15 days of making that decision, including the information listed in Annex 11.	11(1)
2	Except in the case of field trials, provide hard copies of the final decision on the National Focal Point of Parties that have notified the Secretariat in advance that they do not have access to the Biosafety Clearing - House.	11(1)
3.	Provide additional information contained in paragraph (b) of Annex 11 about the decision to any Party that requests it.	11(3)
4.	In response to the posting of a decision by another Party, a Party that decides to import many take a decision on the import of LMO-FFPs: - either as approved under the domestic regulatory Framework consistent with the Protocol; OR - in the absence of a Regulatory framework, on the basis of a risk assessment in accordance with Annex 111 within no more than 270 days. In this case, a declaration must be made to the Biosafety Clearing - House	11(4), (6)

APPENDIX III

NATIONAL BIOSAFETY FRAMEWORK DEVELOPMENT PROJECT-WORK PLAN 2003-2004

	2003							2004									
ACTIVITY	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**
NBF STAFF TRAINING		*															
SURVEY		*															
COLLECTING OF LEGAL DOCs.	*	*	*	*	*	*											
COLLECTING OF POLICY DOCs.	*	*	*	*	*	*											
PUBLIC AWARENESS *MEDIA			*														
*LEGISLATORS			*														
*NGOs, CONSUMER ORG., SERVICES						*											
*SCIENTIFIC COMMUNITY							*										
*PRIVATE SECTOR AND NON SCIENCE LECTURERS, BANKS								*									
*STUDENTS AND TEACHERS									*								
NATIONALWORKSHOP- INSTITUTIONAL COORDINATORS AND NCC MEMEBERS									*								
TRAINING WORKSHOPS (RISK ASSESSMENTAND MANAGEMENT) 1.MEMBERS OF INSTITUTIONAL COORDINATORS										*							
2.PRIVATE, CUSTOMS, LEGAL SECTORS, MINISTRIES											*						
3.FARMER ORGANIZATION, GOVERNMENT DEPARTMENTS AND AUTHORITY												*					
4.UNIVERSITIES, POSTGRADUATE INSTITUTES AND RESEARCH INSTITUTES													*				
5. SECRETARIETS (MINISTRIES) AND LEGAL OFFICERS, POLICY MAKERS														*			
ATTENDANCE AT REGIONAL OR SUB REGIONAL WORKSHOP- COORDINATORS AND NCC MEMEBERS													*				
STAKEHOLDER WORKSHOP- NCC AND COORDINATORS														*			
STAKEHOLDER WORKSHOP- NCC AND COORDINATORS																*	