UNIDO BIOSAFETY MANUAL

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CARTAGENA PROTOCOL ON BIOSAFETY

INTRODUCTION

The UNIDO 'South – South Biosafety Networking Programme' entails several components, such as a distant learning biosafety program, which is a network that comprises universities from all over the world[1]. As part of this programme, UNIDO also coordinating the preparation of a manual with practical guidance for the development of national biosafety regulations.

An important point of reference of this manual is the Cartagena Protocol on Biosafety (CPB).

Building on the recognition in the Preamble of the CPB that

> *" modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health"*,

the overall objective of the CPB is:

> " … to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."

In order to achieve its objective, the CPB has a number of important functions:

1. It gives countries that do not yet have domestic biosafety regulations in place a legal basis and a methodology to make informed decisions on import of Living Modified Organisms (LMOs)[2].
2. It contributes to international harmonization of national biosafety regulations by international agreement on some of the key elements of domestic biosafety regulations such as definitions, information requirements, principles and methodology on risk assessment, treatment of confidential information etc.
3. It contains a crucially important mechanism for international information exchange on biosafety through its Biosafety Clearing House (BCH[3]).

In this context, this manual provides practical guidance for national authorities that are in the process of developing national biosafety regulations:

> Part I contains an overview of the broader international context relevant to biosafety.

1 See for details http://binas.unido.org/moodle/mod/resource/view.php?id=197

2 A more commonly used name is Genetically Modified Organisms (GMOs). For the use of this manual, LMOs and GMOs can be used interchangeably.

3 http://bch.cbd.int/

Part II contains guidance on what is needed to establish adequate regulatory oversight capacities for the development and/or trade of LMOs.

Part III contains guidance on some practical aspects when applying the procedures of the CPB for the import of LMOs for intentional releases.

This version of the manual, which is currently being used in UNIDO the distant learning biosafety program, contains Part I and Part III. In the Summer of 2010 the will be completed with Part II and updates of Part I and Part II and published on the UNIDO website.

PART I: THE INTERNATIONAL CONTEXT RELEVANT TO BIOSAFETY

Countries' national regulations need to be consistent with the international policy declarations, organisations, and agreements that a country has joined.

This part contains a brief overview of some of the international policy declarations, organisations, and multilateral agreements that have relevance to biotechnology and biosafety.

It is emphasized that this overview focuses on the main international documents and organisations, and that there are many more international fora and documents that may have relevance to LMOs, such as the 2003 Report of the UN Secretary-General to General Assembly, "Impact of new biotechnologies, with particular attention to sustainable development, including food security, health and economic productivity".

The text below addresses:

a. International Policy Declarations
b. International Organisations
c. International Standard Setting Bodies
d. Multilateral Agreements

a. International Policy Declarations

Although international policy declarations are not legally binding, the can have a strong political influence.

Examples of international policy declarations that have relevance to biotechnology:

- Agenda 21 (1992)
- The World Summit on Sustainable Development (WSSD, 2005)

Agenda 21

Agenda 21 is the outcome of the United Nations Conference on Environment and Development (UNCED, Rio De Janeiro, Brazil, 1992) and together with the 'Rio Declaration' it provides a detailed roadmap how to achieve the goals of both environmental protection and sustainable development in the 21st century (hence "Agenda 21"). Agenda 21 contains about 40 chapters, including Chapter 16: "Environmentally sound management of modern biotechnology"

Chapter 16 is based on two key considerations:

1. Biotechnology can make a significant contribution to strengthening the sustainable production of food, feed and fibre, to addressing water shortage, to improving health care and to environmental protection
2. Given the relatively limited experience with modern genetic modification and biosafety, there is a need for further development and implementation of internationally agreed principles on risk assessment and management.

Based on these considerations, Chapter 16 gives a detailed blue print for international action and collaboration for development of biotechnology aimed at:

a. Improving sustainable production of food, feed and renewable raw materials
b. Improving human health
c. Enhancing protection of the environment
d. Further development and implementation of internationally agreed principles on risk assessment and management and application of the precautionary approach.

The 2005 World Summit on Sustainable Development (WSSD)

The 2005 High-level Plenary Meeting of the 60th Session of the General Assembly; (September 2005, Johannesburg, South Africa), also called the World Summit on Sustainable Development (WSSD). The WSSD reaffirmed the commitment to Agenda 21, the Rio Principles and Millennium Development Goals.

The WSSD concluded with commitments to improve the lives of people living in poverty and to reverse the degradation of the global environment in the Johannesburg Plan of Implementation. As the WSSD Secretary General stated: “the greatest danger that we face is the growing gap between those who have access to knowledge and those who do not.”

The Political Declaration pledged to “assist one another to have access to financial resources, benefit from the opening of markets, ensure capacity building, use of modern technology to bring about development, and make sure that there is technology transfer, human resource development, education and training to banish forever underdevelopment.”

b. International Organisations

Examples of international organisations relevant to biotechnology include:

- World Trade Organisation (WTO)
- Food and Agriculture Organisation (FAO)
- World Health Organisation (WHO)
- World Organisation for Animal Health (OIE)

World Trade Organisation (WTO[4])

Building on GATT (1947), the WTO was established on 1 January 1995 by the Uruguay Round negotiations (1986-94). WTO's main function is to ensure that trade flows as smoothly, predictably and freely as possible.

Becoming a member means agreeing to the general WTO Agreements, which define the rules of international trade. There is a 'panel' process for dispute settlement.

The general WTO Agreements are:

- GATT: General Agreement on Tariffs and Trade in goods
- GATS: General Agreement on Trade in Services.
- TRIPS: Trade-Related Aspects of Intellectual Property Rights

Additional agreements and annexes deal with specific sectors or issues, such as:

- The Agreement on Technical Barriers to Trade (TBT).
  These are WTO rules preventing product requirements from becoming unnecessary obstacles to trade.
- The agreement on Sanitary and Phytosanitary Measures (SPS)
  These are WTO rules preventing, inter alia, food/feedstuff safety measures and measures to control the spread of pests, from becoming unnecessary obstacles to trade.

The SPS Agreement Sets out the rules by which countries establish their regulatory frameworks for food safety and animal and plant health:

- Science based
- Applied only to the extent necessary for protection
- Cannot be arbitrary or discriminatory
- No undue delay

Important in this context is that SPS applies also to products of modern biotechnology, and that SPS acknowledges international standard setting bodies (see next section) such as the Codex Alimentarius.

[4] www.wto.org

The Food and Agriculture Organization (FAO)

The Food and Agriculture Organization (FAO)[5] was created in 1945 to lead international efforts to defeat hunger. Serving both developed and developing countries, FAO acts as a neutral forum where all nations meet as equals to negotiate agreements and debate policy. FAO also assists developing countries and countries in transition modernize and improve agriculture, forestry and fisheries practices and ensure good nutrition for all. Since its founding, FAO has focused special attention on developing rural areas, home to 70 percent of the world's poor and hungry people. FAO's overall mandate is to raise levels of nutrition, improve agricultural productivity, better the lives of rural populations and contribute to the growth of the world economy.

The Committee on Agriculture (COAG) in 1999 recommended FAO to develop a strategic approach in biotechnology and biosafety.

The resulting FAO Statement on Biotechnology, which was published in March 2000, includes, among others, the following points:

- Biotechnology provides powerful tools for the sustainable development of agriculture, fisheries and forestry, as well as the food industry. When appropriately integrated with other technologies for the production of food, agricultural products and services, biotechnology can be of significant assistance in meeting the needs of an expanding and increasingly urbanized population in the next millennium. Genetic engineering could lead to higher yields on marginal lands in countries that today cannot grow enough food to feed their people.
- FAO is also aware of the concern about the potential risks posed by certain aspects of biotechnology. FAO supports a science-based evaluation system that would objectively determine the benefits and risks of each individual LMO. This calls for a cautious case-by-case approach to address legitimate concerns for the biosafety of each product or process prior to its release.
- FAO considers that efforts should be made to ensure that developing countries, in general, and resource-poor farmers, in particular, benefit more from biotechnological research, while continuing to have access to a diversity of sources of genetic material.

These notions in the FAO Statement on biotechnology of 2002, are further elaborated and built upon in a number of subsequent documents and statements, such as:

- The Committee on Agriculture (COAG) in 2003 recommended to work in biotechnology capacity building and to provide advice to member countries
- 2003 -2004 report on the State of Food and Agriculture is entitled "Agricultural biotechnology: meeting the needs of the poor?"

International Standard Setting Bodies

The technical standards produced by international setting bodies are not directly binding, but still have great impact, as they can be recognised through, for example, the SPS agreement (see the section on 'WTO').

[5] www.fao.org

Examples of international standard setting bodies with that are relevant to biotechnology and/or biosafety include:

- The Codex Alimentarius Commission
- Commission on Phytosanitary Measures

The Codex Alimentarius Commission

The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. Its aim is to protect the health of consumers and ensuring fair trade practices in the food trade.

Directly relevant to Biotechnology is the ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology - Guidance for food safety assessment

The SPS Agreement acknowledges Codex standards

Commission on Phytosanitary Measures,

The International Plant Protection Convention (IPPC[6]), was adopted by the Conference of the FAO in 1951. The aim of the IPPC is to control and prevent the spread and introduction of pests of plants and plant products

The Commission on Phytosanitary Measures develops standards for phytosanitary measures, which includes a standard for living modified organisms (ISPM 11)

The IPPC standards are recognised by SPS

Multilateral Agreements

Multi-lateral agreements are binding agreements between countries, and sometimes regional groups of countries such as the European Union. The countries and regions that are member of international agreements are called ‘Parties’.

Two multi-lateral agreements that are relevant to biotechnology and biosafety are discussed below:

- The Convention on Biological Diversity
- The Cartagena Protocol on Biosafety

[6] www.ippc.int

The Convention on Biological Diversity

The Convention on Biological Diversity (CBD[7]) was adopted in 1992 and has currently over 190 Parties

The objectives of the CBD are: the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources

Two articles of the CBD are directly relevant for to biotechnology and biosafety: article 8 and article 19.

Article 8 is titled "In situ conservation of biodiversity"

Article 8.g. contains an obligation to develop and maintain National Biosafety Systems, i.e.:" 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;

Article 19 is titled "Handling biotechnology and distribution of its benefits"

The first paragraph of Article 19 requires that each Contracting Party takes appropriate measures 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.

The second paragraph requires that each contracting party to 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.

The third paragraph of Article 19 instructs the Parties to "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."

At its second meeting, the Conference of the Parties(COP) to the Cartagena CBD, in 1995 in Jakarta, Indonesia, the COP decided that such a Protocol was needed and the process of negotiations started in 1996. After 5 years of negotiations, the Cartagena Protocol on Biosafety was adopted in January 2000 and came – after the 50th ratification – into force in September 2003.

[7] www.biodiv.int

The Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety (CPB[8]) was adopted in 2000 and came into force in 2003. It has currently over 150 Parties.

Building on the recognition in the Preamble of the CPB that

> *" modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health"*,

the overall objective of the CPB is:

> " … to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."

In order to achieve its objective, the CPB has a number of important functions:

- It gives countries that do not yet have domestic biosafety regulations in place a legal basis and a methodology to make informed decisions on import of Living Modified Organisms (LMOs).
- It contributes to international harmonization of national biosafety regulations by international agreement on some of the key elements of domestic biosafety regulations such as definitions, information requirements, principles and methodology on risk assessment, treatment of confidential information etc.
- It contains a crucially important mechanism for international information exchange on biosafety through its Biosafety Clearing House (BCH).

[8] http://www.cbd.int/biosafety/

PART II: GUIDANCE FOR THE ESTABLISHMENT OF REGULATORY OVERSIGHT CAPACITIES FOR THE DEVELOPMENT AND/OR TRADE OF LMOS

This part discusses elements for regulatory oversight systems.

This part will be completed in the Summer of 2010

PART III: PRACTICAL ASPECTS WHEN APPLYING THE PROCEDURES OF THE CARTAGENA PROTOCOL FOR THE IMPORT OF LMOS.

Note:

This manual aims to provide practical guidance on practical aspects when applying the procedures of the CPB for import of LMOs. This manual does not aim nor claim to offer any authoritative interpretation of the Cartagena Protocol on Biosafety, as this can only be provided by the Parties themselves or a judicial body in the event of disputes. In addition, there are various publications that may aide in understanding the background and history of certain provisions, such as the IUCN publication *"An Explanatory Guide to the Cartagena Protocol on Biosafety*[9]*"*.

To keep this manual legible for people who do not read legal texts on a daily basis, the articles of the CPB are often summarised in this manual, whereby links are provided to the texts of the articles of the Protocol, which is included in its entirety at the end of this manual. The bookmarks in this pdf file can be used to "switch back and forth" between the text in the manual and the text of the CPB.

[9] http://www.cbd.int/doc/books/2003/B-01669.pdf

Introduction.

The procedures of the Cartagena Protocol on Biosafety (CPB) focus specifically on transboundary movements of LMOs (see article 1).

As we can see in the CPB, there are several ways in which LMOs can be imported in a country:

1. As a transboundary movement for the purpose of subsequent
   a. contained use in the Party[10] of Import, or
   b. intentional introduction into the environment of the Party of import.

2. As part of an imported shipment of commodities for food, feed or processing[11].

Transboundary movement for the purpose of subsequent contained use.

The CPB does not contain specific procedures for the transboundary movement for the purpose of subsequent contained use, yet it does contain some general provisions such as the provisions of article 18 regarding handling, transport, packaging and identification.

Transboundary movement for the purpose of intentional introduction into the environment of the Party of Import.

The CPB contains specific procedures for the transboundary movement of LMOs from one Party (the 'Party of Export') for subsequent intentional introduction into the environment of another Party (the 'Party of import'.).

Article 7 of the CPB states that the Advance Informed Agreement (AIA) procedure applies prior to the first transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import. The second paragraph of article 7 explains that "Intentional introduction into the environment" does not refer to living modified organisms intended for direct use as food or feed, or for processing ("LMO-FFP"). For LMO-FFPs, the procedure of article 11 of the CPB applies. This part of the manual focuses on the AIA procedure.

Starting point of the CPB procedures is that an intended transboundary movement must be notified to the Competent Authority of the Party of Import. (article 8).

In response to such a notification, the CPB requires in article 9 that the Party of Import shall acknowledge receipt of the notification and indicate whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in article 10 of the CPB.

[10] A Party is a country or a region that has ratified the CPB. For current list of Parties see: http://www.cbd.int/biosafety/parties/list.shtml

[11] In addition, LMOs could also enter a country as an unintentional transboundary movement (by wind, for example), and as part of an illegal transboundary movement. These cases are not the subject of this manual.

This is a pivotal provision of the CPB. When the Party of import has a domestic regulatory framework for biosafety in place that is consistent with the CPB, then the procedures of that domestic regulatory framework apply[12].

When a Party of Import does not have such national biosafety regulations in place, then the AIA procedures of the CPB apply for import of LMOs for introduction into the environment.

This part of the manual provides guidance about the practical aspects of applying the AIA provisions of the CPB for informed decision making, and it gives references to resources.

For the application of the AIA procedures it is important to understand what is considered an "introduction into the environment". Generally speaking, "introduction into the environment" refers to activities outside "contained" facilities such as laboratories and research greenhouses[13].

Intentional introduction into the environment can take various forms, ranging from small scale, confined field trials for experimental, controlled releases to unconfined or commercial releases. While the CPB has no procedural differentiation between these different cases, the practical implications vary from one case to another.

Chapter I. Preparations and general obligations.

Before a Party can apply the procedures of the CPB, it needs make several 'preparatory' arrangements. Many of these arrangements are in fact general obligations resulting from the CPB.

Important preparatory arrangements to be made are:

- Designate one or more competent authorities and a national focal point
- Establish information requirements for notifications
- Prepare infrastructure for processing notifications and record keeping
- Enter information in the BCH

Designation of competent authorities and national focal points

Article 19.1 of the CPB states that each Party shall designate:

- one national focal point (FP) responsible for liaison with the Secretariat.
- one or more competent national authorities (CA), authorized to execute the administrative functions required by the CPB.

[12] Part II of this manual provides guidance for the development of such domestic regulations. In accordance with article 20, Parties must inform the BCH of existing laws, regulations and guidelines

[13] Article 3 of the CPB defines "Contained use" as " any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment".

The FP and CA can be different entities or one single entity. There is no general rule of the thumb as to what is the best approach. In some countries the FP and CA are different entities, whereas in other countries the FP and CA for biosafety are one single entity. In cases where the FPs and CAs are different entities, it is very important that they coordinate closely.

The names and addresses of the FP and CA(s) must be notified to the Secretariat. Where a Party designates more than one CA, it shall convey to the Secretariat, of the respective responsibilities of those authorities. The Secretariat enters this information on the BCH.

Establish information requirements for notifications

The starting point of the AIA procedure is that a notification is sent to the appropriate national competent authority that has been designated by the Party of Import. The term ‘ appropriate’ is important, because countries can designate one or more competent authorities[14]. The Competent Authorities designated by Parties can be found on the BCH[15].

As article 8 explains, notifications can be sent to the Party of Import by either the Party of Export or by the exporter. In practice it is in most cases the exporter that notifies the Party of Import. Article 8 also states that he notification shall contain at least the information specified in Annex I.

The information in Annex I is mostly presented as general categories, and depending on the case further detail may be required. Annex III on Risk Assessment, specifies in section 9 the technical and scientific details which, depending on the case, may be necessary. It is important to bear in mind that not all the points mentioned will apply to every case, and that the level of detail required is likely to vary according to the nature and the scale of the proposed release. In general, a notification for an unconfined large-scale release of GM crops typically requires more detail than a notification for a small scale confined fined trial with GM crops[16].

National competent authorities are advised to make known in advance through the BCH the information categories that it requires in individual applications. The matrix with information requirements can be used as a basis for this purpose.

For the information requirements it is practice to make a distinction between small-scale confined field trials and large scale unconfined releases[17].

It is further recommended to clarify whether the information is to be presented in the national language, or whether notifications in other language are also acceptable. Having notifications in the national language facilitates internal discussions, whereas having notifications in UN languages such as English facilitates international discussions and support. It is therefore that

[14] See above section on national competent authorities.
[15] http://bch.cbd.int/database/contacts/
[16] To facilitate the work of both notifiers and reviewers, the categories mentioned in Annex I of the Protocol and the technical and scientific details specified in Annex III have been combined in a matrix with information requirements This matrix will be made available in the Summer of 2010 on the UNIDO website, and the next version of this manual will provide link to that matrix.
[17] In a next version of this manual, guidance will be added illustrating what information is generally pertinent in cases of small-scale confined field trials and what level of detail for large scale unconfined releases.

often the general information and a summary are presented in the national language, while the technical information is presented in English.

Finally, it is advisable to make known how confidential information will be treated in accordance with Article 21 of the CPB.

Infrastructure for processing notifications

Once a request is formally submitted, it is usually recorded and a tracking number (dossier number) is assigned. The dossier numbers are best kept in an electronic database to allow for progress control (deadlines), and to make the information quickly available. An electronic database enables the information to be easily searched, and it can be integrated into other aspects of providing information. It also helps transmitting information to other databases, such as the BCH.

To prepare for the processing of notifications, it is advisable to prepare a database to enter basic information of the notifications, including a consistent system of dossier numbers.

In the stat up phase, a simple spreadsheet may suffice as a database, to gain experience and allow for fine tuning. Such a spreadsheet will typically be expanded and amended several times, before it meets the needs of the users. The experience with the spreadsheet will help the design more elaborate databases in later stage[18].

Enter information in the BCH

Article 20 of the CPB establishes the BCH, and states that each Party shall make available to the BCH relevant information.

This information includes:

- The names and addresses of the FP and CA(s) (see also the section on FP and CA above).
- Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;
- Any relevant bilateral, regional and multilateral agreements and arrangements the country has entered
- information requirements for notifications (see also the section above).

The BCH contains a number of clear tutorials how to use and register information on the BCH[19], as well as a link to the YoutubeBCH channel[20].

[18] In the Summer of 2010, an example of such a spread sheet will be included on the UNIDO website, and the next version of this manual will provide link to that spreadsheet.
[19] http://bch.cbd.int/help/tutorials/
[20] http://www.youtube.com/user/bchcpb

Chapter II: applying the provisions of the CPB for Import of LMOs for intentional introduction into the environment

As said above, starting point of the CPB procedures is that an intended transboundary movement must be notified to the competent authority of the Party of Import. (article 8).

In response to a notification the following steps need to be taken as laid down in article 9 and article 10 of the CPB:

1. Within 90 days after receipt of notification: **acknowledge receipt** of the notification .
2. Within 270 days after receipt of notification: **communicate the decision** to the notifier.

These steps are discussed below[21].

1. Acknowledgement of receipt of the notification.

Before acknowledgement of receipt can be sent to the notifier, a number of steps are typically taken:

a. Once a request is formally submitted, it is recorded in a database or spreadsheet, and a tracking number ("dossier number") is assigned. For spreadsheets and databases, see the section "infrastructure".
b. The date of receipt and dossier number are marked on the notification and entered in the spreadsheet or database. Deadlines for acknowledgement of receipt and final decisions are also entered in the database or spreadsheet.
c. A responsible reviewer may be assigned to the dossier.
d. Verification for completeness of the notification needs is conducted, to check whether the notification contains the information required. This 'verification for completeness' is a crucial step, because it defines the quality of the rest of the process. The check for completeness concerns both the general administrative information (e.g. name and address of the notifier) as well as the technical information in the notification[22].

After the verification of completeness is conducted, and in any case within 90 days after receipt of the notification, the CA shall send to the notifier a letter of acknowledgement of receipt, which includes:

- The date of receipt of the notification (article 9.2.a), and preferably the dossier-number
- Whether the notification, *prima facie*, contains the information required (article 9.2.b), and if not: which additional information has to be provided by the notifier,
- that the procedure will be conducted according to the provisions specified in Article 10 of the CPB (article 9.2.c),
- whether the intentional transboundary movement may proceed:

[21] NB: These steps start from the moment that a notification has been formally submitted to the CA. Yet, notifiers often contact the CAs informally to explain their plans and to seek guidance. Such informal contacts often very useful, as they may avoid duplication of work later.
[22] In the Summer of 2010, an example of a checklist for verification of completeness will be included on the UNIDO website, and the next version of this manual will provide a link to that example.

- Only after the Party of import has given its written consent (article 10.2.a); or
- After no less than ninety days without a subsequent written consent (article 10.2.b).

Some practical observations:

A letter of acknowledgement of receipt is often sent by registered mail to avoid unnecessary discussion[23].

The maximum period for this part of the procedure is 90 days. In the early stages of establishing the system it is to be expected that the CA may indeed need up to that full period. However, with gaining familiarity and experience, this first part can often be done - especially in the simpler cases of small scale confined field trials - in a much shorter period. There are good reasons to keep this first stage as short as possible, obviously without making concessions to quality. Apart from the fact that it is a general rule of good governance not to unduly delay administrative procedures, keeping the administrative processing as short as possible gives more time for the next phase of evaluation of the risk assessment and decision making (see sections below).

The phrase "Whether the notification, *prima facie*, contains the information required" means that even if at "first sight" (*prima facie)* the information in the notification appears sufficient, it may still happen that in the course of the risk assessment process it appears that further information is required to finalise the risk assessment.

In the acknowledgement of receipt, the CA should indicate whether the proposed transboundary movement may only proceed after a written consent, or that it may proceed without written consent after a specified period of 90 days or more

2. Decision making - communicating the decision to the notifier.

Article 10 para 3 specifies that within 270 days after receipt of notification, the CA has to reach a decision and communicate its decision to the notifier[24].

Article 10 clarifies that decisions shall be taken in accordance with Article 15 of the CPBArticle 15 states that risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques.

Key steps in this process are:

1. The evaluation of the risk assessment in the notification
2. The decision making process.
3. Communicating the decision to the notifier.

[23] In the Summer of 2010, an example of a letter of acknowledgement of receipt will be included on the UNIDO website, and the next version of this manual will provide a link to that example

[24] *Notate bene*: the 270 period for decision making starts from the day of receipt of the notification, not from the day of acknowledgment of receipt.

1. Evaluation of the risk assessment in the notification

As Annex I of the CPB shows, the notification will contain, in addition to administrative information and technical information about the LMO: "A previous and existing risk assessment report consistent with Annex III.".

An important part of the work of the CA of the Party of Import is to assess or arrange an assessment (or "audit") whether the risk assessment submitted in the dossier is consistent with Annex III of the CPB.

As Annex III explains, **the objective** of risk assessment is

> *"to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health"*.

The **general principles** that govern risk assessment listed in Annex III are:

- Scientifically sound and transparent,
- Case by case
- Comparative - risks are compared with risks posed by the non-modified host organism.
- Addressing uncertainties.

Annex III also describes the ***methodology of risk assessment***, which follows a numbers of steps:

1. it starts with an identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health
2. Evaluation of the likelihood of these adverse effects being realized,
3. An evaluation of the consequences,
4. An estimation of the overall risk posed, and
5. A recommendation as to whether or not the overall risks are acceptable or manageable.

Annex III further describes the "Points to consider", i.e. that depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a) Recipient organism or parental organisms.
(b) Donor organism or organisms.
(c) Vector.
(d) Insert or inserts and/or characteristics of modification.
(e) Living modified organism.
f) Detection and identification of the living modified organism.
(g) Information relating to the intended use. and
(h) Receiving environment.

In short, a risk assessment consistent with the CPB can be done in a very methodical way, following a number of steps identified in Annex III, and takes into account a number of scientific parameters described in Annex III.

Likewise, the evaluation of the risk assessment can be done in a similar methodical way. It is underlined that risk assessment primarily means making use of existing knowledge in an intelligent way. It varies from country to country who does the actual verification of teh risk assessment. In some countries it is done by the CA itself, whereas in other countries the risk assessment is done by an advisory body or external experts. What works best depends on teh local situation.

There are very many guidance and other resource documents for risk assessment available, and many of those can be found via the Biosafety Information Resource Centre (BIRC[25]) on the BCH.

At its fourth meeting, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP/MOP-4), in its decision BS-IV/11, established an open-ended online forum on specific aspects on risk assessment and an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management. The result of the discussions in the on line forum and in the AHTEG[26] will be presented to COP/MOP-5, in October 2010, in Nagoya, Japan.

2. The decision making process

The decision making process itself will vary from country to country, depending on countries' legal situation and administrative practices, and may include consultation with other Ministries and agencies, as well as a consultation of the general public.

The CPB does not prescribe that process, other than establishing some basic points, such as the fact that decisions have to be based on scientifically sound risk assessment (article 10 and article 15).

It is advisable to work out in advance internal procedures that describe for each of the steps in the whole process which body will be doing what, in which time frame and on the basis of what information[27].

3. Communicating the decision to the notifier.

Generally speaking, the final decision can be to allow, with or without conditions, or to deny a the requested activity. The final decision has to be communicated in writing to the notifier.

In different regulatory systems, different terms are used for these written decisions, such as permits, consents, approvals, authorizations etc. These terms may have different meanings in different systems. With 'permit 'often reference is made to a permission to a legal or natural person to carry out certain activities. This permission is limited to that particular person. A drivers license is an example of a permit. 'Approvals' are often used in the sense of 'product approvals'. Product approvals are usually not given to a legal person but are more 'attached' to a

[25] http://bch.cbd.int/database/resources/
[26] http://bch.cbd.int/onlineconferences/forum_RA.shtml
[27] In the Summer of 2010, an example of such internal procedures will be included on the UNIDO website, and the next version of this manual will provide a link to that example

certain product. After a product approval has been granted, then others do not require a permit to buy, sell or use that product as long as the product is used according to the conditions of the product approval. In this manual, the generic term ‘decision document’ will be used.

The form of decision documents varies from country to country. Some decision documents are relatively short, whereas other decision documents include a detailed report of the risk assessment and the decision making process.

Despite differences in the level of detail, most decision documents do have a similar overall structure, containing the following elements[28]:

- A summary of the request or application
- A description of the procedure followed, including the solicitation of advice and comments, and the reaction of the competent authority to the input received.
- A summary of the risk assessment carried out, based on the approach described before.
- The final decision, which can be to allow, with or without conditions, the requested activity or to not to allow.

[28] In the Summer of 2010, examples of decision documents will be included on the UNIDO website, and the next version of this manual will provide a link to that example

CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,

Recalling also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Recognizing also the crucial importance to humankind of centres of origin and centres of genetic diversity,

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,

Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements,

Have agreed as follows:

Article 1

OBJECTIVE

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Article 2

GENERAL PROVISIONS

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.

2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

Article 3

USE OF TERMS

For the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

(c) "Export" means intentional transboundary movement from one Party to another Party;

(d) "Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

(e) "Import" means intentional transboundary movement into one Party from another Party;

(f) "Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) "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;

(j) "Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence

in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

Article 4

SCOPE

This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 5

PHARMACEUTICALS

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations.

Article 6

TRANSIT AND CONTAINED USE

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

Article 7

APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 8

NOTIFICATION

1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.

2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

Article 9

ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.

2. The acknowledgement shall state:

(a) The date of receipt of the notification;

(b) Whether the notification, prima facie, contains the information referred to in Article 8;

(c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.

3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.

4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

Article 10

DECISION PROCEDURE

1. Decisions taken by the Party of import shall be in accordance with Article 15.

2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:

(a) Only after the Party of import has given its written consent; or

(b) After no less than ninety days without a subsequent written consent.

3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:

(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;

(b) Prohibiting the import;

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.

4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.

5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

Article 11

PROCEDURE FOR LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

(a) A risk assessment undertaken in accordance with Annex III; and

(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also

into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.

9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

Article 12

REVIEW OF DECISIONS

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

(a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or

(b) Additional relevant scientific or technical information has become available.

3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

Article 13

SIMPLIFIED PROCEDURE

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:

(a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and

(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

Article 14

BILATERAL, REGIONAL AND MULTILATERAL AGREEMENTS AND ARRANGEMENTS

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.

3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

Article 15

RISK ASSESSMENT

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Article 16

RISK MANAGEMENT

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article 17

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of

biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

Article 18

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification,

handling, packaging and transport practices, in consultation with other relevant international bodies.

Article 19

COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

Article 20

INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of living modified organisms; and

(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 21

CONFIDENTIAL INFORMATION

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this 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. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

(a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(d) Any methods and plans for emergency response.

Article 22

CAPACITY-BUILDING

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology

and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

Article 23

PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

Article 24

NON-PARTIES

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.

2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

Article 25

ILLEGAL TRANSBOUNDARY MOVEMENTS

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.

2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

Article 26

SOCIO-ECONOMIC CONSIDERATIONS

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms

on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Article 27

LIABILITY AND REDRESS

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

Article 28

FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, mutatis mutandis, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article 29

CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the

Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, mutatis mutandis, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article 30

SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

Article 31

SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, mutatis mutandis, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article 32

RELATIONSHIP WITH THE CONVENTION

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

Article 33

MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

Article 34

COMPLIANCE

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

Article 35

ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years

thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

Article 36

SIGNATURE

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

Article 37

ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 38

RESERVATIONS

No reservations may be made to this Protocol.

Article 39

WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article 40

AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

DONE at Montreal on this twenty-ninth day of January, two thousand.

Annex I

INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLES 8, 10 AND 13

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(j) Quantity or volume of the living modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with Annex III.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(o) A declaration that the above-mentioned information is factually correct.

Annex II

INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING UNDER ARTICLE 11

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the living modified organism.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

(e) Any unique identification of the living modified organism.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(i) Approved uses of the living modified organism.

(j) A risk assessment report consistent with Annex III.

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

Annex III

RISK ASSESSMENT

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realized;

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.
