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UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION
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BIOSAFETY MANUAL

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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 coordinates 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).

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.
>
> Part II contains guidance on practical aspects when applying the procedures of the CPB for the import of LMOs for intentional releases.
>
> Part III contains guidance on developing domestic regulatory frameworks.

This manual is a so called 'living document' that will be regularly updated and expanded.

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

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"[2].

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, they can have a strong political influence.

Examples of international policy declarations that have relevance to biotechnology, are:

- Agenda 21 (1992)[3]
- The World Summit on Sustainable Development (WSSD, 2005)[4]

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[5] it provides a detailed roadmap of 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 titled "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] http://unctad.org/en/docs/a58d76_en.pdf
[3] https://sustainabledevelopment.un.org/content/documents/Agenda21.pdf
[4] http://www.un.org/womenwatch/ods/A-RES-60-1-E.pdf
[5] http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm

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:

1. Improving sustainable production of food, feed and renewable raw materials;
2. Improving human health;
3. Enhancing protection of the environment;
4. 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) reaffirmed the commitment to Agenda 21, the principles of the Rio Declaration and the 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[6]. 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)[7]

Building on GATT (1947), the WTO was established on 1 January 1995 by the Uruguay Round negotiations (1986-94). The 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.

[6] http://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/WSSD_PlanImpl.pdf
[7] www.wto.org

The general WTO Agreements are:

- GATT: General Agreement on Tariffs and Trade in goods[8].
- GATS: General Agreement on Trade in Services[9].
- TRIPS: Trade-Related Aspects of Intellectual Property Rights.[10]

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

- The Agreement on Technical Barriers to Trade (TBT)[11].
  These are WTO rules preventing product requirements from becoming unnecessary obstacles to trade.
- The agreement on Sanitary and Phytosanitary Measures (SPS)[12]
  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;
- spplied only to the extent necessary for protection;
- cannot be arbitrary or discriminatory;
- no undue delay.

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

The Food and Agriculture Organization (FAO)

The Food and Agriculture Organization (FAO)[13] 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 in modernizing and improving 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 to biotechnology and biosafety.[14]

The resulting FAO Statement on Biotechnology[15], published in March 2000, includes, among others, the following points:

[8] http://www.gatt.org/
[9] https://www.wto.org/english/docs_e/legal_e/legal_e.htm#services
[10] https://www.wto.org/english/tratop_e/trips_e/trips_e.htm
[11] https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm
[12] https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm
[13] http://www.fao.org/home/en/
[14] http://www.fao.org/unfao/bodies/Coag/coag15/default.htm

- 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[16] recommended to work in biotechnology capacity building and to provide advice to member countries
- The 2003 - 2004 report on the State of Food and Agriculture, entitled "Agricultural biotechnology: meeting the needs of the poor?"[17]

c. 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

Examples of international standard setting bodies 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[18] 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.

[15] http://www.fao.org/biotech/fao-statement-on-biotechnology/en/
[16] http://www.fao.org/unfao/bodies/coag/coag17/coag17-e.HTM
[17] http://www.fao.org/docrep/006/y5160e/y5160e00.htm
[18] http://www.codexalimentarius.org/

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[19]), 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)[20].

The IPPC standards are recognised by SPS.

d. 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 multilateral agreements that are relevant to biotechnology and biosafety are discussed below:

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

The Convention on Biological Diversity

The Convention on Biological Diversity (CBD[21]) 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.

Three articles of the CBD are directly relevant for to biotechnology and biosafety: article 16, article 8 and article 19.

Article 16 states in the first paragraph that access to and transfer of biotechnology are essential elements to attain the objectives of the CBD.

Article 8 is titled "In situ conservation of biodiversity":

[19] www.ippc.int
[20] http://www.fao.org/docrep/009/a0450e/a0450e00.htm
[21] http://www.cbd.int/

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 CBD, in 1995 in Jakarta, Indonesia, 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.

The Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety (CPB)[22] was adopted in 2000 and came into force in 2003.

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."

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

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).

PART II: APPLYING THE PROCEDURES OF THE CARTAGENA PROTOCOL ON BIOSAFETY.

This part provides 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*[23]*"*.

a. Introduction.

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

In accordance with 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[24] 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[25].

<u>Transboundary movement for the purpose of subsequent contained use.</u>

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

<u>Transboundary movement for the purpose of intentional introduction into the environment of the Party of Import.</u>

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

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

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

[25] 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.

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, another procedure applies as explained in article 11 of the CPB applies. This part of the manual focuses on the AIA procedure.

The 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. 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 Party of import will inform exporters that the domestic regulatory framework applies. Parties must inform the BCH of existing laws, regulations and guidelines (article 20)[26].

- When a Party of Import does not have such national biosafety regulations in place, the AIA procedures of the CPB will 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.

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[27].

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.

b. 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:

- Designating one or more competent authorities and a national focal point.
- Establishing information requirements for notifications.

[26] Part III of this manual provides guidance with regard to national regulatory frameworks for biosafety.

[27] 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".

- Preparing infrastructure for processing notifications and record keeping.
- Entering information in the BCH.

1. Designating 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.

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.

2. Establishing 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' refers to the fact that countries can designate one or more competent authorities[28]. The Competent Authorities designated by Parties can be found on the BCH[29].

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 the 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[30].

National competent authorities are advised to make known in advance through the BCH the information categories that it requires in individual applications.

[28] See above section on national competent authorities.

[29] http://bch.cbd.int/database/contacts/

[30] 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 with a next version of this manual.

For the information requirements it is practice to make a distinction between small-scale confined field trials and large scale unconfined releases[31].

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 official languages such as English, facilitates international discussions and support. It is therefore that 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.

3. Establish an infrastructure to process 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 start 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 to design more elaborate databases in later stages.

4. Entering 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
- Iformation requirements for notifications (see also the section above).

The BCH contains a number of clear tutorials on how to use and register information on the BCH[32], as well as a link to the Youtube BCH channel[33].

[31] 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.
[32] http://bch.cbd.int/help/tutorials/

c. Applying the provisions of the CPB for Import of LMOs for intentional introduction into the environment.

As said above, the 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[34].

1. Acknowledgement of receipt of the notification.

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

1. 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".
2. 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.
3. A responsible reviewer may be assigned to the dossier.
4. 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[35].

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.
- If the procedure will be conducted according to the provisions specified in Article 10 of the CPB (article 9.2.c),

[33] http://www.youtube.com/user/bchcpb

[34] NB: These steps start from the moment that a notification has been formally submitted to the CA. 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.

[35] In a next version of this manual, an example of a checklist for verification of completeness will be included.

- whether the intentional transboundary movement may proceed:
  - 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[36].

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 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 and communicating the decision to the notifier.

Article 10 paragraph 3 specifies that within 270 days after receipt of notification, the CA has to reach a decision and communicate its decision to the notifier[37].

Article 10 clarifies that decisions shall be taken in accordance with Article 15 of the CPB. Article 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.

[36] In a next version of this manual, an example of a letter of acknowledgement of receipt will be included.

[37] NB: 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 describes the **methodology of risk assessment***,* which follows a number 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[38].

[38] An illustration of this risk assessment process will be included in a next version of this manual.

Likewise, the evaluation of the risk assessment can be done in a similar methodical way. It varies from country to country who does the actual verification of the risk assessment. In some countries, the risk assessment is carried out by the CA itself, whereas in other countries it is carried out by an advisory body or external experts. What works best depends on the local tradition, situation and resources.

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[39]).

The Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP/MOP), 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[40].

2. The decision making process

The decisionmaking 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 the decisionmaking 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 each of the steps in the whole process, e.g. which body will be doing what, in which time frame and on the basis of what information[41].

3. Communicating the decision to the notifier.

Generally speaking, the final decision can be to allow, with or without conditions, or to deny 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 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.

[39] http://bch.cbd.int/database/resources/
[40] http://bch.cbd.int/onlineconferences/forum_ra.shtml.
[41] An example of such internal procedures will be included in a next version of this manual.

Despite differences in the level of detail, most decision documents do have a similar overall structure, containing the following elements[42]:

- 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.

[42] Links to examples of decision documents will be included in a next version of this manual.

PART III: DOMESTIC REGULATORY FRAMEWORKS FOR BIOSAFETY

a. Introduction

Article 8g of the CBD states that "each Contracting Party shall, as far as possible and as appropriate establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology that 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".

The CPB in its Preamble recalls article 8g of the CBD, and article 9, paragraph 2 instructs that upon receipt of a notification, the Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt, and that the acknowledgement shall state "whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10."

Paragraph 3 of article 9 of the CPB states that "the domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol."

The guidance in this document aims to assist countries in developing a domestic regulatory framework as referred to in article 8(g) of the CBD that is consistent with the CPB.

Regulatory frameworks typically have a legal basis in primary legislation i.e. a law, act or bill, which lays down some basic aspects such as objective, scope, definitions, general obligations and institutional arrangements, and operational provisions such as obligations to obtain permits and/or approvals for certain activities. Technical aspects are typically worked out in secondary legislation, e.g. implementing regulations, decrees, orders, ordinances, etc, which are often complemented by guidelines.

Recognising that there is no "one size fits all" domestic regulatory framework for biosafety and that it varies from country to country what is addressed on the level of a law and what in implementing regulations and guidelines, Section b. of this part provides an overview of the type of provisions that are typically addressed at each different level. Section c. gives examples of provisions that are typically found in primary legislation. Section d. gives examples of provisions that are typically found in secondary legislation.

Examples of guidance documents, including formats for applications, decision documents and other administrative aspects will be provided in a next version of this manual.

b. Overview of the typical content of primary legislation, secondary legislation and guidance documents.

	Primary Legislation (e.g. Law, Act, Bill)	Secondary Legislation (e.g. Regulation, Order)	Guidance Documents
GENERAL PROVISIONS			
Objective	*Objective of a biosafety Act is typically based on:* *1) the country's biotechnology policy* *2) the country's international obligations*	Objective of the Regulation is to implement provisions in the Act	
Definitions	Definitions conform international agreements	Only those terms are defined that are used in the Regulation and that are not already defined in the law	Glossary of terms
Scope	Scope *(e.g. contained use, release, placing on the market, and/or export)* • exemptions from the scope • enabling mechanism and criteria to exempt through an implementing regulation *(cf 7.4 CPB)*	Procedure for exemptions	Guidance on requests for exemptions
Competent Authority (CA)	Provision identifying or establishing the CA by law		
National Focal Point (NFP)	Obligation for CA to establish a NFP cf the CPB. Enabling provision to provide further details by implementing Regulation	Tasks of the National Focal Point	
Scientific Advisory Committee (S AC)	Establishing the SAC by law, defining its mandate, the number of members, and the nomination procedure	Nomination of members, rules of procedure, including election of the Chair	Examples for specific expertises
	Right of the SAC to establish sub-committees and involve outside experts	Rules of procedure on subcommittees and outside experts	
	General principle on Confidentiality and Conflict of interest	Rules of procedure on Confidentiality and Conflict of interest	

	Primary Legislation (e.g. Law, Act, Bill)	Secondary Legislation (e.g. Regulation, Order)	Guidance Documents
	Enabling provision to provide further details by implementing Regulation		
OPERATIONAL PROVISIONS			
Contained use	Requirement to 1) obtain certification or permit for the installation , and 2) adhere to notification procedures outlined in an implementing Regulation, with maximum of [60] days in case of permit procedures.	Requirements: • Containment measures • Work procedures Differentiated notification / permit procedures, depending on risk category	
		Obligation to establish Institutional Biosafety Committees	Detailed guidance on IBCs
Releases	Requirement to obtain permit for releases unless exempted	Permit procedures	Enabling provision to provide further details by implementing Regulation
	Enabling provision to provide further details by implementing Regulation, with max of [90] days		
Placing on the market	Requirement to obtain approval unless exempted	Authorisation procedures	
	Enabling provision to provide in an implementing Regulation further details of the approval procedures, with max of [180] days		
Export –	Requirement to adhere to CPB provisions		
General procedural provisions			
Confidentiality	Right of applicants to request CIB, and identification of information that cannot be kept confidential	Procedures for confidentiality	
Risk Assessment and Risk Management	General principles	Methods and approaches based on CPB Annex III - Annexes	RA Guidelines

	Primary Legislation (e.g. Law, Act, Bill)	**Secondary Legislation (e.g. Regulation, Order)**	**Guidance Documents**
Decision-making	- General principles - basis of decision is the RA, possibility for inclusion of socio economic considerations conform art 26 CPB	Procedures	
Differentiated Procedures	Enabling provision plus criteria to establish differentiated procedures for certain categories		
Appeal	Right of appeal Enabling provision to provide in an implementing Regulation further details	Procedures for appeal	
New information and revision of decisions	Enabling provision to give the CA the right to review and revises decisions on the basis of new information	Procedures for review and revision	
Monitoring	General obligation to conduct monitoring where indicated by the results of the risk assessment	Monitoring requirements	
Unintentional release	General obligation to inform the CA in case of unintentional release that may have adverse effects	Procedures in case of unintentional release	
	Enabling provision to provide in an implementing Regulation further details		
Documentation and identification	General obligation to identify GM in accompanying documentation in case of contained use, release and placing on the market (above certain thresholds)		
	Enabling provision to provide further details by implementing Regulation		

	Primary Legislation (e.g. Law, Act, Bill)	Secondary Legislation (e.g. Regulation, Order)	Guidance Documents
OTHER / FINAL CLAUSES			
Public information and participation			
Implementing regulations	General rules for developing and adopting implementing regulations		
Enforcement and inspections	Assignment of the authory(ies) responsible for enforcement and inspections, including their mandate		
Penal provisions	Reference to Penal Code		
Liability and Redress	Definitions and key aspects of N-KL SP	Procedures and criteria for assessing damage, identifying responsible party, and determining response measures.	
Financial security			
Coming into force	[ ] days after adoption by Parliament *The number of days will depend on the local rules and traditions*		
Transitional provisions	Provision allowing activities with GMOs that started before the day of adoption by Parliament a reasonable period to comply with the rules of the act		
Review	Obligation to review the Act and the implementing regulations after a period of [5] years for effectiveness and efficiency.		
Annexes			

c. Examples of provisions typically addressed in primary legislation.

Abbreviations used in Explanatory Notes:
CBD – Convention on Biological Diversity
CPB – Cartagena Protocol on Biosafety
IUCN Guide - IUCN Environmental Policy and Law Paper No. 46: "An Explanatory Guide to the Cartagena Protocol on Biosafety"
SP – Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the CPB
LMO-FFPs – LMOs imported for direct use as food or feed or for processing
SPS – World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures

Articles	***Explanatory Notes, Comments:***
PART ONE: GENERAL PROVISIONS	
Article "Objective"	
The objective of this Act is	
i. to ensure an adequate level of protection in the field of the safe transfer, handling, and use 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;	*Art. 8.g CBD, art. 19 CBD, and Art. 1 CPB.*
ii. To implement Article 8g of the Convention of Biological Diversity, the Cartagena Protocol and its Supplementary Protocol.	
iii. To provide transparent, science based and predictable rules and procedures for activities subject to this Act.	
Article "Definitions"	
The following definitions apply to this Act and any regulations promulgated hereunder:	
"**Applicant**" means a person submitting an application, notification or petition pursuant to the provisions of this Act or its implementing regulations.	
"**Biological diversity**" means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.	*CBD, Art. 2.*
"**Biosafety Clearing House**" means the information exchange mechanism established under the Cartagena Protocol.	*CPB, Art. 20.*
"**Cartagena Protocol**" means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.	
"**Competent Authority**" means the entity responsible for implementation of this Act.	
"**Contained use**" means any operation or activity, undertaken within a facility, installation or other physical structure, which involves LMOs that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment and the general population.	*CPB, Art. 3(b).*
"**Damage**" means a significant adverse effect on the conservation	*SP, Art. 2.2b.*

Articles	*Explanatory Notes, Comments:*
and sustainable use of biological diversity, taking also into account risks to human health, that is measurable or otherwise observable, taking into account, wherever available, scientifically-established baselines recognized by the Competent Authority that take into account any other human induced variation and natural variation.	
"**Ecosystem**" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.	*CBD, Art. 2.*
"**Export**" means the intentional transboundary movement from the area of national jurisdiction of [name of country] to the area of national jurisdiction of another country.	*CPB, Art. 3(d).*
"**Micro-organisms**" means organisms that are not visible with the anked eye, including viruses, viroids, bacteria, yeasts or filamentous fungi.	
"**Import**" means the intentional transboundary movement into the area of national jurisdiction of [name of country] from the area of national jurisdiction of another country.	*CPB, Art. 3(e).*
"**Living modified organism**" or "LMO" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.	*CPB, Art. 3(g).*
"**Living organism**" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.*	*CPB, Art. 3(h).*
"**Modern biotechnology**" means the application of: (i) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (ii) 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.	*CPB, Art. 3(i).*
"**National Focal Point**" means the entity designated to be responsible on behalf of [name of country] for liaison with the Secretariat of the Cartagena Protocol and its Supplementary Protocol.	*CPB, Art. 19*
"**Operator**" means any person conducting activities authorized or otherwise allowed under this Act.	***Meaning of "Operator":*** *The term "Operator" is used in this Act to cover any person conducting activities regulated by the Act. An Operator who was in direct or indirect control of an LMO at the time it caused damage can be held responsible under the liability provisions of the Act in accordance with the SP.*
"**Person**" means a natural or legal person.	
"**Placing on the market**" means making LMOs available to third parties on a commercial basis, other than pre-commercial licensing.	
"**Release into the environment**" means any intentional use of	***LMO-FFPs:*** *This Act follows the approach taken in the CPB and*

Articles	*Explanatory Notes, Comments:*
LMOs subject to this Act that is not: - contained use; - placing on the market; or - import for direct use for food or feed or for processing.	*excludes LMO-FFPs from regulatory approval requirements under this Act because they are not "intentionally introduced into the environment." LMO-FFPs would be subject to food and feed safety approvals under other legislation.*
"**Response measures**" means appropriate an proportionate actions to: (i) Prevent, minimize, contain, mitigate, or otherwise avoid damage, as appropriate; or (ii) Restore biological diversity.	*SP, Art. 2.2d.*
"**Risks to human health**" means the potential impact on human beings as a direct result of an adverse effect on the conservation and sustainable use of biological diversity.	
"**Secretariat of the Cartagena Protocol**" means the Secretariat established by Article 31 of the Cartagena Protocol.	
"**Significant adverse effect**" means a quantitative or qualitative change that negatively affects the components of biological diversity or reduces their ability to provide goods or services and which is long-term or permanent, i.e. a change that will not be redressed through natural recovery within a reasonable period of time.	*See SP, Art. 2.3.*
"**Socio-economic considerations**" means social or economic effects arising from the impact of LMOs on the conservation and sustainable use of biological biodiversity, especially with regard to the value of biological diversity to indigenous and local communities.	*CPB, Art. 26.1.*
"**Supplementary Protocol**" means the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.	
ARTICLE "SCOPE"	
1. Subject to the exemptions set forth in this Act or provided for by regulation hereunder, this Act shall apply to the following activities with LMOs: a. Contained use; b. Release into the environment; c. Placing on the market; and d. Export.	***Contained Use:*** *The Act covers contained use of LMOs, notwithstanding its exemption from CPB procedures, because of the importance of contained use regulation as part of domestic law.* ***Intentional introduction into the environment:*** *The CPB uses "intentional introduction" without distinguishing between experimental releases subject to controls and unconfined releases for purpose of placing on the market. This Act uses the term "release into the environment" to cover, inter alia, field trials and defines "placing on the market" in a manner distinct*

Articles	*Explanatory Notes, Comments:*
	from "release."
2. This Act shall not apply to: a. LMOs that are pharmaceuticals for human use; b. LMOs in transit through but not destined for use in [name of country] provided that any such LMOs are packaged and transported in accordance with any applicable international requirements; and c. Any other activities with LMOs, or categories of LMOs that are exempted pursuant to the Article "Exemptions and Differentiated Procedures" of this Act.	***Scope of the Act**: The exemptions to the Act generally follow the exemptions to the CPB. CPB, Art. 5 (Pharmaceuticals) and Art. 6 (Transit).* *See also para 237. IUCN Guide*
Article "Competent Authority and National Focal Point(s)"	
1. [Name of office or agency] is the Competent Authority for purposes of the administration of this Act and any regulations promulgated hereunder.	
2. The primary functions of the Competent Authority are: a. To establish implementing regulations and guidelines pursuant to this Act. b. To receive, respond to and make decisions on notifications, applications and information submitted pursuant to this Act; c. To establish administrative mechanisms to ensure the appropriate handling, dissemination, and storage of documents and data in connection with the processing of applications and notifications and other matters covered by this Act; and d. To promote public awareness and education concerningthe safe transfer, handling and use of LMOs.	
3. The Competent Authority shall designate a National Focal Point for the Cartagena Protocol and one for the Supplementary Protocol.	
4. The primary functions of the National Focal Point(s) are: a. To receive, process, and respond to information and notifications from the Secretariat of the Cartagena Protocol and its Supplementary Protocol; and b. To facilitate international information sharing as set forth in Article 21 of the Cartagena Protocol.	
Article "Scientific Advisory Committee"	
1. A Scientific Advisory Committee (SAC) shall be established by the Competent Authority for the purpose of providing scientific and technical advice and assistance to the Competent Authority. The Competent Authority shall establish the tasks, composition and modus operandi of the SAC in an implementing regulation.	
2. All members of the SAC and any experts consulted by it shall be required to disclose publicly any and all actual and potential conflicts of interest. An individual having an actual or potential conflict of interest with regard to a particular matter shall not	

Articles	*Explanatory Notes, Comments:*
participate in any risk assessment, discussions or deliberations concerning that matter and shall be removed from the SAC in cases where the Competent Authority determines that actual or potential conflicts impair the individual's ability to serve in an independent or impartial manner.	
PAR TWO: OPERATIONAL PROVISIONS	
Article "Contained Use"	
1. Contained of LMOs is prohibited unless conducted in conformity with this Act and its implementing regulations.	
2. The Competent Authority shall promulgate at the same time as the coming into force of this Act implementing regulations, including rules for: a. Risk assessment and classification of contained activities with GMOs b. Containment levels for classes of contained use activities c. Work procedures for classes of contained use activities	
Article "Release into the Environment"	
1. Release of LMOs into the environment is prohibited unless conducted pursuant to a permit issued by the Competent Authority in conformity with this Act and its implementing regulations.	
2. The Competent Authority shall inform the applicant of its decision no later than 90 days from the date of receipt of the application.	
3. Applicants shall submit information that is relevant to the proposed activity in accordance with implementing regulations promulgated by the Competent Authority.	
Article "Placing on the Market"	
1. Placing on the market of LMOs is prohibited unless authorized by the Competent Authority in conformity with this Act and its implementing regulations.	
2. The Competent Authority shall inform the applicant of its decision no later than 180 days from the date of receipt of the application.	
3. Applicants shall submit information that is relevant to the proposed activity in accordance with implementing regulations promulgated by the Competent Authority.	
Article "Export"	
Persons proposing to export LMOs to a Party to the CPB shall: i. Notify the Competent Authority of the proposed Party of Import in accordance with the provisions of the Cartagena Protocol, and include a declaration that all information provided in such notification is factually correct, and ii. Conduct such export in accordance with the Cartagena Protocol.	***Notification of Exports**: The CPB does not require notification or approval by the country of export prior to exporting to another country. It does, however, require that exporting countries establish a legal requirement to ensure that exporters under their jurisdiction*

Articles	*Explanatory Notes, Comments:*
	provide accurate information to other Parties. CPB, Art. 8. To accommodate this, a simple notification requirement is proposed.
Article "Confidential Information"	
1. The Competent Authority shall: a. Permit the Applicant to identify information provided to the Competent Authority as confidential, with justification for claims of confidentiality to be provided upon request; b. Decide whether it accepts as confidential the information designated by the Applicant; and c. In the event that an Applicant withdraws or has withdrawn an application, respect the Applicant's claims of confidentiality, including claims for that information on which the Competent Authority and the Applicant disagree as to its confidentiality.	*CPB, Art. 21.*
2. Prior to any disclosure of information identified by the Applicant as confidential, the Competent Authority shall inform the Applicant of its rejection of the claim of confidentiality, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.	
3. Without prejudice to paragraph (a) above, the following information shall not be considered confidential: a. The name and address of the Applicant; b. A general description of the LMO; c. A summary of risk assessments performed on the LMO; and d. Any methods and plans for emergency response.	
4. The Competent Authority shall neither use nor permit the use of confidential information accepted as confidential under paragraph (a) or proprietary regulatory data submitted by Applicants for any purpose not specifically authorized under this Act except with the written consent of the Applicant.	***Protection of Regulatory Data:*** *Paragraphs (1)-(3) address confidential information. Paragraph (4) ensures that neither confidential information not any other proprietary information is misused (for example, by competitors).*
Article "Risk Assessment and Risk Management"	
1) The Competent Authority shall ensure that appropriate and adequate risk assessments are carried out for all activities that require a permit under the Article "Release into the Environment" or an authorization under the article "placing on the market of this Act.	
2) Risk assessments and reviews of risk assessments by the SAC, shall be conducted in a scientifically sound manner, in accordance with Annex III of the Cartagena Protocol and recognized risk assessment techniques. Such risk assessments shall be based on the information included in the application	***Content of Risk Assessment:*** *The CPB risk assessment principles (Annex III) are reproduced in Annex II of this Act. In an approach similar to the CPB, SPS Article 5.2 allows*

Articles	*Explanatory Notes, Comments:*
and any other relevant scientific evidence.	*regulators to take into account relevant ecological and environmental conditions, which would include assessing the consequences both of authorizing the LMO/activity and not doing so (i.e., continuing with the existing situation).*
3) The SAC shall provide to the Competent Authority a risk assessment report within 30 days for applications under the Article "Release into the Environment" of this Act and within 60 days for applications under the article "placing on the market of this Act.	
4) The risk assessment report shall include the SAC's recommendation(s), with justifications, on the application and indicate any risk management measures that may be necessary to regulate, manage or control any identified risks. The report should include a summary of the risk assessment that does not include any confidential information subject to protection under the article "Confidential Information" of this Act.	***Risk Management measures**: Note: SPS Article 2.2 requires that measures be "applied only to the extent necessary to protect human, animal or plant life or health" (see also SPS 5.3 through 5.6).*
Article "Decision-making and Communication of Decisions"	
1) Following receipt of the risk assessment report from the SAC, the Competent Authority shall make a final decision concerning a permit requested under the article "release into te environment" of this Act or an authorization or approval requested under the article placing on the market" of this Act.	
2) Any decision rendered under paragraph (1) shall be based upon: a) The information submitted by the Applicant; b) The risk assessment report prepared by the SAC ; and c) Any relevant comments submitted pursuant to the article "Public Information and Participation" of this Act.	
3) In making a decision, the Competent Authority may, consistent with its international obligations, take into account relevant socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.	***Consideration of Socio-economic Aspects**: The definition of "Socio-economic Considerations" in Article "definitions" of this Act is taken from the CPB, which allows consideration of certain socio-economic aspects in decision-making. CPB, Art. 26.*
4) An application shall be approved if the proposed activity: a) Does not pose a significant risk to the conservation and sustainable use of biodiversity, taking also into account human health; b) Poses an acceptable risk in light of expected benefits; or c) Poses a risk that can be effectively addressed through specified risk management measures.	
5) An Applicant may withdraw its application at any time prior to the issuance of a final decision by the Competent Authority.	

Articles	*Explanatory Notes, Comments:*
Article "Exemptions and Differentiated Procedures"	
1) The Competent Authority shall exempt from further regulation under this Act LMOs or categories of LMOs agreed pursuant to Article 7(4) of the Cartagena Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity.	*Exemptions/differentiated procedures agreed under the CPB are incorporated into the domestic regulations. See CPB, Art. 13.*
2) The Competent Authority may exempt from provisions in this Act or establish differentiated procedures for activities with any LMOs or categories of LMOs where it determines that sufficient experience or information exists to conclude that the LMOs or activities are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.	***Exemptions and Differentiated Procedures:*** *This article enables the Competent Authority, on its own initiative, to propose and decide, based on input from the SAC and public comments, to exempt or apply differentiated procedures for specified LMOs/activities based on experience gained, etc.*
3) Any person may petition the Competent Authority to exempt or to establish differentiated procedures for LMOs or activities under paragraph (2) of this article at any time. Such petitions shall be decided on by the Competent Authority within 120 days	***Petition for Exemption or Differentiated Procedures:*** *This provision provides the opportunity for Applicants to trigger Competent Authority consideration of a proposed exemption or differentiated procedure by submitting a request and supporting evidence.*
4) In addition to or instead of the procedures set forth in this Article, the Competent Authority may enter into bi- or multi-lateral agreements to provide for differentiated procedures for trade in specified LMOs.	*Art. 14 CPB*
Article "Review of Decisions"	
1) The Competent Authority, after consultation with SAC, may review any decision under this Act at any time upon obtaining significant new scientific information pertaining to potential adverse affects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.	
2) The Competent Authority shall inform the Applicant of its intent and reasons for initiating a review of the decision prior to undertaking the review.	
3) A written decision, pursuant to a review conducted under paragraph(1) shall be provided to the Applicant by the Competent Authority within ninety (90) days from the date the Applicant is notified of the review and shall set out the reasons for the decision.	
Article "Right of Appeal"	
1) Any Applicant who is aggrieved by any decision of the Competent Authority under this Act may appeal to [name of administrative appeals authority] on either procedural or	***Administrative Appeal:*** *Provision needs to be made for an administrative review of decisions by*

Articles	*Explanatory Notes, Comments:*
substantive grounds.	*an entity that is independent of the Competent Authority. Resolution of administrative reviews is generally a prerequisite for filing a legal complaint in a court of law.*
2) The [name of administrative appeals authority] shall decide on such appeals within a reasonable time, not to exceed sixty (60) days, and shall communicate its decision and the reasons therefore in writing to the Competent Authority and the Applicant.	
3) An Applicant who remains aggrieved following an appeal under paragraph (1) or who does not receive a response within the timeframe stated in paragraph (b) shall have the right to appeal the decision of the Competent Authority to a competent court.	
PART THREE FINAL CLAUSES	
Article "Monitoring and Notification"	
1) Operators shall monitor their activities to ensure that they comply with the requirements of this Act and any conditions or requirements imposed in connection with the authorization or allowance of activities under this Act.	
2) Operators who become aware of significant new scientific information indicating that authorized activities with LMOs may adversely affect the conservation and sustainable use of biological diversity, taking also into account risks to human health, shall immediately advise the Competent Authority of the new information and of any new measures put in place.	
3) Any Operator with knowledge of an unintentional or unauthorized introduction into the environment of an LMO subject to this Act 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, shall, within 24 hours of when the Operator knew of the introduction, notify the Competent Authority of the occurrence.	
Article "Cessation Orders"	
1) The Competent Authority may issue an order for the immediate cessation of any activity permitted or authorized under this Act or for the immediate imposition of additional risk management measures with respect to such activity, if the Competent Authority has obtained new scientific information indicating that there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking also into account risks to human health, based on validated scientific evidence.	
2) The Competent Authority also may issue a cessation order upon the failure of any Operator to demonstrate substantial compliance, after a reasonable period of time, with an order issued under the article "Right of Appeal or, with respect to an authorization granted or notification submitted under this Act,	

Articles	*Explanatory Notes, Comments:*
when there exists a material infringement of any provision of the Act or regulations made hereunder.	
3) An order issued pursuant to paragraph (1) or (2) shall be withdrawn once the Competent Authority determines that sufficient information exists to permit the activity to resume or to resume in the absence of additional risk management measures without posing a significant risk to the conservation and sustainable use of Biological Diversity, taking also into account risks to human health.	
Article "Guarantees"	
1) Operators shall ensure that all information submitted under this Act or its implementing regulations is factually correct.	
2) Operators shall be governed by financial and other requirements as set forth in {reference to provisions of applicable corporate or commercial law}.	*The Act specifies that existing law would apply. This would be the case even if it were not specified in biosafety legislation.*
Article "Enforcement"	
1) Subject to the protection of confidential information in accordance with Article "confidential information", Operators shall supply to the Competent Authority, upon request, such information about their activities as is necessary for the Competent Authority to carry out its supervisory, monitoring or enforcement tasks under this Act and its implementing regulations or to deal with any emergency situations.	
2) The Competent Authority may appoint as inspectors such number of persons appearing to him to be qualified for the purposes of ensuring compliance with the Act and its regulations.	
Article "Offences and Penalties"	
1) Any person who knowingly violates a material provision of this Act shall be guilty of an offence upon conviction by a competent court of law or a duly appointed administrative body and shall be subject to sanctions in accordance with the {Penal Code}.	***Criminal Sanctions:*** *As a matter of law, criminal offences can only be established where acts or omissions are wilful (knowing or intentional).*
2) Any person who is convicted of repeated offences may be prohibited from engaging in any further activities subject to this Act.	
Article "Public Information and Participation"	
1) The Competent Authority shall promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health.	*CPB, Art. 23.1.*
2) The Competent Authority shall publish: a) Notices concerning proposals under the article "Exemptions and Differentiated Procedures", section (1) ; and	*CPB, Art. 23.2.*

Articles	*Explanatory Notes, Comments:*
b) Proposed decisions on applications and petitions filed pursuant to the operational provisions of the Act.	
Upon request, the Competent Authority shall make available to any person portions of any application or petition subject to paragraph (2)(b) that are not protected as confidential information under Article "Confidential information".	
Article « Documentation and Identification »	
Operators shall comply with requirements for documentation accompanying LMOs destined for Contained Use, for Release into the Environment, and for Placing on the Market as set forth in implementing regulations.	
Article "Notification and Evaluation of Damage"	
1) When an Operator becomes aware of damage for which there is a scientifically plausible scenario that it could be related to an LMO, the Operator shall immediately inform the Competent Authority of such damage.	
2) Where there is a likelihood that further damage will result if timely action is not taken, the Operator shall take appropriate measures to avoid such damage.	*See SP, Art. 5.1.*
3) Where the Competent Authority becomes aware of possible damage for which there is a scientifically plausible scenario that it could be related to an LMO, it shall evaluate it in accordance with the generally accepted scientific methodology.	*See SP, Art. 5.2b.*
Article "Response Measures"	
1) Where damage is confirmed, a causal link shall be established by the Competent Authority between the damage and the LMO in question.	*See SP, Art. 4.*
2) A causal link shall be established where the Competent Authority determines that: a) General causation exists, i.e. the change can generally be caused by the LMO; and b) Specific causation exists, i.e. the damage would not have occurred but for the release of the LMO, and results directly from the phenotypic or genotypic modification of the LMO; and c) No superseding incident alters the chain of events that otherwise might have connected the release of the LMO in question to the damage.	
3) If a causal link is confirmed, the Competent Authority shall identify the Operator(s) in direct or indirect control of the LMO at the time that it caused the d.	*See SP, Art. 5.2a.*
4) The Competent Authority shall determine which Response Measures should be taken by the responsible Operator(s) and shall promulgate regulations for this purpose.	*See SP, Art. 5.2c.*
5) Decisions of the Competent Authority requiring the Operator(s) to take Response Measures should be reasoned. Such decisions should be notified in writing to the Operator. The Competent Authority shall inform the Operator of the available remedies,	*See SP, Art. 5.6.*

Articles	*Explanatory Notes, Comments:*
including both administrative and judicial review.	
6) The Competent Authority may implement appropriate Response Measures, including, in particular, when the Operator has failed to do so.	*See SP, Art. 5.4.*
7) The Competent Authority has the right to recover from the Operator the costs and expenses of, and incidental to, the evaluation of the Damage and the implementation of any Response Measures not carried out by the Operator.	*See SP, Art. 5.5.*
8) An Operator shall not be held responsible upon proof that the Damage was caused by: a) An Act of God or *force majeure*; or b) An act of war or civil unrest.	*SP, Art. 6.1.*
9) In addition, an Operator shall not be held responsible upon proof that: a) The damage was caused by an act or omission that was the subject of a compulsory order by the government; b) The Operator(s) was in compliance with this Act and its regulations and the negligent or intentional act or omission of another person caused the damage.	*See SP, Art. 6.2.*
10) Liability for harm to persons or property that occurs as a result of activities subject to this Act shall be addressed by applicable laws.	*See SP, Art. 12.2a.*
Article "Regulations"	
1) Consistent with the objective and scope of this Act, the Competent Authority shall propose and, after public notice and an opportunity for public comment pursuant to the Article "Public Information and Participation", finalize and publish such regulations as may be necessary for implementing the provisions of this Act.	
2) The Competent Authority shall publish a schedule of fees to cover administrative costs of processing notifications, applications and petitions submitted under this Act.	***Uniformity of Fees Imposed:*** *Under WTO rules, any such fees may not exceed the cost of services rendered and must be equitable in relation to fees charged for similar services for like products of domestic origin. SPS Annex C.1.f.*
Article "Effective Date	
This Act shall enter into force on […..].	
Article "Transitional Provisions"	
(a) Any application pending at the date of the entry into force of this Act shall be subject to the provisions of this Act.	
(b) Activities that were ongoing at the date of the entry into force of this Act shall be permitted to continue but shall be subject to the review procedure set forth in Article "Review" of this Act.	
Article "Review and assessment"	
1) This Act and its regulations shall every 5 years be reviewed in	*Art. 35 CPB*

Articles	*Explanatory Notes, Comments:*
light of technical and scientific advances and its implementation assessed for the purpose of improving the effectiveness and efficiency. Regulations created under this Act shall be reviewed at regular and appropriate intervals to improve effectiveness and workability and to facilitate decision-making and compliance.	
2) Review of the Act and its regulation shall include notice to the public of the review process and an opportunity for the public to comment on proposed changes.	

d. Examples of provisions that are typically found in secondary legislation.

Abbreviations used in Explanatory Notes:
CBD – Convention on Biological Diversity
CPB – Cartagena Protocol on Biosafety
SP – Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the CPB
LMO-FFPs – LMOs imported for direct use as food or feed or for processing
SPS – World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures

Articles	***Explanatory Notes, Comments***
PART ONE: GENERAL PROVISIONS	
Article "Objectives"	
Pursuant to Article "Regulations" of the Act, this Regulation is established to further implement the provisions of the Act.	
Article "Definitions"	
1) The definitions set forth in the Act apply *mutandis mutandis* to these Regulations.	
2) For purposes of this Regulation, the following additional definition applies: "**Registry**" means the compilation of LMOs and activities that have been authorized, exempted or subject to differentiated procedures in accordance with the Act.	
Article "Establishment of the National Focal Point"	
1) [_____] shall serve as the National Focal Point for the Cartagena Protocol.	
2) [_____] shall serve as the National Focal Point for the Supplementary Protocol.	
Article "Operation of the Scientific Advisory Committee"	
1. The responsibilities of the Scientific Advisory Committee (SAC) referred to in the article "Scientific Advisory Committee" of the Act shall include: a. Developing and updating scientifically sound and transparent guidance on risk assessment, consistent with the general principles and methodology laid down in Annex III of the Cartagena Protocol; b. Conducting risk assessments and reviewing risk assessments provided in applications or notifications; c. Reviewing risk management measures; d. Recommending containment measures, limitations on the duration of authorizations, reporting mechanisms, remedial measures, monitoring procedures and other appropriate	

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and science based conditions and risk management measures; and e. Providing other expert advice and assistance related to biosafety upon request of the Competent Authority, the National Focal Points or on its own initiative.	
2. The SAC shall consist of a core group of maximally 15 scientific experts appointed by the Competent Authority from in any case the following fields: a. Plant breeding and genetics; b. Agronomy; c. Weed science; d. Plant pathology; e. Animal breeding and genetics; f. Mammalian toxicology; g. Environmental toxicology; h. Ecology; i. Entomology; j. Medical or veterinary Virology; and k. Medical Microbiology l. Environmental microbiology	
3. Members of the SAC shall be drawn from government agencies, independent scientific and research institutes and universities, and other academic institutes.	
4. The SAC may establish any subcommittees it deems necessary for the execution of its tasks. The SAC also may invite expert advisors from scientific disciplines not otherwise adequately represented to participate in the work of the SAC and its subcommittees on a non-voting basis.	
5. Internal procedures for the operation of the SAC and its subcommittees shall be proposed by the SAC and approved by the Competent Authority. Such internal procedures shall provide for all matters necessary for the science based, effective, efficient and transparent operation of the SAC and any subcommittees and shall include, at a minimum, mechanisms and procedures for: a. Designating chairpersons and vice chairpersons of the SAC and any subcommittees, inviting expert advisors, and specifying rules of procedure for the SAC and its subcommittees, and for the participation of expert advisors in the SAC or its subcommittees; b. Ensuring the absence of conflicts of members of the SAC and its subcommittees and advisors to the SAC and its subcommittees in conformity with Article “Scientific Advisory Committee” of the Act;	

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c. Ensuring the protection of confidential information as required by the Article "Confidential information" of the Act, including written declarations that any confidential information obtained by virtue of membership in the SAC or a subcommittee, or participation as an expert advisor to the SAC or a subcommittee, shall not be disclosed to others or used for any research, development or commercial purpose without the express written authorization of the supplier of the information identifying the information as confidential pursuant to the Article "Confidential information" of the Act.	
PART TWO: OPERATIONAL PROVISIONS	
Article "Procedures for Contained Use"	
1) The Competent Authority will publish criteria for the assignment of risk classes of contained use operations with LMOs, indicating whether a risk class corresponds with neglible, low, medium, or high risk, and indicating the containment levels and workprocedures required for those classes.	
2) When contained use operations are intended to be carried out in a premise for the first time, the Operator shall be required before commencing such use to submit a notification to the Competent Authority, specifying the containment level(s) of the premise and the work procedures for specified classes of contained use operations with LMOs. Within 90 days after the notification, the Competent Authority will either a) confirm the proposed containment level(s) and work procedures for specified classes of contained use operations , or b) inform the notifier of adjustments to be made in the proposed containment level(s) and/or work procedures, for specified classes of contained use operations.	
3) After the confirmation by the Competent Authority of the containment level(s) of a premise Contained Use operations with LMOs shall be conducted as follows: a) Contained use operations with classes of activities corresponding with negligible risk may proceed without further notification, provided they are conducted under the corresponding containment levels and workprocedures ; b) Contained use operations with classes of activities corresponding with low risk must be notified to the Competent Authority prior to the commencement of the operations, and the operations may proceed immediately following the new	

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notification. However, the Applicant may himself request from the Competent Authority a decision on the granting of a formal authorisation. The decision must be made within a maximum of 45 days from the notification; c) Contained use operations with classes of activities corresponding with medium risk must be notified to the Competent Authority prior to the commencement of the operations, and the operations may, in the absence of any indication to the contrary from the Competent Authority, proceed 45 days after submission of the notification or earlier with the agreement of the Competent Authority; and d) Contained use operations with classes of activities corresponding with high risk may not proceed without the prior consent of the Competent Authority, which shall communicate its decision in writing at the latest [45] days after submission of the notification.	
4) The notifications of contained use operations referred to in the previous paragraphs shall include: i) The name and contact information for the Applicant; ii) The premises where contained use operations will be undertaken; iii) The name and identity of the LMOs involved; iv) The nature and purpose of the activities; v) A risk assessment of the activities and the risk classification, based on this risk assessment; vi) A description of the containment measures and work procedures; and vii) Contained use operations with classes of activities corresponding with medium or high risk, an emergency plan to react effectively in case of accidents.	
1) Article "Procedures for Release into the Environment and Placing on the Market" a) Applicants shall include in their submissions pursuant to Article "Release into the Environment" and the article "Placing on the Market" of the Act: (1) For release into the environment, the information specified in Schedule I; (2) For placing on the market, the information specified in Schedule II; (3) A risk assessment in conformity with the principles set forth in Schedule III; and (4) Any additional information applicants deem relevant to an assessment of the potential risks and/or benefits of	

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the requested activity.	
b) All applications shall include a declaration that the information contained therein is factually correct.	
Article "Confidential Information"	
1) For any documentation submitted to the Competent Authority that contains information the Applicant claims as confidential, the Applicant shall submit: a) A complete version marked "CONFIDENTIAL"; and b) A redacted version in which information considered by the Applicant to be confidential is omitted or blacked out and substituted by a summary of any confidential information that is essential to the risk assessment.	
2) Subject to Article "confidential information" of the Act, only documentation that is not marked as "CONFIDENTIAL" shall be made available to the public.	
Article "Acknowledgment and Preliminary Response"	
1) Upon receipt of an application submitted under Article "Release into the environment" and the article "Placing on the market" of the Act, the Competent Authority shall immediately screen the application for prima facie completeness.	
2) As soon as possible and, in any event, within thirty (30) days of receipt of the application, the Competent Authority shall acknowledge in writing receipt of the application.	
3) The acknowledgement shall include: a) The date of receipt of the application; and b) Whether the application, prima facie, contains the required information or, if not, a specification of what additional information within the scope of Schedule I or Schedule II is required so that the Applicant may take corrective action.	
4) If additional information is required, the number of days of the waiting period of the Competent Authority for receiving the requested and any other additional information, shall not be included in calculating the timeframe for making a decision on the application.	
5) Applications that are considered by the Competent Authority to be prima facie complete shall be sent to the SAC at the same time acknowledgement is provided to the Applicant or at such time the Competent Authority receives all of the additional information requested under paragraph (4).	
Article "Auditing of Risk Assessment and Proposed Risk Management"	
1) The SAC shall audit risk assessments submitted by the Applicant and shall conduct or cause to be conducted any additional risk	

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assessments as required on a case-by-case basis. In carrying out its risk assessment and auditing activities, the SAC shall take into account the principles and methodology set forth in Schedule III and any risk management measures proposed by the Applicant.	
2) Upon conclusion of the auditing process, the SAC shall provide to the Competent Authority a risk assessment report that: i) Sets forth its recommendation, with justifications, on the application; and ii) Specifies risk management measures, if any, that it deems necessary to manage or monitor identified potential risks.	
Article "Decision-making and Communication of Decision"	
1) The decision of the Competent Authority shall be recorded in a decision document that: a) Identifies the Applicant and summarizes the objective and nature of the request; b) Describes the procedure followed in reviewing the application; c) Includes the summary of the risk assessment audit prepared by SAC; d) States whether the requested activity is approved, with or without conditions, or whether the requested activity is not approved; and e) Provides the reasons for the decision.	
2) Decisions granting authorisation for applications for release into the environment under Article "Release into the environment" of the Act shall take the form of a permit valid only for the named applicant.	
3) Decisions granting approval for applications for placing on the market under Article "placing on the market" of the Act shall take the form of an authorisation for the specified LMO to be placed on the market.	
4) Any specific conditions, limitations or requirements related to a permit or authorization must be clear in the decision document.	
5) Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of an identified potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, shall not prevent the Competent Authority from making a decision, as appropriate, including measures to avoid or minimize such potential adverse effects.	
6) Activities permitted or LMOs authorized under Article "Placing on the market" of the Act respectively shall be included in the Registry.	

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Article "Exemptions and Differentiated Procedures"	
1) The Competent Authority may identify classes of contained use operations, for which no further notification is required under Article "contained use" provided the activities are conducted in conformity with applicable laws, regulations and good laboratory practice standards.	
2) Where sufficient experience or information exists to conclude that LMOs or activities are not likely to pose a risk, the Competent Authority may designate types or categories of LMOs or activities otherwise subject to article "release into the environment' and the article "placing on the market" of the Act that may proceed sixty (60) days after the submission of a notification.	
3) A notification of intent to conduct an activity for which a designation has been made with respect to an activity or LMO under paragraph (2) shall be submitted to the Competent Authority at least sixty (60) days before the activity covered by the notification is due to begin and shall include: i) The name and contact information for the person submitting the notification; ii) The location(s) where the activity will be undertaken; iii) The name and identity of the LMO involved; iv) The nature and purpose of the activity; and v) A description of any risk management measures and the suitability of those measures for the LMO and activity to be undertaken.	
4) If the Applicant subject to notification under paragraph (3) receives no response within sixty (60) days of the submission of the notification, the proposed activities may commence.	
5) LMOs or activities exempted or subject to differentiated procedures under Article "Exemptions or Differentiated Procedures" of the Act shall be included in the Registry.	
Article "Petition for Exemption or Differentiated Procedures"	
1) Petitions pursuant to the article "Exemption and Differentiated Procedures" of the Act shall contain the following information: i) Name and address of the Applicant; ii) Name and description of the LMOs or types and classes of LMOs and/or activities for which exemption or differentiated procedures are sought; iii) A comprehensive discussion of the scientific basis for the requested action accompanied by supporting documentation; and **iv)** Any scientific information known to the Applicant that would be unfavourable to the petition.	

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2) Within ten (10) days of receipt, the Competent Authority shall publish the petition in accordance with Article "public information and public participation" of the Act and transmit the petition to the SAC for review.	
3) The Competent Authority shall make within 90 days a final decision on the petition based upon the scientific review conducted by SAC and relevant comments submitted by the public. The final decision may either approve or deny the petition in whole or in part and shall be communicated in writing to the Applicant.	
4) LMOs or activities exempted or subject to differentiated procedures under Article "Exemptions and Differentiated procedures" of the Act shall be included in the Registry.	
Article "Unintentional release"	
1) A notification of an unintentional release of an LMO into the environment under Article "public information and participation" of the Act shall include the following: a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the LMO; b) Information on the circumstances and estimated date of the introduction; c) Any available information about the possible adverse effect on the conservation and sustainable use of Biological Diversity, as well as available information about possible risk management measures; d) Any other relevant information; and e) A point of contact for further information.	
2) The Competent Authority, in consultation with SAC, shall consult with the Operator(s) providing notifications under paragraph (a) and determine whether any action is necessary to minimize any adverse effect on the conservation and sustainable use of Biological Diversity, taking also into account risks to human health.	
Article "Enforcement"	
1) The powers of an inspector are: a) at any reasonable time , or, in a situation in which in the inspector's opinion there is an imminent danger for adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health, at any time: i) to enter premises, including but not limited to a facility, vessel or property, which the inspector has reason to believe it is necessary for him to enter and to take with him any person duly authorized by the Competent Authority; and	

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ii) to collect or sample any equipment or materials required for any purpose for which the power of entry is being exercised. b) to carry out such tests and inspections (and to make such recordings), as may in any circumstances be necessary; c) to direct that any, or any part of, premises which he has power to enter, or anything in or on such premises, shall be left undisturbed (whether generally or in particular respects) for so long as is reasonably necessary for the purpose of any test or inspection; d) to take samples of any organisms, articles or substances found in or on any premises which he has power to enter, and of the air, water or land in, on, or in the vicinity of, the premises; e) in the case of anything found in or on any premises which he has power to enter, which appears to him to contain or to have contained LMOs which have adversely affected or are likely to adversely affect the conservation and sustainable use of Biological Diversity, taking also into account risks to human health, to cause it to be dismantled or subjected to any process or test (but not so as to harm or destroy it unless this is necessary); f) in the case of anything mentioned in subparagraph (v) above or anything found on premises which he has power to enter which appears to be a LMO or to consist of or include LMOs, to take possession of it and detain it for so long as is necessary for all or any of the following purposes, namely: g) to examine it and handle it in accordance with subparagraph (v); h) to ensure that it is not tampered with before his examinations have been completed; and i) to ensure that it is available for use as evidence in any proceedings for an offence under the article "Offences and Penalties" of the Act; j) to require the production of, or where the information is recorded in computerised form, the furnishing of extracts from, any records which are required to be kept under this Act or it is necessary for him to see for the purposes of any test or inspection under this Article and to inspect, and take copies of, or of any entry in, the records; k) to require any person to afford him such facilities and assistance with respect to any matters or things within that person's control or in relation to which that person has responsibilities as are necessary to enable the inspector to	

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exercise any of the powers conferred on him by this Article.	
2) Where goods are seized by an inspector without reasonable cause, the aggrieved person may bring an action in any competent court for appropriate relief, including an order for the return of the goods seized, and, if the claim prevails, shall be entitled to the costs of such proceedings.	
Article "Biosafety Clearing House"	
1) The Competent Authority shall notify the Biosafety Clearing House that its domestic regulations shall apply with respect to any imports of LMOs to the area of national jurisdiction of [name of country].	
2) The Competent Authority shall provide to the Biosafety Clearing House: a) A copy of the Act, including any amendments, decisions pursuant to the article articles "exemptions and differentiated procedures" of the Act, or regulations promulgated hereunder, and any other legislation or national guidelines of relevance to the implementation of the Cartagena Protocol or the management of LMOs; b) Summaries of risk assessments generated pursuant to the Article "risk assessment and risk management" of the Act; c) Final decisions regarding the importation or intentional introduction into the environment of LMOs pursuant to the article "release into the environment" and the article "placing on the market" of the Act; d) Reports concerning national implementation of the Cartagena Protocol in accordance with Article 33 of the Protocol; e) Within thirty (30) days of taking a decision under article "review of decisions" of the Act, a copy of the decision describing the changes to the previous decision and the reasons for the decision; and f) Any other information required under the Cartagena Protocol or other international agreements concerning the subject matter addressed by this Act.	
3) Where the Competent Authority renders a final decision regarding domestic use, including placing on the market, of an LMO that may be subject to export for direct use as food or feed or for processing, it shall ensure that information concerning the authorization of that LMO, as specified in Schedule IV, is provided to the Biosafety Clearing House established under the Cartagena Protocol within fifteen (15) days of making the decision.	
Article "Public Awareness and Participation"	
1) Any person may submit written comments relevant to the objective	

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of the Act on a proposed decision for any application for placing an LMO on the market and any petition for an exemption or differentiated procedures within sixty (60) days from the date the notice is posted. Such comments shall be given due consideration as part of the decision-making process in accordance with the article "Petition for Exemption or Differentiated Procedures". Any comments received by the Competent Authority and responses thereto also shall be made available to the public upon request.	
2) The Competent Authority shall publish notices of notifications, applicants and petitions referred to in the article "release into the environment", the article "placing on the market", and the article "Review of Decisions" of the Act, as well as final decisions concerning those applications and petitions and notices concerning the final resolution of any compliance matters in cases involving non-compliance with material provisions of the Act.	
3) The Competent Authority shall establish and maintain a Registry of: a) LMOs for which a permit is granted under the article "release into the environment" or an authorization is given under the article "placing on the market" of the Act; and **b)** LMOs and activities that are exempted or subject to differentiated procedures in accordance with the article "Exemptions and differentiated procedures" of the Act.	
4) Any regulations proposed under Article "Regulations" of the Act must be published and a period of sixty (60) days allowed for the submission of written comments by any person. Comments pertaining to the objective of the Act shall be considered as part of the regulatory process in accordance with the article "Regulations". Any comments relevant to the objective of the Act received by the Competent Authority and responses thereto also shall be made available to the public upon request.	
Article "Transport Documentation for Contained Use Activities with LMOs"	
1) Without prejudice to other applicable regulations, documentation for LMOs that are transported, including imported into and exported from [name of country], for purposes of Contained Use shall include: i) A clear identification of the content as "living modified organisms"; ii) Requirements for the safe handling, storage, transport and use, if any. In the event that there are no requirements, state "not applicable"; iii) A statement that "the LMOs are not intended for	

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intentional introduction into the environment"; and iv) A contact point for further information, including the name and address of the individual and institution to whom the GMMs or designated LMOs are consigned.	
2) The documentation shall accompany the transport and shall be available for inspection on the premises where the Contained Use activities are carried out for the duration of the activities.	
Article "transport Documentation for LMOs for release into the Environment"	
1) Transport documentation for LMOs intended for release into the environment shall include a i) Clear identification as "living modified organisms"; ii) A brief description of the LMOs , including the identity (common and scientific names and, where appropriate, the commercial name), relevant traits and/or characteristics; iii) Requirements for safe handling, storage, transport and use, if any. In the event that there are no requirements, state "not applicable"; iv) The contact point for further information including, where applicable, the name and address of the importer and exporter; and v) A declaration that the movement of the LMOs is in conformity with the foregoing requirements.	
2) The transport documentation referred to under paragraph (1) shall accompany LMOs during importation into and exportation from [name of country] and, for introductions for purposes other than placing on the market, shall accompany the LMOs during transport within [name of country] and be available for inspection by the Operator responsible for the introduction.	
Article "Documentation for LMOs for Direct Use as Food or Feed or for Processing"	
1) Documentation for LMOs that are imported into and exported from [name of country], for direct use as food or feed or for processing shall include the following: a) In cases where the identity of the LMOs is known through specified means such as identity preservation systems, that the shipment "contains living modified organisms that are intended for direct use as food or feed, or for processing"; b) In cases where the identity of the LMOs is not known through such means, that the shipment "may contain one or more LMOs that are intended for direct use as food or feed, or for processing"; c) The common, scientific and, where available, commercial	

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names of the LMOs, noting that the expression "may contain" in subparagraph (b) does not require a listing of LMOs of species other than those that constitute the shipment; d) The transformation event code of the LMOs or, where available, its unique identifier code; e) A statement that "the LMOs are not intended for intentional introduction into the environment"; f) The Internet address of the Biosafety Clearing-House (www.bch.cbd.int); and g) A contact point for further information.	
2) Documentation for LMOs for direct use as food or feed or for processing under paragraph (a) shall accompany LMOs during import or export and shall be available for inspection by the Operator responsible for the import or export	
Article "Response Measures"	
The Competent Authority shall determine which Response Measures as referred to in the article "Response measures" of the Act should be taken by the Operator after evaluating the reasonable remedial options, using best available technologies in accordance with generally accepted scientific methodology used in the relevant scientific community of endeavour, and based on consideration of, among other relevant factors: a) the likelihood of success of each option; b) the cost of implementing each option; c) the extent to which each option will prevent future damage and avoid collateral damage as a result of implementing the option; d) the length of time it will take for the prevention, minimization, containment, mitigation, or avoidance of damage to be effective; and e) the geographical linkage of each option to the site of the Damage.	
Article "Guidance Documents"	
The Competent Authority may publish such guidance documents as may assist with implementation of the Act and this Regulation.	
Article "Fees"	
Applicants shall pay fees in accordance with Schedule V.	
PART THREE: FINAL CLAUSES	***Explanatory Notes:***
Article "Date" This Regulation shall enter into force [.....] months upon publication.	

SCHEDULE I - Information Required in Applications for Release into the Environment

1) Name, address and contact details of the Applicant.
2) Name, address and contact details of the contact person .
3) Name and identity of the living modified organism, as well as the domestic classification, if any.
4) Intended date or dates of the release.
5) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
6) 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.
7) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
8) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
9) 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.
10) Quantity or volume of the living modified organism to bereleased.
11) A previous and existing risk assessment report consistent with Schedule III.
12) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
13) In case of import: Regulatory status of the living modified organism within the State of export .

SCHEDULE II - Information Required in Applications for Placing on the Market

1) Name, address and contact details of the Applicant.
2) Name, address and contact details of the contact person.
3) Name and identity of the living modified organism, as well as the domestic classification, if any.
4) Intended date of the placing on the market.
5) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
6) 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.
7) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
8) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
9) 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.
10) Any previous and existing risk assessment report consistent with Schedule III.
11) Any suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
12) In case of import: Regulatory status of the living modified organism within the State of export.

Schedule III Risk Assessment

Objective and General Principles

1) The objective of risk assessment, under the Act, is to identify and evaluate the potential adverse effects of living modified organisms on the environment that will affect the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.
2) 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.
3) 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.
4) 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.
5) 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

1) 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.

2) 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

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.

Schedule IV - Information for the Biosafety Clearing House

1) The name and contact details of the applicant for a decision for domestic use.
2) The name and contact details of the authority responsible for the decision.
3) Name and identity of the living modified organism.
4) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.
5) Any unique identification of the living modified organism.
6) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
7) 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.
8) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
9) Approved uses of the living modified organism.
10) The summary of the risk assessment report created pursuant to the article “Risk assessment and risk management” of he Act.
11) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

Schedule V - Fees

{Standard fees should be set consistent with costs for similar regulatory processes.}