DRAFT 30 June 2002

IMPLEMENTING THE BIOSAFETY PROTOCOL

Claudia Martans

Introduction

Human activities have in the past few decades led to an unprecedented loss of biological diversity. In order to halt the rapidly growing erosion of species, genetic and ecological diversity, the need for a global instrument for the conservation and sustainable use of the biological diversity was gradually recognised. This ultimately led to United Nations Environmental Programme (UNEP) Governing Council to call for the negotiation of such an instrument.[1] UNEP established an *ad hoc* working group with the view to develop a framework convention in this field. Elements for a convention were prepared, building upon the work of several international organisations on this subject, in particular, the efforts of the World Conservation Union (IUCN). Two years of negotiations followed, leading to the adoption of the Convention on Biological Diversity (CBD) in Nairobi in 1992. It was opened for signature at the United Nations Conference on Environment and Development in 1992; it entered into force on 29 December 1993. The CBD has become one of the most popular environmental conventions: at the beginning of 2002 the convention had 183 Parties. It has three objectives: the conservation of biological diversity, the sustainable use of biological resources, and the equitable sharing of benefits arising from the use of genetic resources, including biotechnology.

Article 19(3) of the Convention provides that the Parties shall consider "the needs for and modalities of a Protocol setting out appropriate procedures, including advance informed agreement, in the field of the safe transfer, handling and use of living modified organisms (LMOs) that may have an adverse effect on biodiversity."

At the first Conference of the Parties (COP) of the CBD held in Nassau in 1994, several parties expressed an interest in developing an international biosafety agreement, while others disagreed.[2] At the second meeting of COP of the CBD, in Jakarta (1995) the discussion continued. While it was reiterated that modern biotechnology has a great potential for human well being when used safely, concerns were increasingly expressed about the lack of safeguards and thus the need to develop a Protocol. It was decided that: "to seek for a solution to these concerns through a negotiation process to develop, in the field of the safe transfer, handling and use of LMOs[3], a Protocol on biosafety, specifically focusing on transboundary movements, of any LMOs that may have adverse effects on the conservation and sustainable use of biological diversity."[4]

Consequently, the COP established an open-ended Working Group of Ad Hoc Experts on Biosafety and determined its mandate.[5] The deadline for completing the negotiations was set at 1996, but was later extended to early 1999. An extraordinary meeting of the

[1] IUCN-ELC "A guide to the convention on biological diversity" (1994), p. 1-3.
[2] Falkner, R. Negotiating the biosafety protocol: the international process. The Cartagena Protocol on Biosafety, reconciling trade in Biotechnology with environmental and development, p. 7.
[3]For the purpose of this paper, LMO means: "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology." As is defined in the Cartagena Protocol.
[4]See details in the article "The state of play: The negotiations towards a Protocol on Safety in Biotechnology. http://www.foeeurope.org/programmes/biotechnology/workshop_text2.htm.
[5] (COP DecisionII/5)

Conference of the Parties (ExCOP) was convened in February 1999, in Cartagena de Indias, Colombia, immediately following the last meeting of the working group. However, delegates were not able to reach agreement, and the Protocol could not be adopted in Cartagena. The ExCOP was suspended. Following informal consultations, it was agreed to resume negotiations. The ExCOP meeting resumed in Montreal, in January 2000 where the Protocol was adopted.[6]

The Protocol will enter into force when the fifty States will have ratified or acceded to it. Two years after its adoption, only nineteen countries have done so. It is currently hoped that the necessary number of ratification or accession will be reached before the next CBD/COP.

In order to implement the Protocol, national legislative and regulatory frameworks will have to be put into place. However, so far very few countries have developed national legislation on biosafety. The purpose of this paper is to highlight the importance of an effective national regulatory system, which will enable the Parties to implement the Protocol in an efficient manner.

[6] Burgiel, S. and A. Cosbey, "The Cartagena Protocol on Biosafety: An analysis of results" (2000) page 4.

I. Background

In the recent past the developments of modern biotechnology has started to change our world. Genetically manipulation of certain organisms has generated a public debate concerning this new technology and its possible adverse effects on the environment and human health.[7] The causes of this debate will be briefly considered below.

1. Biotechnology

Biotechnology has a long history of usage; humans have altered plants and animals through breeding selection process and cross-fertilisation for a very long time. Moreover, biotechnology has been used in numerous processes such as making bread and beer. The discovery of modern biotechnology, however, has allowed scientists to develop organisms which could not be developed through conventional methods, and would not develop naturally. Such Genetically Modified Organisms (GMOs) are already used in many different areas e.g. agriculture, health care, livestock, biosensors, chemical manufacturing and bio-remediation.[8]

1.1. Agriculture

Genetically modified plants are being designed to have specific characteristics. Some, for instance, have specific characteristics to protect themselves against frost, but also against pest and diseases leading to a reduced usage of pesticides. Increased crop yields are expected for other developments, for example plants that grow faster and with longer growing seasons, leading to a reduction of the use of fertilisers. Examples include genetically modified tomatoes which have frost resistant genes from arctic flounder and genetically modified potatoes that have increased diseases resistance transferred to it from a chicken gene. Transgenic crops are capable of withstanding draught, floods and climate changes, while others are modified to produce vitamins and vaccines for the consumers.

The agro-biotech[9] sector argues that traditional methods of plant breeding are slow and expensive, therefore, modern biotechnology is needed. Furthermore, advocates of agro-biotechnology argue that its use will be increasingly necessary, in order to help meet the food demand of the expanding populations in developing countries.[10] Non-profit organisations like International Service for the Acquisition of Agri-Biotech Applications (ISAAA) have the mission to contribute to poverty alleviation by increasing crop productivity and generate income especially to poor farmers through the transfer of modern biotechnology products. Opponents express doubts about the real benefits of such products and their environmental and socio-economic consequences, for instance the promotion of intensive monoculture, with dramatic disadvantages for genetic

[7] See details on http://www.cai.org.ar/medioambiente/protocolodebioseguridad.htm

[8] Hall, S. The Genie in the Bottle: The International Regulation of Genetically Modified Organisms. *Journal of International Wildlife Law and Policy*. Vol. 1 (1998) p. 358.

[9] Is an abbreviation of agricultural biotechnology.

[10] ISAAA is a non-profit international organisation co-sponsored by public and private institutions that facilitates the transfer of agribiotechnology applications-particularly private sector proprietary technology from industrial to developing countries for their benefit. See http://www.isaaa.org

diversity in crops, as well as the disruption of small-scale farming systems in developing countries.[11] Critics also point out that transgenic plants may transmit their genes to other crops and wild relatives through cross-pollination, or may become invasive, both with serious consequences on biological diversity.

Major crops using these techniques are now commercially available: soybeans, corn, cotton, rice, canola and tomatoes, grown mainly in the United States of America (USA), Canada and Argentina. USA grew genetically engineered crops on 35.7 million acres by 2001.[12]

1.2. Pharmaceutical

The potential contribution of biotechnology to medicine is immense: early applications in pharmaceutical products were insulin for diabetics and clot busting drugs for heart attack patients. It is being applied to the development of genetically modified bacteria used in vaccines for certain diseases like diabetes. Moreover, modern biotechnology is helping to create medicinal tools to treat multiple sclerosis, haemophilia, hepatitis, heart disease and AIDS, among others.[13]

In Africa, bananas have been genetically modified to insert into them the vaccine for cholera and diarrhoea which are two of the foremost causes of child mortality in developing countries.

1.3. GM animals

Some genetically modified animals have been engineered for commercial reasons. An example is the genetically modified Atlantic salmon that grows to market weight in about 18 months, compared to the 24 to 30 months that it normally takes a fish to reach that size.[14] These animals, because they grow faster, take less food and time for a crop to sell in the market.

Transgenic animals have also been created to advance basic biomedical research. Inserting oncogenes into lab rats, mice and rabbits, facilitate cancer research. Moreover, researchers now seek ways to genetically modify organs of animals, such as pigs, for possible transplantation into humans.[15]

[11]Kormos, C & L. Hughes, Regulationg Genetically Modified Organisms: Striking Balance Between Progress and Safety. *Center for Applied Biodiversity Science Series.* (2001) p. 8.
[12]See details of countries which have grew transgenic crops on 2001 http://www.isaaa.org
[13] See details on http://vm.cfsan.fda.gov/~lrd/biotechm.html
[14] See details on the article written by Carol Lewis "A new kind of fish story: the coming of biotech animals." http://www.fda.gov
[15] Hall, supra note No. 8, p. 2

2. The pros and cons of GMOs

2.1. Pros of GMOs

As mentioned earlier, genetically engineered products have been used in a variety of fields such as, agriculture, pharmaceutical purposes, animals and food. Examples of potential benefits of GMOs may be summed up as follows:

2.1.1. Agriculture

- Plants that grow faster, have longer growing seasons and higher yields, have higher pest and herbicide resistance, increased tolerance for changes in climate and soil composition.
- Possibility to change soil composition through bacteria capable of retaining nitrogen and to reduce the use of pesticides for the agriculture.
- Increased resistance to pests and diseases in livestock.

2.1.2. Biodiversity

- Increasing agricultural efficiency, thus reducing pressure on forests by decreasing the need for new farmland.
- Rehabilitation of polluted and contaminated soil through bio-remediation.
- Cloning of endangered species.[16]

2.1.3. Health Care

- Development of new medicines and vaccines cultivated through genetically engineered bacteria and micro-organisms.
- Elimination of need for needles and cold storage of vaccines because they could be provided in the food.[17]
- Transplant organs from genetically modified animals to humans.

2.2. The Cons of GMOs

Critics to GMOs, including consumer groups and environmental organisations argue that genetically modified organisms are likely to have adverse effects to the environment (particularly biodiversity) and human health. They criticised the lack of sufficient tests on potential effects before placing them on the market, and the lack of labelling of such products when in circulation. Moreover, the socio-economic impact of the technology are questioned, in particular, developing countries are concerned about the consequences on small-scale farming in particular the fact that new seeds must be bought every year, therefore making farmers dependent on seed providers, usually multinational companies.

[16]Acosta, J. "Los organismos modificados genéticamente: el poder blando del tercer milenio. Habana. Cuba. (2001) p. 7.

[17] Young, T. "IUCN Biosafety and genetically modified organism: background for the enunciation of IUCN position and action plan, p. 14.

The most disturbing risks for the public however, are related to food, i.e. the production of GM crops and related products placed on the market for human consumption.[18]
Critics also point out that:

2.2.1. Agriculture

- There is little evidence to support the claim for increased agricultural yield.
- Resistance to herbicide may create "super weeds".

2.2.2. Biodiversity

Risks include:

- The potential dispersal of the GMOs into the environment.
- Alteration of ecosystems and habitats as a result of monoculture.(GM crops).
- Potential impacts on soil bacteria.
- Cross-pollination with genetic engineered pollen, creating the "genetic pollution".[19]

2.2.3. Health

- There is insufficient information related to the toxicity and allergenicity of GM food products.[20]

[18] Brañes, R & O. Rey, "Biosafety policy, Law and Administration in Latin America and the Caribbean." Seminar sponsored by the Economic Commission for Latin American and the Caribbean, UNEP and Latin American Association of Environmental Law. (1999) p. 7.
[19] Kolehmainen, S. Precautionary before profits: an overview of issues in genetically engineered food and crops. *Virginia Environmental Journal.* (2001) p. 281.
[20] IUCN explanatory guide, p 7.

II. The Cartagena Protocol

1. Background

The Biosafety Protocol was adopted on 29 January 2000 in Montreal. The Protocol addresses the safe transfer, handling and use of LMOs, as defined by the Protocol but focuses on transboundary movements.

2. Legal status of the Protocol

The Cartagena Protocol is a binding international instrument concluded under the CBD. Its origin is article 19(3) of the CBD which mandates its Parties to consider the need for that for a Protocol. A Protocol is an international instrument which is separate from, but linked to its parent instrument. It has to be negotiated, signed and ratified separately. But it is bonded to CBD and refers to several of its provisions and mechanisms. It could also not deal with subjects beyond the scope of the Convention on Biological Diversity.
As an international instrument, the Protocol creates obligations between States. In order to comply with these obligations the Parties must adopt the legislation necessary to implement it.[21] Hence the importance of creating national biosafety frameworks.

3. Important elements of the Biosafety Protocol

3.1. The Scope of the Protocol

The Protocol applies to the transboundary movement, transit, handling and use of all LMO that may have adverse effects on the conservation and sustainable use of biological diversity, and taking into account human health.

The Protocol excludes from its scope LMOs that are pharmaceuticals for humans that are addressed by other international organisations or agreements.[22]

3.2. Definition of LMOs

LMOs is defined as "any living organism[23] that possesses a novel combination of genetic material obtained through the use of modern biotechnology[24]."
The term LMO has its origin in the CBD[25] where the term was intentionally to include not only genetically engineered organisms but also those resulting from any form of

[21] Craig, D., Robinson, N. & K. Kheng-Lian. "Capacity Building for Environmental Law in the Asian and Pacific Region. Vol. II (2002) p. 371.
[22] Article 5 of the Cartagena Protocol.
[23] According to the Protocol Living organisms means "any biological entity capable of transferring or replicating genetic, material, including sterile organisms, viruses and viroids".
[24] Article 3 of the Protocol, refers as modern technology the application of: "In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA), and direct injection of nucleic acid into cells or organelles or 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".
[25] The article 19(3) CBD: "The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, AIA, in the field of the safe transfer, handling and use of

biotechnology using conventional or techniques. During the negotiations of the Protocol however, it was agreed to refer to modern biotechnology only, thus excluding conventional and traditional techniques from the scope of the definition.
The Term LMO was nevertheless kept, in order to keep consistent with the terminology of the Convention.

3.3. The Advance Informed Agreement Procedure (AIA)

The AIA procedure is similar to a prior informed consent procedure (PIC)[26] which has been used in several environmental treaties. The AIA constitutes the central part of the procedure regarding transboundary movements of LMOs and it applies to the first transboundary movement of LMOs for intentional introduction into the environment of another Party.[27] The elements of the AIA procedure includes designation of a competent authority, notification, risk assessment, and decision of the Party of import, as explained below.

3.3.1. Competent Authority

All Parties must designate the competent national authorities to be responsible for carrying out the administrative functions required by the Protocol.[28] The competent authority, for instance, will authorise or reject applications for imports.

3.3.2. Notification and information

The Party of export or the exporter shall notify in writing the competent national authority of the Party of import before the movement takes place.[29] Information to be provided with the notification is specified in the Annex I (e.g. the exporter, the LMO, the intended use).

3.3.3. Decision of the Party of Import

After receiving the notification of a transboundary movement, the Party of import shall acknowledge receipt within 90 days. It must communicate its decision regarding the import to the Party of export and the Biosafety Clearing House (BCH) within 270 days.[30] However, failure by the Party of import to communicate its decision shall not imply its consent.

---

any *living modified organism* resulting from biotechnology that may have adverse effects on the conservation of sustainable use of biological diversity.

[26] PIC procedure it was first introduced to control import of unwanted chemicals, which have been banned or restricted in other countries. This procedure helps countries to learn more about the characteristics of potentially hazardous chemicals that may be shipped to them, initiates a decision making process on the future import of these chemicals by the countries themselves and facilitates the dissemination of this decision to other countries. The aim is to promote a shared responsibility between exporting and importing countries in protecting human health and the environment from the harmful effects of certain hazardous chemicals being traded internationally.

[27] Article 7(1) Cartagena Protocol.

[28] Article 19 of Cartagena Protocol.

[29] Article 8 of Cartagena Protocol.

[30] Article 9 of Cartagena Protocol.

3.3.4. Risk Assessment

The decision of the Party of import is to be based on a risk assessment. The Party of import carry out the risk assessment on the basis of the information provided in the notification and other available scientific evidence in order to identify and evaluate the possible adverse effects of the LMO on the conservation and sustainable use of biological diversity taking into account risks to human health. It may also require the exporter to conduct and/or bear the costs of the risk assessment.[31]

The main objective of risk assessment is to identify and evaluate in a scientific manner any adverse effects of the LMO considered on the conservation and sustainable use of biological diversity in the receiving environment, taking also into account human health.[32] The risk assessment has to comply with the requirements of Annex III of the Protocol.

3.3.5. Confidential Information

The Protocol permits the notifier to indicate which of the submitted information must be treated as confidential.[33] The Party of import cannot disclose any confidential information for commercial purposes, unless written consent of the notifier is obtained. However, description of the LMO, the name and address of the notifier, and the summary of the risk assessment may not be considered confidential.

3.3.6. National Discretion

The Protocol allows a measure of national discretion to Parties in relation to the AIA procedures.

First, a Party of import may decide to apply its national legislation in reaching an import decision, in as far as, the legislation is consistent with the Protocol.[34]

Second, Parties of import may decide to apply simplified procedures for the import of certain LMOs.[35]

Third, Parties may enter bilateral, regional and multilateral agreements and arrangements regarding the international movement of LMOs. These must be consistent with the aims of the Protocol and therefore, may not result in a lower level of protection that that provided for by the Protocol.[36] Parties must inform the BCH of any agreement or arrangement.

Fourth, the Parties can take more protective measures for the conservation and the sustainable use of biological diversity, provided that those measures are consistent with the Protocol's objective and provisions.[37]

---

[31] Article 15 of Cartagena Protocol.

[32] Andrén R & B. Parish, "Risk Assessment" The Cartagena Protocol on Biosafety, Reconciling Trade in Biotechnology with Environment and Development, p. 329.

[33] Article 21 of Cartagena Protocol.

[34] Article 9(3) and 14(4) of Cartagena Protocol.

[35] Article 13 of Cartagena Protocol.

[36] Article 14 of Cartagena Protocol.

[37] Article 2(4) of Cartagena Protocol.

3.4. LMOs not subject to AIA provisions

The Protocol stipulates that certain LMOs will not be subject to AIA procedure.
The AIA provisions does not apply to the transboundary movement of LMO such as, LMOs in transit, LMOs destined for contained use, and LMOs intended for direct use for food, feed or for processing (LMO-FFPs).

3.4.1. LMOs in transit

The AIA procedure does not apply to LMOs in transit. However, this provision is without prejudice to the right of a Party of transit to regulate in its national legislation the transport of LMO within its jurisdiction.[38] Parties have to make available to the Biosafety Clearing House decisions related to the transit of LMO through their territory.

3.4.2. LMOs destined for contained use

The AIA procedure also does not apply to LMOs destined for contained use.[39] However, it is without prejudice to the right of a Party to subject all LMOs to risk assessment prior to decisions on import and to set standards for contained use within its national legislation.[40]

3.4.3. LMOs intended for direct use for food, feed or processing (LMO-FFPs)

The AIA procedure does not apply to LMO-FFPs.[41] However, the Protocol provides the different procedure for LMO-FFPs. Any Party that makes a final decision regarding domestic use, including placing on the market, of a LMO-FFPs has to inform, within fifteen days, all Parties of these approvals through the Biosafety Clearing House. Parties to the Protocol may however request prior consent for import of LMO-FFPs if this is in compliance with its national regulations. However, Parties with national frameworks related to LMO-FFPs must make these available to the BCH, moreover, developing countries or countries with economies in transition, which do not have domestic legislation may make their decision regarding import known through BCH prior to the first import of any LMO-FFPs. The failure of a Party to communicate its decision may not be interpreted as consent or refusal to the import of LMO-FFPs.[42] Such, Parties are entitled to apply the precautionary principle when reaching decisions regarding imports LMO-FFPs.

Article 18(2a) establishes that each Party shall take measures to ensure that documentation accompanying shipments of LMO-FFPs is clearly identified as "may contain" LMOs and specifying that they are not intended for international introduction into the environment.

---

[38] Article 6 of Cartagena Protocol.
[39] The Protocol defines the contained use means any operation, undertaken within a facility, installation or other physical structure, which involves LMO that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.
[40] Article 6(2) of Cartagena Protocol.
[41] The term LMO-FFPs covers activities such as exports of GM agricultural commodities, for instance, soya, sugar, potatoes, casaba, tomatoes, or maize.
[42] Article 11 of Cartagena Protocol.

3.5. Risk Management

Risk management measures are those taken on the basis of the risk assessment to prevent any adverse effect of the LMOs in the environment and also risks to human health within the territory of the Party of import. The Parties has to ensure that any LMO, whether imported or locally developed, has been under observation for certain period of time before it is put to its intended use.[43]

3.6. Biosafety Clearing-House (BCH)

The Protocol creates the BCH, in order to facilitate the exchange of information on LMOs and to assist countries to implement the Protocol. In addition, the Protocol identifies certain information that must be available to BCH by the Parties, such as laws, regulations and guidelines for implementation of the Protocol; bilateral, regional and multilateral arrangements; decisions on import or release of LMOs; summaries of risk assessments.[44] As mentioned above, the BCH also plays a key role in transboundary movement of LMO-FFPs.

3.7. Capacity-Building and Financial Resources

The Protocol requires Parties to co-operate in the development and/or strengthening of human resources and institutional capacities in biosafety in developing countries, small islands States and countries with economies in transition.[45] Moreover, the Protocol supports the transfer and access to technology from developed countries to less developed ones.

3.8. Unintentional transboundary movements of LMOs

The Parties to the Protocol shall notify immediately or potentially affected States and BCH when an unintentional transboundary movement of LMOs has occurred that is likely that may have adverse effects on the environment and risks to human health.[46] Furthermore, the Parties to the Protocol have to make available to BCH information on points of contact for receiving the notification, in the event of unintentional transboundary movement.

3.9. Illegal Transboundary Movement of LMOs

Each Party may adopt appropriate domestic measures in order to prevent and penalise transboundary movements; i.e. movements carried out in contravention to domestic measures implementing the Protocol.[47] Moreover, it establishes that in the event of an illegal transboundary movement, the affected Party may require the Party of origin to dispose at its own expense of the illegal LMO. The Parties have to notify the BCH each time there is an illegal transboundary movement of LMO into its country.

[43] Article 16 (4) of Cartagena Protocol.
[44] Article 20(3) of Cartagena Protocol.
[45] Article 22 of Cartagena Protocol.
[46] Article 17 of Cartagena Protocol.
[47] Article 25 of Cartagena Protocol.

3.10. Liability and Redress

The Protocol provides that at the first meeting of the Parties to the Protocol, the Parties shall start considering rules and procedure on liability caused by LMOs. It requires adoption of the liability and redress process within two years. [48]

3.11. Dispute and Settlement

The Protocol does not contain provisions related to dispute settlement, but refers to those of the Convention on Biological Diversity, which provides for optional recourse to judicial settlement, arbitration, or conciliation.[49]

3.12. The Precautionary Principle

The Cartagena Protocol endorses the precautionary approach, it should be noted that for the first time this principle has been included in the body of an international treaty, as part of the operational provisions.[50]

The Protocol contains references to the concept of precaution in some of its provisions:

- The Preamble and Article 1 of the Protocol, which makes reference of the precautionary approach, contained in the Principle 15 of the Rio Declaration.
- Provisions regarding in the decision-making process in articles 10(6) and 11(8), which remarks import decisions for LMOs and LMO-FFPs and in Annex III which concerns to risk assessment.

4. Interim Arrangements on the Intergovernmental Committee on the Cartagena Protocol (ICCP)

The ICCP was created by the Conference of Parties to the CBD to prepare for the first meetings of the Parties to the Protocol. The first meeting was held from 11-15 December 2000 in Montpellier, France.[51] The second meeting of ICCP 2 took place in Nairobi, Kenya, December 2001 and the third meeting of the ICCP 3 has taken place this year in The Hague, just after the meeting of the 6th COP of CBD. ICCP 3 continued the work of the two previous meeting in preparing for the entry into force of the Protocol.[52]

[48] Jabara, K. "Biosafety Protocol." *Journal of Environmental Law.* Vol. VII(2001), p. 136.
[49] Articles 27 and 32 of the Convention on Biological Diversity.
[50] The precautionary principle is introduced in the operative mechanism applied to imports, placing on the market of LMOs.
[51] Burhenne-Guilmin, F. & Y. Osafo, "First Intergovernmental Committee" *Environmental Policy and Law*. Vol. 31, No. 1. (2001) p. 22.
[52] See for details the official report of ICCP 3, a detailed report of the meeting and its results. http://www.iisd.ca/linkages/biodiv/iccp3

III. International Instruments relevant to Biosafety

Several international organisations have adopted legal instruments of relevance to biosafety. Some of these instruments are guidelines, others are legally binding. Some are relevant because they address biosafety issues, others because they address trade issues.

1. *Biosafety related instruments*

1.1. International Plant Protection Convention

The International Plant Protection Convention (IPPC) is a multilateral agreement which is legally binding. It was originally adopted in 1951 and revised in 1997. Its main objective is to implement a secure joint and effective action to prevent the spread and introductions of pests of plants and plant products, and to promote appropriate measures for their control.[53] It is currently developing standards regarding plant pest risk caused by products of biotechnology.[54] Currently, an IPPC working group review, the risk to plants associated with GMOs/products.

1.2. Codex Alimentarius

The Codex Alimentarius Commission was established in 1963, in order to advise on the developments of the Codex Alimentarius, which is a non-binding Code related to food safety.

It created in 1999 an *Ad hoc* intergovernmental task force on foods derived from biotechnology. The task force is expected to draft guidelines regarding risk assessment, safety and nutrition assessment, long-term health effects, monitoring and labelling. It should complete this task in 2004.[55] The food standards that may be adopted will address potential allergenicity and pathogenicity of the foods concerned, as well as authorisation procedures.

1.3. The Office International des Epizooties (OIE)

The OIE, the World Organisation for Animal Health was established in 1924. It sets out standards for movement of animals and animal products. The main objectives are to prevent the spread and introduction of animal diseases and harmonise regulations for trade in animals and animal products.[56] In regards, to GMOs the OIE has conducted work on scientific evaluation of GMOs that are pharmaceuticals for animals.

2. *Trade Related Instruments*

2.1. The World Trade Organisation (WTO)

The WTO is an organisation which addresses trade between nations. It was created by the Marrakech treaty signed on 1 January 1995. The main objectives are free international

[53] Article 1 of the IPPC Convention.
[54] Supra Note 20, p. 25. See IUCN Explanatory Guide.
[55] In relation to Codex Alimentarius, see FAO website http://www.fao.org
[56] See for more details the website of the organisation. http://www.oie.int

trade, further liberalisation through negotiation, and an impartial means of settling disputes. Another objective of the WTO is to facilitate international trade, in order to contribute to international economic welfare.[57] Consequently, it seeks to eliminate trade barriers and promotes non-discrimination and transparency in this field. Any Party to WTO, becomes ipso facto Party to WTO-related multilateral trade agreements, i.e, the General Agreement on Tariffs and Trade (GATT), the Agreement on Phytosanitary Agreement (SPS Agreement), the Agreement on Trade-Related Intellectual Property (TRIPs) and the Agreement on Technical Barriers to Trade (TBT).

The GATT is the most general one and addresses the international trade in goods.
The article XI of GATT "promotes the elimination of quantitative restrictions."[58] Article III also prohibits countries from discriminating between national and foreign "like" products originating from member countries.[59] There are some exceptions to those rules, provided in article XX[60] of GATT. This article provides exceptions to the trade rules mentioned above, i.e. prohibitions of quantitative restrictions and non-discriminatory rules.[61] These concern measures necessary for the protection of human, animal or plant health. These exceptions should, however, not be applied in a manner that constitutes a means of arbitrary discrimination among states or that would establish a disguised restriction for international trade rules.[62]

The Sanitary and Phytosanitary Measures are closely bonded to GATT article XX, and allows States to take sanitary and phytosanitary measures essential to protect human, animal, or plant life or health. Those measures must be based on a risk assessment.[63] Article 5.1, states that: "members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by relevant international organisations." The relevant organisations in question are the IPPC (for plants), the OIE (for animals) and the Codex Alimentarius for food.

---

[57] Stoll, P. Controlling the Risks of Genetically Modified Organisms: The Cartagena Protocol on Biosafety and the SPS Agreement. *Yearbook of International Environmental Law.* Vol. 10 (1999) p. 100.

[58] GATT, article XI (1) states: "No prohibitions or restrictions other than duties, taxes or other charges…shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party on the exportation or sale of export of any product destined for the territory of any other contracting party."

[59] GATT, article III states: "The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that recorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use."

[60] GATT, article XX states: " Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures."

[61] See details on the webpage of the WTO, http://www.wto.org

[62] Stoll, supra note 57, p.102.

[63] The risk assessments are defined in section 4 of Annex A to SPS Agreement as including "the evaluation of the potential for adverse effects on human or animal health."

The relationship between the Cartagena Protocol and the WTO-related agreements was one of the most controversial issues during the negotiation of the Protocol.

IV. Regional Efforts to Create Biosafety Frameworks Regarding GMOs

There have been regional efforts for creating Biosafety frameworks regarding GMOs. For the purpose of this article, the discussion will be focused on two regional economic intregration organisations: the Andean Pact and the European Union. These two Institutions have been vested with law-making powers which are binding on there Member States.

1. Andean Pact

1.1. General Overview

The Andean Pact[64] is a sub-regional organisation endowed with an supra-national legal status, which consists of five (5) countries of South America: Bolivia, Colombia, Ecuador, Peru and Venezuela. The Andean Community was created through the Cartagena Agreement. It establishes a series of bodies and institutions, such as the Commission of the Andean Community, the General Secretariat of the Andean Community, the Court of Justice of the Andean Community, and the European Parliament which enables Andean Community Law.[65]
The Commission proposes the legislation, which is revised and approved by the Andean Parliament. These Decisions are directly applicable to the Member States of the Andean Community and its legally binding in all Member States.[66]

Currently, the Andean Pact is working on a common regime on biosafety, but there has been disagreement among the member's states on this so far, which prevented its approval.[67]

2. The European Union

The European Union is an economic integration organisation based on the principles of free movement of goods, persons, services and capitals.[68] It is constituted of fifteen Member States. Community law is binding on Member States and prevails in the event of a conflict with national law. This paper will only discuss the latest community legislation related to GMO.

2.1. Biosafety and the EU

The European Union has played an important role as a leader in the negotiations of Cartagena Protocol.

---

[64] The Andean Pact is a regional economic and political integration organisation formed in 1969 by treaty between Colombia, Bolivia, Peru, Venezuela and Ecuador.
[65] For more details see the establishment of the Andean Community, through the Trujillo Protocol, which was signed in 1996 and entered into force on June 3, 1997. This Treaty repeals some chapters of the Cartagena Agreement. http://www.comunidadandina.org
[66] Article 42 of the Cartagena Agreement.
[67] Caillaux, J. & M. Ruiz, "Acceso a Recursos Genéticos" (1998) p. 80.
[68] Weatherill, S. & P. Beaumont, EC Law (1995) p. 20.

The EU is a Party to the Convention on Biological Diversity, and a signatory to the Cartagena Protocol. The European Union environmental regime is based on principles such as prior informed consent, polluter-pays, and precaution, as well as, of preventive action and transparency, access to public information, public participating and generally aims at achieving sustainable development.

The European Union's has had regulatory framework on biosafety which predates the Protocol negotiation. It has been created to safeguard the protection of human health and the environment while at the same time ensuring a single European market for biotechnological goods.[69]

2.2. Deliberate Release of GMOs into the Environment: Directive 2001/18

Directive[70] 2001/18/EC will repeal Directive 90/220 on 17 October 2002. However, the Directive 90/220 is in force until October 2002.

2.2.1. Objective of the Directive

According to the article 1 of the Directive, the main objective is the approximation and harmonisation of laws among the Member States, with the view to protecting human health and the environment.[71]

2.2.2. The Scope of the Directive

The Directive regulates the deliberate release into the environment of GMOs, as well as, placing them on the market of any Member State of the Union. It has been divided into four parts. The first part concerns general provisions and the obligations of the Member States. The second part deals with the deliberate release of GMOs[72] for any purpose other than for placing them on the market. It concerns the standard authorisation procedure, differentiated procedures, handling of modifications and new information and consultation of information to the public. The third part is devoted to the placing on the market of GMOs as such or in products, and deals for example, with assessment report, standard procedure, consent, labelling, free circulation and safeguard clause. The fourth part has provisions as confidentiality, adaptation of Annexes, consultation of Scientific and Ethics Committee, exchange of information and penalties.

[69] Mackenzie, R. & S. Francescon, "The Regulation of Genetically Modified Foods in the European Union: An Overview. *N.Y.U. Environmental Law Journal*. Vol. 8 (2000), p. 533.

[70] Directive is binding on the Member States as regards the objective to be achieved, though leaves it to the national authorities of each Member State how the objective will be incorporated into their domestic legal systems.

[71] Supra note 69, p.531.

[72] The Directive 2001/18 defines genetically modified organisms as: "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

2.2.3. Exemptions

The Directive exempts the organisms obtained through traditional techniques of genetic modification.[73] Moreover, it will not apply to the carriage of GMO by rail, road, inland waterway sea or air.[74]

2.2.4. Procedure for deliberate release of GMO

Any person or legal entity, which intends to make a deliberate release of GMOs, has to submit a notification accompanied by the risk assessment to the competent authority of the Member State within which the release has to take place. The notification has to fulfil some requirements, including information relating to the GMO in question, information relating to the conditions of release and potential receiving environment, information on control, remediation methods, waste treatment and risk assessment. The Directive is very clear, on the issues related to who has to be performed and bare costs of the risk assessment, which, is the responsibility of the notifier.[75] The competent authority shall acknowledge the receipt of the notification and shall respond within ninety (90) days of receipt of the notification.[76] The notifier can proceed only when the written consent of the competent authority has been granted. However, the Directive enshrines differentiated procedures when sufficient experience has been obtained on the release of certain GMOs in certain ecosystems. Moreover, if the GMO concerned meets certain safety criteria, then the competent authority may submit to the Commission a reasoned proposal for the application of differentiated procedures to such types of GMOs, following mandatory consultation of the public and scientific committee(s). In this case, however, the notifier cannot proceed with the release until the written consent of the competent authority obtained.[77] If the consent includes a favourable opinion the release may proceed, the competent authority will send the report, to the Commission, who will forward it to the competent authorities of the Member States for their observations.[78] If there is no objections, the competent authority must give its consent regarding the release of GMOs. The competent authority must inform the notifier, the Commission and the other Member States.

2.2.5. Procedures of placing on the market of GMOs as or Products

Placing on the market of any GMO or a combination of GMOs or GMO product requires an authorisation. The competent authority of the Member State where a GMO is to be placed on the market for the first time shall notify the Member States and the Commission about the intended placing on the market of the GMO or product. The notification shall contain an environmental risk assessment, including imposed conditions

[73] The Annex I B of the Directive excludes techniques/methods of GMO on the condition that they do not involve the use of recombinant nucleic acid molecules or GMO other than those produced by one or more of the techniques/methods of mutagenesis and cell fusion.
[74] Article 3 of Directive 2001/18.
[75] In this case, the notifier is the manufacturer or importer of the product containing or consisting of GMOs who submits for notification.
[76] Article 6 of the Directive 2001/18/EC.
[77] Article 7 of the Directive 2001/18/EC.
[78] Francescon, S. "The New Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms into the Environment: Changes and Perspective. *RECIEL* 10 (3) 2001 p. 312.

for placing the product on the market, including specific conditions for use and handling, labelling and packaging.[79]

Within ninety (90) days of the acknowledgement of receipt the competent authority shall prepare an assessment report and send it to the notifier and to the Commission, who will send it for comments to the competent authorities of the other Member States. If there are comments of Member State, they will be forwarded to the Commission, who will discuss it with the competent authorities, in order to reach an agreement within hundred and five (105) days from the date of circulation of the assessment report. If there is no objections to the assessment report, the competent authority may grant the approval for placing on the market for a maximum of ten (10) years.[80] However, these permits are without prejudice to Member States to apply stricter measures on the basis of article 23[81] concerning safeguards clause. It means that a Member State can prohibit the use and/or sale of GMO and GMOs products in its territory, if it has reasons to consider that the product constitutes a risk to human health and environment.

After placing the product on the market, the notifier shall ensure that monitoring and reporting is carried out. The notifier must submit information relevant to post-marketing control.[82]

2.2.6. Labelling

The Directive requires Member States to take appropriate measures to ensure that at all stages of the placing on the market, labelling and packaging comply with the relevant requirements of the Annexes.[83]

Labelling is one of the most controversial issues. On the one hand, those in favour of labelling argue that it is a consumer's right. On the other hand, those who are against argue that risks being unknown "labelling creates an unnecessary restrictions on international trade."[84]

2.2.7. Sanctions

The Directive provides for penalties, which leave Member States discretion in order to penalise the breaches of the national provisions adopted under the Directive.[85] The

[79] Article 13 of Notification procedures of Directive 2001/18/EC.
[80] See Francescon, Supra note 78, p. 313.
[81] The Article 23 establishes "Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment o reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory. The Member State shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public.
[82] Supra note 78, p. 314.
[83] Article 21 of the Directive 2001/18/EC.
[84] Supra note 78, p. 314.
[85] Article 33 of the Directive 2001/18/EC.

Directive does not include any provisions regarding liability for damaged caused by GMOs.

V. Biosafety Law in selected countries of Latin America

1. Legislation in Colombia

1.1. General overview

The foundation of Colombian environmental law are stipulated by its constitution. Article 8 establishes that "it is the obligation of the State and of persons to protect the cultural and natural wealth of the Nation." Article 95 further establishes that the citizens have a duty to protect the cultural and natural resources of the country and safeguard the conservation of a healthy environment.[86] The However, there is no specific provision related to biosafety.

As mentioned earlier, Colombia is part of the Andean Community, and therefore, has to comply with Decisions 345/93 and 391/96 related to access to genetic resources and certain provisions related to needs to develop biosafety regulations.

The national legislation contain some basic provisions related to biosafety, embodied in the Code of Renewable Natural Resources and Environmental Protection, which was complemented by Law No. 99 of 1993. This law addresses environmental conservation and management in Colombia. Moreover, it creates the Environmental Ministry of Colombia.[87] The Ministry of the Environment regulates the activities regarding to use, management, investigation, import and export of trade in wild plants and animal species. Furthermore, it states that when activities regulated under this law may affect human health, or concerns about animal or plant health,[88]consultations with the Ministry of Health and with the Ministry of Agriculture should be held. It is also the Ministry of Agriculture that is principally responsible for matters related to Biosafety.

1.2 Laws related to Biosafety

On the basis of the Decree No. 1840 of 1994 the Colombian Institute of Agriculture and Livestock (ICA) (forming part of the Ministry of Agriculture) has been granted competence to adopt and enforce legislation in the field of modern biotechnology.

The Decree provides the ICA with the legal competence over the prevention and control of pests, manipulation of genetic material, surveillance over agricultural production, and commercialisation of seeds.

The Resolution No. 3492 of 1998 regulates and creates the procedure for introducing, producing, transportation, use, handling, releasing and marketing GMOs, which are used in agriculture. This resolution is applicable to GM plants that have been deliberately altered by the introduction of genetic material or through the manipulation of its

[86] Article 95 of the Colombian Constitution.
[87] Branes & Rey, supra note No. 18, p. 32.
[88] See more details on the webpage of the Comunidad Andina, which has the legislation of the 5 Member Countries. http://www.comunidadandina.org

genome.[89] Therefore, it does not apply to plants that have been obtained through traditional techniques.

For the commercialisation of seeds, the resolution establishes that GM seeds, plants are other reproductive material intended for planting should be labelled as "Genetically Modified Organisms."

After the placing on the market of a GMO, the person responsible for marketing should monitor the products for at least three years. It must submit a report to the ICA authorities. Likewise, this Resolution enshrines the precautionary principle, as ICA can withdraw materials from the market, even though the materials have been released, without indemnification.

The ICA is entitled to sanction[90] the following acts of non-compliance with provisions of the resolutions:

- Failing to inform ICA, in a timely manner, of any biosafety risk or imminent damage.
- Hiding or altering data, or refusing to provide information.
- Hindering ICA´s measures to carry out, in a timely manner, inspection of the greenhouse and field tests, storage sites, packing facilities and means of transport.
- Failure to comply with the provisions of the Regulations.

In 1998, ICA created the National Technical Council (CTN) for the introduction, production, release and marketing of GMOs used in agriculture. The Council is a consultative body and it consists of the representatives of various governmental institutions, as well as agriculture producers associations.

2. Legislation in Brazil

2.1. General overview

Brazil is characterised as a country with the highest level of endemic plants and biodiversity in the world, which are distributed in 8,5 million Km^2. The protection of this megabiodiversity is a high priority for the country.

2.2. Laws related to biosafety

The legal basis for any biosafety regulations in Brazil is set out in article 225 of the Federal Constitution of 1988 and Law No. 8974 of 1995 (Biosafety Law).[91]
The Federal Constitution 1988 addresses biosafety in the Title VII, Chapter V.
Article 225: "Is the duty of public authorities to preserve the diversity and integrity of the genetic heritage of the country and to monitor the entities dedicated to research and

[89] It includes the protoplast fusion only when at least one of the DNA donors is a GMO. Material produced by conventional improvement in which an unreleased parental GMO has been used is also included.
[90] The sanctions includes fines and compensations.
[91] Branes & Rey, Supra note No. 18, p. 18.

manipulation of genetic material, as well as to control the production, marketing and use of techniques, methods and substances that may pose risk to life, to the quality of life and to the environment."

These fundamental principles have been implemented in both federal (Brazil being a Federal States) and state level legislation, Brazil has so far adopted the following federal legislation in the field of biosafety:

1) Biosefty Law No. 8974 of 5 January 1995.
2) Decree No. 1752 of 1995.
3) Provisional Legislative Measure No. 2137 of 2000.

It is in order to develop the constitutional principles that law No. 8974 of 5 January 1995 was enacted. Its specific aim is to regulate the use of GM techniques and the release of GMOs into the environment.[92] This law focuses mainly on the development, manipulation, transportation, marketing, consumption, release and disposal of GMOs[93], and means of genetic engineering.[94]

Article 7 states that: "The responsibilities of the inspection agencies of the Ministry of Health, of the Ministry of Agriculture and Supply, and of the Ministry of the Environment, Water Resources and the Legal Amazon are the following:

- The control and inspection of all activities and projects related to GMOs.
- The granting of an authorisation for the operation of laboratories, institutions or companies carrying out activities related to GMOs.
- The issuance of registrations for the products containing GMOs or derived from GMOs which are to be marketed for the human, plant use or release into the environment.
- The maintenance of a register of all institutions and professionals carrying out activities and projects related to GMOs in the national territory.
- The submission to the National Technical Commission on Biosafety (CTNBio), for its technical opinion, of all procedures related to projects considered by the agency.

These functions also involve the participation of the Ministry of Science and Technology, through the CTNBio, which sets out administrative requirements, such as registration of the products that contain GMOs or products derived from them; authorisation for the operation of entities that conduct GMO activities and granting permits for the imports of GMOs or GMO products.[95]

Law No. 8974 of 5 January 1995 has been implemented by Decree No. 1752 of 1995, which creating the CTNBio and sets out its competence. However, this Decree was

[92] Brañes & Rey, supra note 18, p. 19.
[93] According to the law, GMO is an organism whose genetic material (DNA/RNA) has been modified by any technique of genetic engineering. The genetic engineering is the activity of manipulating recombinant DNA/RNA molecules.
[94] Article 1 of law 8974 of 1995.
[95] Ibid. Supra note No. 18, p. 21.

highly criticised because creating the Commission through a Decree and not through a Law. The Decree was subsequently amended by the Provisional Legislative Measure No. 2137 of 2000. Due to the problems of constitutionality of the legislative technique applied, the lawfulness, as well as the effective enforcement of these biosafety regulations may be questioned.[96]

2.3. The Scope of application of the Laws

The Brazilian Law on Biosafety addresses the subjects related to genetic engineering techniques as well as the release of GMOs into the environment. The law defines a GMO as an organism whose genetic material has been modified by any technique of genetic engineering.[97] Furthermore, it defines genetic engineering as the activity of manipulating recombinant DNA/RNA molecules. The law does not consider GMO organisms arising from techniques that imply the direct introduction, into an organism, of hereditary material, when this does not involve the use of recombinant DNA/RNA molecules or GMO, such as: in vitro insemination, conjugation, transduction, transformation, polypoid induction and any other natural process.[98] Moreover, the law excludes from its scope the GMOS obtained from the following technique, as long as they do not imply the use of a GMO as a receptor or donor:

- Mutagenesis.
- The formation and use of somatic cells from an animal hybridome.
- Cell fusion, including that of protoplasm, of plant cells, which can be produced by means of traditional culture techniques.
- The self-cloning of non-pathogenic organisms when processed in a natural fashion.

In order to protect the life and health of humans, animals, plants and the environment, this law sets the standards for the development, cultivation, manipulation, transportation, marketing, consumption, release and disposal of GMOs.

2.4. Consultative Bodies

The CTNBio is part of the Executive Secretariat of the Ministry of Science and Technology. CTNBio[99] is a consultative body for the Federal government and its main objective is to propose and implement the National Biosafety Policy. CTNBio being a part of the Ministry of Science and Technology is an aspect which contrasts with other

[96] In compliance with Article 62 of the Federal Constitution of Brazil the Provisional Measures have the power of a law and it is sanction by the President of Brazil only in the cases of national urgency. However, in the event that the Congress is on recess the President has the power to call for extraordinary sessions within five days, in order to pass this provisional legislative measure. Moreover, this measure has a limited time of thirty days in which it has to be transformed into a law.

[97] Article 3(IV) of the Biosafety Law No.8974 of 5 January 1995.

[98] Article 3(V) of the Biosafety Law No. 8974 of 5 January 1995.

[99] The Commission is constituted by 36 members in the field of: experts on human, animal, plants and environmental biotechnology, representatives from the ministries of health, agriculture supply, environment and water resources, foreign relations, and education; representatives of the workers´health agency, consumer defence agency and business sector.

legislation in Latin America, where the issue of biosafety is usually the responsibility of the Ministry or Agency for Agriculture.[100]

The Commission has the responsibility to monitor the development and technical and scientific progress of biosafety and related areas, aimed at the safety of consumers and the population in general. It classifies GMOs according to their degree of risk[101]; establishes operating mechanisms for the Internal Biosafety Commission to monitor the development of technical and scientific progress of biosafety and related areas. It requires an environmental impact assessment and risk analysis for projects and applications involving the release of GMO into the environment.[102]

2.5. Inspection Agencies

Article 7 of the Brazilian Biosafety Law states that "the responsibilities of the inspection agencies of the Ministry of Health, Ministry of Agriculture and Supply, Ministry of Environment, Water and the Legal Amazon, within their respective jurisdiction have to take into considering the final technical opinion of the CTNBio." [103] This article means that the authorities have to take into account the technical opinion of the CTNBio at the time of authorising a release of GMO into the environment.

There are three administrative procedures, which are carried out by these agencies mentioned above:

- The issuance of registrations for products containing GMOs or derived from GMOs which are to be marketed for human, animal or plant use or for release into the environment.
- Granting the authorisation for the operation of laboratories, institutions or companies carrying out activities related to GMOs.
- The issuance of authorisation for the entry into the country of GMO, of any product containing GMOs or derived from GMOs.

2.6. Certificate on Quality in Biosafety

The CTNBio has the responsibility to issue, upon request of the applicant, a Biosafety Quality Certificate (BQC), referring to installations devoted to any project involving GMOs or derivates.

The CTNBio issues the certificate to public and private, foreign or international institutions, which finances or sponsors activities such as scientific research, technological development and industrial production involving GMOs in Brazil. Therefore, these institutions shall assure themselves of the technical and scientific competence and full compliance of the body to be financed, sponsored or contracted.

---

[100] Branes & Rey, supra note 18, p. 23.
[101] The Law on Biosafety establishes a classification of genetically modified organisms, in accordance with their degree of risk. Group II includes all of these organisms that present a major degree of threat or risk, and for that reason are not included on Group I.
[102] Valle, S. "Biosafety Regulation in Biotechnology, Brazilian Biosafety Law." (1996) p. 28.
[103] Article 7 of the Biosafety Law of Brazil.

2.7. Internal Commission

Article 10 of the Law creates the Internal Biosafety Commissions (CIBio)[104] it means that every institution that conducts activities related to the genetic engineering activities has to have an CIBio with the responsibilities of maintaining the employees informed when they may be affected by the activity; submission to the CTNBio of documents; maintaining individual progress reports for each activity or project involving GMOs and Investigation in the occurrence of an accident. Three specialists on the field of biotechnology form this CIBio.[105] In each institution there is a chief researcher or chief technician responsible for each project.

2.8. Regulatory Process

Any application related to GMOs or derivatives, including registration of products shall be submitted to the CTNBio. Therefore, CTNBio establishes a Specific Sectoral Committee to provide technical support from the inspection agencies, in order to analyse the application. This sectoral commission is in charge of writing up conclusive opinions about the GMOs, which will be forwarded to the competent authority. After this review, the Specific Sectoral Committees will return the case to the CTNBio, which will inform the interested Party whether the application has been accepted or rejected. If it is rejected the petitioner can challenge the decision as established by administrative procedures.

2.9. Sanctions

The Law argues that all acts against its objective, as well as the disobeyance of norms made by the competent administrative agencies or authorities, constitutes an offence. Moreover, the law authorises CTNBio to set the fines which will be applied by the inspection agencies, and is proportionate to the potential direct or indirect damages. In addition, the following activities are considered crimes therefore sanctioned with penalties of twenty years imprisonment in the case of the release of GMOs:

- Genetic manipulation of human germ cells;
- The in vivo intervention in the genetic material, except for the cases in which such intervention constitutes a significant advance in scientific research and in technological development, in obeyance with ethical principles such as the principle of autonomy and subject to the previous approval of the CNTBio;
- The release or disposal into the environment of GMO other than in conformity with the standards set by CTNBio.[106]

[104] The CIBio is responsible for maintaining the employees, any person and the community informed when they may be affected by the activity, with regards to all issues related to health and safety, as well as related procedures in the event of accidents. It establishes prevention and inspection programs to assure the operation facilities under their responsibility, within the rules and standards of biosafety. Moreover, submits information to CTNBio regarding the documents to be listed in the legislation. It maintains individual progress reports for each activity or project that is underway involving GMOs.

[105] Branes & Rey supra note 18, p 25.

[106] Article 13 of the Brazilian Biosafety Law.

2.10. Access to public information

Access of the public to biosafety information is provided through the WebPages of the Brazilian Commission CTNBio which provides information about the companies which have been granted authorisations.

2.11. Labelling and traceability

In light of Cartagena Protocol, even though Brazil is not yet a Party to it, Brazil has enacted the Decree No. 3,287 of 2001 relating to the labelling and packaging of GMOs placed on the market or in products thereof. Furthermore, when the adventitious traces with a maximum level of 4%, i.e. in the case that the product contains different GMO ingredients the permissible level is up to 4% in each product. This Decree is focused on food products for human consumption.

Brazil has up until now prohibited, the production, importation and commercialisation of GMO within its territory. However, clandestine production and harvesting of GMO soya is taking place especially in the Sates of the south of Brazil.[107]

3. The legislation in Argentina

3.1. General Overview

Argentina is a very interesting case study, as being one of the largest producers of transgenic crops in the world. Its transgenic crops vary from soybeans, maize, sunflower, to tomatoes, rape, sugar and cotton. Moreover, it has developed biotechnologies of its own.

Argentina is a Federal State divided into provinces, consequently there is federal and provincial legislation. Regarding, the preservation of the biodiversty is a constitutional duty of authorities to safeguard the natural environment from the biological risks to which it is exposed as enshrine in 1994 Constitution.[108] Article 41 of the National Constitution provides that "is the duty of the Nation to issue regulations that contain minimum budgets for protection, and the duty of the provinces to issue any necessary regulations to supplement them, without the national regulations altering jurisdictions."

Whereas other countries in the region have enacted an specific law on biosafety, Argentina has not get done so, it is also special case considering that agriculture is the most important sector of the economy and one of the largest producer of GMOs. It has new guidelines regarding to modern biotechnology, which have arisen in response to the inquiries of the companies for authorisation for activities related to GMOs.[109] At the moment there are also three legislative proposals that are at the level of discussion in the National Congress of Argentina. One is a draft national biosafety law, the second is on risk assessment and the third labelling issues.

[107] For more information see the Decree No. 3871 of 2001 at the webpage http://www.agrodigital.com. "Brasil regula etiquetado de los OGM a pesar de estar prohibida su venta."
[108] Branes and Rey, supra note 18, p. 14.
[109] Brañes and Rey, supra note 18, p. 15.

Biosafety system has been established since 1991, due to the fact that United States multinational companies were interested in establishing branches offices with the view to performing "off- season trials". In addition, Argentina's strongest economic sector is agriculture and the use of new technologies will increase production.

3.2. Scope of applications of laws

According to the Resolution No.289 of 1997 a genetically modified organism[110] is considered "any organism with genes or other genetic material that have been modified through the following techniques:

- The insertion by any method of a virus, bacterial plasma or other vector system of nucleid acid molecule, which has been produced by any method outside this virus, bacterial plasma or other vector system, in order to produce a new combination of genetic material which is capable of being inserted in an organism in which this combination does not occur naturally and within which it will be inheritable genetic material.
- The insertion in an organism, by micro-injection, micro-encapsulation or other direct means, of inheritable genetic material prepared outside this organism.
- Use of recombinant DNA molecules in *in vitro* fertilisation that involves the genetic transformation of eukaryotic cell.

3.3. Advisory and regulatory agencies

Argentina's system on Biosafety takes into account five agencies for the development and the surveillance of GMOs.

- The National Advisory Commission on Agricultural Biotechnology (CONABIA). It was established as a consultative and technical support body, in order to evaluate the potential environmental impacts of GMOs. It makes recommendations to the Secretariat of Agriculture, Livestock, Fisheries and Food (SAGPyA) regarding the issue of permits for the field trials, flexibility[111]and commercialisation.[112] In other words, the Commission evaluates the information, and thereafter makes a report for the SAGPyA concerning the approval or rejection of a permit. CONABIA has also certain operational functions such as to deal with the applications for laboratory and greenhouse testing, field trials, flexibilisation[113] conditions.

[110] Argentina considera y define como Organismo Genéticamente Modificado a aquel organismo en el que cualquiera de sus genes u otro material genético ha sido modificado por medio de las técnicas siguientes: . la inserción por cualquier método de un virus, del plasma bacteriano u otro sistema vector de una molécula de ácido nucleico, que ha sido producido por cualquier método fuera de ese virus, plasma bacteriano u otro sistema vector, de manera tal de producir una combinación nueva de material genético el cual es capaz de ser insertado en un organismo en el que esa combinación no ocurra naturalmente y dentro del cual será material genético heredable; la inserción en un organismo, por microinyección, macroinyección, microencapsulación u otros medios directos, de material genético heredable preparado fuera de ese organismo; donde se involucre el uso de moléculas de ADN recombinante en fertilización in vitro que implique la transformación genética de una célula eucariótica.

[111] See Infra note 122.

[112] Burachik, M. & P Traynor, Analysis of a National Biosafety System: Regulatory Policies and Procedures in Argentina. ISNAR country report 63 (2002) p. 12.

[113] See Infra note 122.

Moreover, the Commission drafts regulations concerning activities related to GMO.

- The National Agrifood Health and Quality Service (SENASA) is an agency inside SAGPyA with the competence to regulate food safety and quality, animal products and pesticides.[114] This authority is legally entitled to propose legislation in the field of food and GMO derived food.
- The National Institute of Seeds (INASE) is the agency in charge of registering and controlling marketable seeds. It also monitors the tests.
- National Commission on Biotechnology and Health (CONByS): the main objective of this commission is to produce documents with regulatory frameworks related to the preparation and approval of biotechnological products for human consumption.[115]

3.4. Regulatory Process

According to Hervé "Argentina on the one hand, regulates the product as a whole, i.e. not the process that made the product; on the other hand, it requires risk assessment on a case by case basis."[116]

Argentina biosafety system allows licenses for experimentation and/or release into the environment in four instances:

- Greenhouse research with transgenic plants.
- Environmental release of plants and microbes for field tests and unconfined plantings.
- Food safety.
- The handling and confined release of transgenic animals.

3.4.1. Review and approval process

The process for commercial release of GM crops encompasses three steps: analysis of the environmental risk assessment by CONABIA, food-safety assessment by SENASA and market evaluation performed by the Directorate of Agri-Food Marketing (DNMA).

First of all, field-test applications[117] are received by INASE, then forwarded to CONABIA for the assessment. If some information is missing or inadequate, the applicant will be requested to complete or correct the information. When all the CONABIA members are satisfied that they have sufficient knowledge of the application,

[114] Ibid. Burachik and Traynor, supra note 112, p. 14.

[115] Hervé, D. "Estudio de Derecho Comparado caso: Argentina" Universidad de Chile, Centro de Derecho Ambiental." (2002) p. 22. For details see: http://www.derecho.uchile.cl/cda/investigacion

[116] As mentioned above, according to Hervé this characteristic of the Argentine legislation is without prejudice of a separate regulation related the transformation release, field trials and commercialisation of GMOs.

[117] In order to apply for formal authorisation the applicant must submit certain information such as: summary of the general information; general information regarding the release of GMO; if the material is imported (permit, granting institution, type of permit granted); objective of the release; transport of GMO; characteristics of the introduction into the country of the GMO; characteristics of the release; description of the GMO (e.g. donor, principal gene, marker and/or selector gene, recipient organism, vector or vector agent and organism or product; detailed description of biosafety measures for preventing the contamination or release.

a decision is taken approval or rejection. Once the application has been approved by Commision, it sends the application file with a letter of recommendation to the SAGPyA for approval. Within the letter it is specified that there is no environmental risk involved in the release.

Licences may contain certain conditions. The CONABIA and SAGPyA monitor compliance with these conditions.[118] These conditions are inter alia, to inform CONABIA in advance (through INASE) of the times at which the timetable of activities will be completed (introduction, sowing, flowering, harvest, completion of the trial and all treatments proposed). In order to prevent accidental releases, the GMO must be handled according to risk management guidelines set out by the Commission; it must comply with the regulations concerning plant health in order to prevent the dissemination of plant diseases. Furthermore, access must be provided to the inspectors appointed by the competent authority to accomplish periodical inspections.[119] In regards to confidential information, the applicant when filling out the Form or the additional information must mark it with the abbreviation (CID: Confidential Information Deleted). This indicates that the applicant wishes to protect certain commercial information, therefore. As a consequence, the competent authority will only forward this information to the groups of experts on this field, who will study it but will not disclose any information.

The application is completed, it is submitted to the Members of CONABIA. After, a review of the application by the full Commission, a letter of approval is sent to the applicant, generally stating additional requirements for ensuring biosafety. The applicant must acknowledge the receipt of the letter and must comply with its requirements.

3.4.2. Flexibilisation License.

After a GMO plant has been field tested, the applicant may request that the crop be flexibilised.[120] It can be said that this flexibilisation[121] does not mean approval for commercial release within Argentina. It pre-empts unconfined use.[122] Furthermore, CONABIA´s risk assessment for flexibilisation evaluates the GMO´s outcrossing potential, weedines potential or its capacity to survive, potential for horizontal transfer of gene exchange, nature of products of introduce sequences, pathogenicity to other organisms, potential harmful effects on humans including allergenicity, and potential effect on rate of resistance development in pest populations.[123]Moreover, the petitioners

[118] Annex I, Part D of the Resolution No. 289/97.
[119] For more details, see the WebPages of the SAGyP has details about the information required. http:www.sagyp.mecon.gov.ar
[120] The flexibilisation is authorised through the Resolution No.131/98 of the SAGPyA.
[121] Flexibilisation is once a plant GMO has been sufficiently tested, the applicant may request that the crop be "flexibilised" that is, be approved for unconfined use. However, flexibilisation does not constitute approval for commercial release within Argentina. It only entails unconfined use usually for large-scale planting.
[122] Burachik and Traynor, supra note 112, p. 24.
[123] Burachik & Taylor, supra note 112, p. 24.

must take into account some food-related issues when applying flexibilisation, for instance, equivalence, safety, composition and food characteristics.[124]

It is worthwhile mentioning that after the crop has passed environmental and food-safety studies and the license for flexibilisation has been granted, isolation distances or other means of confinement are no longer needed.

3.4.3. Food-safety review

SENASA is in charge of the protection of human health from the products derived from biotechnology. The technical advisory committee evaluates food-safety issues in GMO foods and feeds.[125] This committee forwards its comments and observations to SENASA. Moreover, SENASA it the competent authority for granting or rejecting the approval for commercialisation.

3.4.4. Market Analysis

The DNMA reviews the market potential and takes into account the benefits and disadvantages of approving the crop. DNMA makes a technical report, in where it is assess the impact of GMO´s commercialisation on Argentina´s international trade. It also includes which GMO varieties seeds companies sold to Argentine farmers. This report thereafter, is forward to CONABIA, SENASA, in order to be reviewed and then proceed to grant approval for commercial use of GMO.

3.5. Monitoring and Reporting

The inspector from INASE or SENASE are responsible for the inspections of the field trials. The inspection report is submitted to CONABIA, in order to monitor that the licensee is complying with the law and the requirements set out by CONABIA.

4. Framework proposal on Venezuela

Two Latin America countries (Panama and Venezuela) are presently considering draft regulations for biosafety. These proposals are being discussed by the parliament of the country concerned and therefore are subject to changes.

4.1. General Overview

Venezuela has ratified the Protocol of Cartagena on 13 May 2002 being the 19th State to ratify it. Venezuela is currently discussing the draft of law related to the register, control and monitoring of the GMOs, derivatives and products.[126]

---

[124] Ibid, supra note 112, p. 25.

[125] The Annex II of the Resolution 511/98 set outs the basic analysis of GM food, for instance, natural toxins, new forms of toxins, sequence, homology of the newly expressed proteins with known allergens and toxic proteins, nutritional changes resulting of the genetic modification, nutritional changes and characterisation with regard to safety for human and animal health.

[126] For more details see the WebPages of the Ministry of Environment and Natural Resources of Venezuela, which is the national competent authority, related to GMO. http://www.marnr.gov.ve/

4.2. The scope of the application of the regulation

The goal of the draft law is to govern the activities related to GMOs or their products, in order to avoid adverse effects on human health and the environment. Moreover, it regulates the activities concerning the assessment, importation, exportation, deliberate release into the environment, consumption, contained use, production, storage and distribution of GMOs or their products. It excludes from the scope of the law the organisms arising from traditional breeding techniques, i.e., the techniques that imply direct introduction, into an organism of hereditary material, when this does not involve techniques as in vitro, recombinant molecules of DNA/RNA, or cell fusion.

A GMO is defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."[127] Moreover, it defines living organism as "any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids."

4.4. National Competent Authority

Article 5 of the proposal designates the Ministry of the Environment and Natural Resources through its Office of National Biodiversity, as the competent authority for the control and monitoring of the GMOs, derivatives or products.

The Ministry of Environment and Natural Resources has the responsibility to comply with the provisions of the CBD and the Cartagena Protocol. It has to co-ordinate with other competent authorities. It must also maintain a register of all institutions and professionals carrying out activities and projects related to GMOs and approve or reject applications for carrying out activities related to GMOs.

4.5. Inspection Agencies

According to this regulation the Ministry of the Environment and Natural Resources has been vested with the power to control and monitor all activities related to GMOs. However, it must co-ordinate with other competent authorities on their own field.

4.6. Consultative Bodies

The National Commission on Biosafety (CNBio) is established under this regulation as a consultative body with scientific and technical expertise. The CNBio is the advisor of the Ministry of the Environment and Natural Resources. Five representatives of the Ministries active in this field constitute the Commission together with representatives of the consumer, agricultural, academic, industrial and NGO sectors.[128]
CNBio has the obligation to make recommendations to competent national authority regarding the adoption of regulations on GMOs, derivatives or products. One of the most important responsibilities is to evaluate the applications for activities or projects involving GMOs and make a technical report on each application. CNBio may require additional documentation, if it deems it necessary for the evaluation of the application.

[127] Article 4 of the proposed regulation of Venezuela.
[128] Article 8 of the project of regulation.

4.7. Regulatory Process

The first step is that any legal entity or individual, who intends to conduct any of the activities described in the draft law, must submit an application to the national competent authority. Within four months after the receipt of its applications, the national authority has to make a decision either accepting or rejecting the inquiry.
Second, the competent national authority verifies the documentation in the application. It forwards it to the CNBio for an evaluation.
Third, the legal entity or individual, after five working days of submitting the application to the competent national authority, must publish of its application in two national newspapers.
Fourth, after the publication, any persons or legal entity may present written objections or comments to the national competent authority about the planned activities related to GMOs.
Fifth, the CNBio must forward to the competent national authority its technical report. This technical report must contain information related to the possible risks of the activity, the classification of the risk, the conditions in which the GMO must be handled and the possible socio-economic impacts of the use of GMOs.
Sixth, the competent national authority will grant the approval or reject the inquiry through an administrative decision. In the case of authorisation, the decision will be published in the Gaceta Oficial (Official Gazette).
Seventh, in the case of rejection, the legal entity or individuals have the right to challenge that administrative decision, according to the procedure established under the Administrative Law.

4.8. Confidential Information

The proposed regulation has a special chapter related to confidential information. It stipulates that the applicants may submit an application to the national competent authority, requiring confidential treatment of certain technological information. The competent authority forwards the petition to the CNBio, who will analyse it and may authorise or reject confidential treatment of the information concerned.

4.9. Monitoring

Monitoring under this regulation will be the responsibility of the competent agencies in its field, for instance: the Ministry of Environment and Natural Resources, Ministry of Health, Ministry of Agriculture, Ministry of Commerce and the Ministry of Science and Technology. Therefore, they will carry out inspections in the places where projects and activities related to GMOs are taking place.

4.10. Sanctions

The non-compliance will be sanctioned according to relevant provisions of environmental law, health law or the phytosanitary law, without prejudice to e.g. criminal law.

4.11. Labelling.

Every GMO, derivatives, or as in products should have clearly visible label with the words “genetically modified organisms” printed on it.

5. Framework proposals on Biosafety Law in Panama

5.1. General Overview

Due to the fact that Panama has ratified the Cartagena Protocol 1 of May 2002, it is committed to internalise the protocol provisions into national legislation, in order to implement it. There are presently three instruments on LMOs[129] before the National Assembly for discussion. One is a draft law, the two others are drafts of decrees related.

5.2. The scope of the application of the laws

Among the three proposed texts the draft Decree of the Ministry of Agriculture is the most important since it regulates the uses of LMOs. The other two draft texts are complementary to the Decree: the draft law creates the National Commission on Biosafety and the Decree establishes the monitoring system.

The scope of the Decree is to regulate the importation, exportation, transport, transit, production, release, commercialisation, assessment, use, handling, and control of the LMOs, derivatives or as an products for the agricultural sector. The regulation applies to LMOs used in the agricultural sector and for environmental purposes. Moreover, includes protoplasm only when one of the donors of DNA is a LMO.[130] It also covers the produced by traditional techniques when the parental is a LMO that has not been released.[131] This draft Decree excludes plants and animals obtained through traditional breeding techniques.

The definition of the LMO according to this proposal is "an organism whose genetic material has been modified through the use of modern biotechnology."[132]

5.3. National Competent Authority

The national competent authority is the environment agency in Panama (ANAM), without prejudice from the provisions that the Ministry of Agriculture and Health may establish according to their legal competence. However, any individual or legal entity that wishes to develop activities related to GMOs must register with the national competent authority.

5.4. Consultative Body

The draft law creates a consultative body called the Intersectoral National Commission on Biosafety (Comisión Nacional Intersectorial de Bioseguridad). This Commission is created with the view to establishing and proposing policies on biosafety, taking into account the protection of human health, animals, plants and the environment.[133] Four

[129] The draft legislation refers to LMO as it is stipulated on the Cartagena Protocol.

[130] La presente propuesta aplica a OVMs (LMOs) para uso agropecuario y ambiental. Se incluye fusión de protoplastos, solamente cuando al menos uno de los donantes de ADN sea OVM. También se incluye material producido por mejoramiento convencional en donde se haya utilizado algún parental OVM, no liberado.

[131] Article 3 of the proposed Decree.

[132] Organismo Vivo Modificado Genéticamente por Biotecnología es un organismos cuyo material genético (AND/ARN) ha sido alterado por técnicas de ingeniería genética.

[133] Article 1 of the proposed Law.

Ministries, the Science and Technology Secretariat, ANAM and representatives from the academic, agricultural sector and NGO sector constitute it.
This draft law clearly defines the competence of each governmental institution, with a view to avoiding overlaps between the institutions. For instance, the Ministry of Agriculture is the competent authority in the field of agriculture, therefore it has legislative power to make regulations and guidelines related to LMOs in the area of agriculture. The Ministry of Health is in charge of making legislation related to the health aspects of LMOs. The Ministry of Commerce is the entity in charge of the co-ordination of the commercial policies regarding Panama commercial transactions. The Ministry of Foreign Affairs co-ordinates the adoption of international instruments related to LMOs. Moreover, ANAM, which as mentioned earlier is the national competent authority, is in charge of technical co-operation between the different governmental authorities.
The main responsibilities of the Commission are as follows:

- Make proposals to the President of the Republic regarding National Biosafety Policies.
- Co-ordinate with other institutions, entities or individuals that have activities related to LMOs.
- Approve or reject authorisations on imports, exports, productions, storage and release of LMOs.

5.5. Procedures

First, any legal entity or individuals, who wishes to develop activities related to LMOs or derivatives has to submit an application to the National Directorate for Natural Heritage (Dirección Nacional de Patrimonio Natural) of the national competent authority or to the office that the Ministry of Agriculture will designate for this purpose.
Second, within thirty working days after the receipt of the application, the authority has to take a decision. However, the competent authority may ask for further information be provided within a period of sixty working days.
Third, the competent authority has to evaluate the potential risks. Thereafter, it has to prepare a report that will be forwarded to the Commission. The Commission has forty-five working days for comments and observations.
Fourth, the competent authority, after receiving the comments and observations, shall decide whether the applicant may proceed or not. The applicant can proceed only after receiving the written consent of the competent authority. When the authorisation is granted, the legal entity or individual shall ensure monitoring and reporting to the competent authority every year for a period of three years after the release of the LMOs.[134]

5.6. Confidential Information

Some articles of the Decree relate to the confidentiality of information. The competent authority, as required by the applicant, may agree to treat some information as confidential.

[134] Article 19 of the proposed Decree.

5.7. Control and Monitoring

The competent authorities will delegate the functions of controlling and monitoring to their inspectors. The inspectors of the national competent authority may to collect the information needed to fulfil their functions, as well as taking samples.

Moreover, this Decree enshrines the precautionary principle when it alleges that for biosafety or precautionary principles the competent authorities may prohibit or restrict the use or/and sale without imdemisation, on the grounds for considering that may constitute risks to the human health and environment.

5.8. Sanctions

For the purpose of this draft Decree, all acts or omissions that constitute non-compliance with its provisions are subject to sanctions under the administrative law.

5.9. Labelling

A proposed label and proposed packaging must be submitted to the competent authority with the application.

VI. Common elements of the legislation in selected countries of Latin America

1. General Overview

The legislation of Latin America normally is based on National Constitutions, which set out the basic principles that will need to be adhered to and by the developed by statuatory law. The right to a healthy or sound environment in some form enshrined in the Constitution of all these States.

The countries of Latin America that have been studied have been selected either on the basis of their high biodiversity or for being GMO producers, or for having biosafety regulatory frameworks in preparation. The European Union legislation on Biosafety has been reviewed as one of the most innovative legislation in this field.

2. Common elements of these frameworks

2.1. Objectives

As exemplified in the previous sections, the main objective of all the national biosafety frameworks[135] studied is to ensure the safe use of GMO and at the same protecting human health and the environment.

2.2. Scope and coverage of regulation

The definition of GMO in the national frameworks is very similar. Some countries such as Venezuela, have the same definition as the Cartagena Protocol. All of the countries exclude from the scope of the application of the regulations organisms obtained through traditional breeding techniques. Some legislation like Brazil, Panama and Venezuela, do not only cover GMO themselves but also cover products and derivatives. Moreover, the national frameworks usually subject to a wide range of activities such as import, export, production, commercialisation, handling, use and transport, Argentina has a more refined approach probably because of being one of the largest exporters of GMOs in the world: Argentine has differentiated regulation in relation to intended use, i.e. the experimental activities, field testing, large-scale releases and marketing. Each type of activity needs a different kind of authorisation.

2.3. Legislative Instruments

The countries analysed have shown that each country has a different hierarchy of legal instruments dealing with biosafety. For instance, Brazil has a biosafety law and Venezuela a draft law. Colombia has adopted regulations on biosafety through decrees and resolutions. Panama has a draft law and two draft decrees. Argentina has regulated the biosafety merely through guidelines.

[135] For the purpose of this article national biosafety frameworks includes binding and non-binding measures, including laws, decrees, regulations, guidelines and proposals of regulations.

2.4. Institutional Arrangements

The national biosafety frameworks analysed designate one or more competent authorities[136] with the responsibility to oversee the regulatory process and decision-making and authorisations. The countries commonly designate the Ministry of Agriculture, or the Ministry of Environment or the Ministry of Science and Technology, as the national competent authority. However, in the case of Brazil these responsibilities falls on the National Technical Commission on Biosafety under the Ministry of Science of Technology. Moreover, in the case of Panama, the agency varies depending on the use of the GMO. Therefore, Panama has a product-based approach. It is our opinion that this approach may raise conflict of competence among the different agencies or ministries, if co-operation and co-ordination among these institutions is not well established. Co-operation and consultation between the various institutions involved is key element to the functioning of such an institutional arrangement.

The designation of an advisory body is also usual, which is constituted as a multidisciplinary composed of representative of sectoral governmental agencies or ministries, and of experts in the field of biotechnology and GMOs. These advisory bodies have usually the responsibility of reviewing and analysing the documentation presented by a permit applicant, in order to make recommendations to the competent national authority regarding approval or rejection. As mentioned earlier, the case of Brazil is different in much as it entrusts or advisory functions to CTNBio, which is also the national competent authority.

Furthermore, the biosafety frameworks of Venezuela, Panama and Brazil establishes Institutional Biosafety Committees[137] with the main responsibility of reporting to the national competent authority on activities related to contained use of GMOs in research in public or private research institutions.

2.5. Public Consultation

All of the national frameworks studied include provisions related to information to the national public. The draft proposal of legislation on Venezuela, for example, requires that the applicants must publish a summary of information related to GMO in two national newspapers,. In Brazil the summary of the application is published in the Official Daily Federal Register. These provisions are for allowing a period of time for public comments. Brazil has developed and created a website in order to inform the public about the permits related to GMOs and the names of the companies to which authorisations have been granted.

2.6. Regulatory process

As a general rules, the national frameworks establish prohibitions regarding activities related to GMO without an authorisation or in contravention of its conditions. They

[136] The competent authorities vary from country to country; it could be Ministries, agencies or government departments.

[137] These frameworks in discussion have provisions related the creation of an Institutional Biosafety Committees, which are responsible for ensuring that activities are conducted in a safe manner.

firmly establish that permission is a pre-requisite to carrying out any activity related to GMO.

2.6.1. Requirements

Most of the national frameworks require a risk assessment as a part of the information that must be submitted by the applicant. It should be noted that Brazil requires risk assessment as well as Environmental Impact Assessment if the CTNBio considers it necessary.[138] The Panamanian draft legislation on biosafety only establishes a risk assessment requirement for GMO used in the agricultural sector. On a basis of case-by-case.

After analysing the information provided including risk assessment data, the national competent authority makes a decision on the application. The inquiry may be approved, rejected or approved subject to certain conditions. The Argentine legislation subjects a priori the authorisation to some conditions to be fulfilled; for instance, how experiments should be conducted and what kind of inspection is deemed necessary.[139]
All the national frameworks studied allows the national competent authority to request additional information.

2.6.2. Risk Assessment

Most all national legislations reviewed have provisions related to risk assessment for every activity on a case by case basis, based on information provided in the notification and other available scientific evidence. The aim is to evaluate the possible adverse effects of the LMOs on the environment and human health. Moreover, in the case of Brazil the national competent authority requires the risk assessment and may require if its necessary the environmental impact assessment. Argentina´s national competent authority requires the risk assessment for flexibilisation of GMOs in addition to the risk assessment.

2.6.3. Labelling

Mostly all the national legislation studied have provisions related to the labelling of GMOs, some legislation also covers products and it derivatives. Brazil threshold for labelling is a level of 4% of GMO into food. Argentine has no requirement related to labelling of GM foods. It is our opinion, labelling on GM food should be strongly recommended, in order to give freedom of choice to the consumer.

2.7. Inspection and enforcement

The national frameworks on biosafety which has been reviewed vest the national competent authorities powers to control and monitored all activities related to GMOs. To have an effective national biosafety frameworks enforcement is key issue, which is done through the inspections of all activities and projects related to GMOs; e.g. samples, supervision and control of the activities authorised. Moreover, some of the frameworks analysed apply the precautionary principle to define cases when the national competent authority may restrict or prohibit the use and/or sale of GMOs.

---

[138] Durán, V. "Estudio de Derecho Comparado Caso Brasil" Universidad de Chile, Centro de Derecho Ambiental (2002) p. 20. http://www.derecho.uchile/cda/investigación
[139] Ibid, Durán, supra note 137, p. 21.

2.8. Sanctions and Penalties

Some of the national frameworks analysed have provisions related to non-compliance which vary from cases of hiding and altering data, hindering inspectors to carry out their routinely inspections, to releases of GMO into the environment without holding the authorisation for that activity. Most of the countries sanction or penalise those responsible for non-compliance through the administrative procedure, without prejudice to criminal or civil liability. Brazil has drastic penalties for those who infringe the national biosafety law: some activities are considered as crimes and are penalised with imprisonment to up to twenty (20) years. By contrast, Argentina biosafety framework is based on guidelines, not on legislation. It means that non-compliance is not legally enforceable.[140]

2.9. Liability and Redress

The only national framework studied that contains provisions related to liability and redress is the Brazilian legislation. The law on biosafety declares that those responsible for any damage caused to the environment and to third parties shall provide indemnification or redress whether or not the damage was unintentional or due to lack of due diligence. The other national frameworks do not address the liability nor redress issues.

2.10. Confidential information

The national frameworks of Venezuela, Argentina and Panama have provisions related to confidential information. The applicant may determine that some information regarding the modification techniques should be confidential. However, the national competent authority will assess whether the information is indeed to be considered confidential or not. If it is confidential, then the competent authorities cannot disclose the information to third parties.

2.11. Unintentional releases

All the national frameworks analysed have provisions for dealing with unintentional release of GMOs into the environment. e.g. Argentina requires the applicant to adopt certain procedures in the event of an unintentional release, and the obligation to notify the competent authority about the unintentional release. In Brazil the failure to notify immediately the competent authorities of any accident that may cause dissemination of GMOs is an offence.

2.12. Imports and Exports

All the national frameworks of the studied countries have implemented legislation related to imports and exports of GMOs. On the one hand, Argentina as an export oriented country, has implemented guidelines of both but with special attention to exports of GMO. On the other hand, other countries focused mainly on imports. [141]

[140] Bucharik & Traytor, supra note 112, p. 39.
[141] Ibid supra note 112, p. 5.

VII. Conclusions

The analysis has shown that the success of the Cartagena Protocol depends on the effective implementation of its provisions through the national legal system of the future Parties. A number of developing countries have begun to address these issues and some have initiated legislative regulatory frameworks on biosafety. These frameworks have to adopt national law not only addressing imports of GMOs but also releases, uses, handling and transfers at domestic level.

The purpose of this article was to review and analyse national biosafety frameworks of five countries in Latin-America, taking as basis of this study the European Union legislation as one of the most innovative regulations on biosafety. It can be said that most of the countries studied have similarities on biosafety legislation or plan legislation. However, it differs in detail from country to country, for instance, each country has different acts of law, i.e. different hierarchy for the application of the legislation some through laws, other through the decrees or resolutions. Some countries concentrate their efforts on exports of GMOs, while others are implementing legislation in order to regulate imports.

In planning for the implementation of the Biosafety Protocol, futures Parties should keep in mind that the field of modern biotechnology is in constant evolution, and national legislation in this regard should be conceived in ways which allows rapid responses to this evolution.