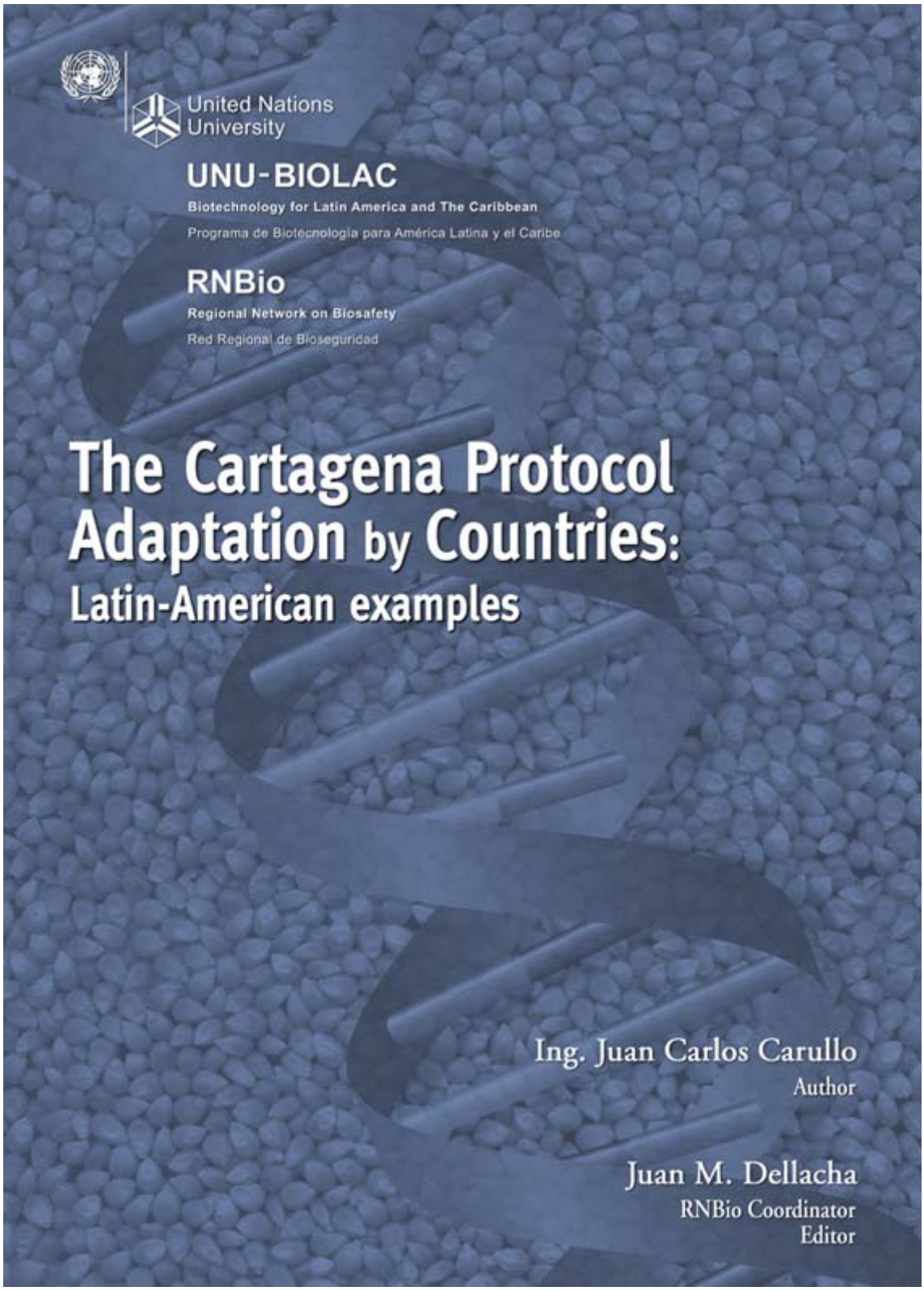
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Latin-American examples
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The Cartagena Protocol Adaptation by Countries: Latin-American examples

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1.- The Cartagena Protocol on Biosafety

1.1 Introduction

The Convention on Biological Diversity (CBD) was signed at the Earth Summit held in Rio de Janeiro in 1992. One of the aims of the Treaty was the conservation of biodiversity on the planet. Research and advancements in the field of biotechnology have been producing a series of important breakthroughs in the obtaining of transgenic organisms which may have enormous implications for the world production of food and raw materials, but at the same time, however, these new techniques could be a potential threat for genetic resources and ecosystems, if there are not constant, systematic and effective control measures.

The Protocol for Biosafety covered in Article 19 paragraph 3 of CBD[1] has been ratified by more than 170 of the 188 member states of the United Nations. The mentioned article called for the parties to look into the need and mechanisms of a Protocol to establish the necessary procedures for transference, handling and use of living modified organisms resulting from biotechnology which may have adverse effect on the conservation and sustainable diversity of biology. The Protocol had to bear in mind the magnitude of the known and potential secondary risks stemming from LMOs, and the fact that many countries, specially those emerging ones, have very limited possibilities to control nature. In the Second Conference of the Parties, held in Jakarta, Indonesia, the initial negotiations to establish this Protocol were begun.

The groups around the meeting table were the European Union [2], countries of Eastern and Central Europe, a Group Sharing the same Opinions from emerging countries and a Commitment Group made up of Japan, Korea, Mexico, New Zealand, Norway, Singapore and Switzerland. Without actually taking part of the Convention, the United States of America has been involved in the negotiations as a member of the Miami Group, a body made up of the main agricultural exporters including Argentina, Australia, Canada, Chile and Uruguay.

After 5 years of negotiations, between January 23rd and 28th 2000, the Protocol of Montreal, Canada was agreed on and signed by more than 130 countries. It was named the Cartagena Protocol on Biosafety to the Convention on Biological Diversity in honour of Colombia, where the First Extraordinary Meeting of the Conference of the Parties was held in 1999. The specific mission of the Protocol is to work towards a guarantee of an acceptable protection level in the sphere of transference, handling and safe use of living modified organisms resulting from modern biotechnology (LMOs) which may produce adverse effects for the conservation and sustainable use of biological diversity, keeping in

[1] State Department of the United States of America, Spokesperson Office. *Protocolo de Cartagena sobre inocuidad biológica*. Washington, 16th of February 2000

[2] Alvarez, P. and Gutiérrez, S. *Protocolo de Bioseguridad. Un repaso de su proceso histórico*. Work presented in the National University of San Martin, Post-graduate School, Doctorate in Environmental Management. Topic: International Environmental Law, Buenos Aires, October 2000

mind the risk to human health. This was to be applied to transboundary movements of LMOs.

The Protocol was opened for signature at the United Nations Offices in Nairobi to States and regional economic integration organizations. As of yet, the Protocol has been signed by more than 100 countries and organizations of regional economic integration. The Protocol will enter into force 90 days after the 50th country has ratified the Document. By May 2002, the Protocol had been ratified by 21 countries and on the 26th of June it was ratified by the Council of the Ministry of the European Union, subject to the necessary ratification by each of the fifteen member countries.

In Latin America and the Caribbean, the following countries have signed the document[3]: Argentina, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Granada, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Trinidad Tobago, Uruguay and Venezuela. Brazil is the only country of the MERCOSUR not to have signed the Protocol. The countries in the region, which have ratified their signatures, are Bolivia, Panama, Trinidad Tobago and Venezuela.

Countries that have ratified the Cartagena Protocol
(May 2002)

1. Trinidad and Tobago	12. Kenya
2. Bulgaria	13. Liberia
3. Norway	14. Switzerland
4. St. Kitts & Nevis	15. Djibouti
5. Fiji	16. Mauritius
6. Lesotho	17. Bolivia
7. Czeck Republic	18. Panama
8. Nauru	19. Venezuela
9. Uganda	20. Botswana
10. The Netherlands	21. Samoa
11. Spain	

Source: CBD Website

1.2 The History of the Cartagena Protocol [4]

Pursuant to Article 19, paragraph 3, of the Convention on Biological Diversity, the Conference of the Parties, by its decision II/5 established an Open-ended Ad-Hoc Working Group on Biosafety to develop a draft protocol on biosafety specifically focused on transboundary movements of any living modified organisms resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

[3]Convention on Biological Diversity. *Firmas y Ratificaciones del Protocolo de Cartagena sobre Bioseguridad.* CBD Website
[4] See CBD Website

The Open-ended Ad-Hoc Working Group on Biosafety held six meetings between July 1996 and February 1999. The Group submitted a draft text of the protocol along with the outstanding concerns of the Parties for consideration by the Conference of the Parties, at its first extraordinary meeting convened for the purpose of adopting a protocol on biosafety to the Convention on Biological Diversity.

In agreement with the decision IV/3, the first extraordinary meeting of the Conference of the Parties was opened on the 22nd of February 1999 in Cartagena, Colombia. The Conference of the Parties was unable to complete its agenda in the time available, so through decision EM-I/1 the Conference of the Parties suspended its first extraordinary meeting and agreed that it should convene again at the earliest possible date and, in any event, no later than the 5th meeting of the Conference of the Parties.

The resumed session took place in Montreal from the 24th to 29th of January 2000, and was preceded by regional and interregional informal consultancy carried out from the 20th to the 23rd at the same venue. On the 29th of January 2000, the Conference of the Parties, by its Decision EM-I/3 adopted the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and approved interim arrangements pending its entry into force.

In Decision EM-I/3 the Conference of the Parties established an Open-ended Ad-Hoc Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) entrusted with the task to undertake, with the support of the Executive Secretary, the preparations necessary for the first meeting of the Parties to the Protocol. The Intergovernmental Committee held its first meeting in Montpellier, France from the 11th to the 15th of December 2000.

1.3 The Precautionary Approach

The use of modern agricultural biotechnology has brought about worldwide debate on contentious aspects. There is general consensus on the need to ensure the safety of the products of biotechnology through an efficient assessment of risks, management and information. However, countries seem to disagree on how these measures should be reflected in public policies and decisions. The systems most used are based on the concepts known as the precautionary approach and substance equivalency.

In 1992, the Conference of the United Nations on Environment and Development adopted Principle 15, which states that "to protect the environment, the preventive approach will be broadly applied by the States depending on the scope. Where there are threats of serious or irreversible damage, the lack of full scientific certainty shall not be used as a reason to postpone economic measures to prevent environmental degradation" A version of this principle was incorporated in the Cartagena Protocol on Biosafety [5], causing notable debate during the negotiation phase with respect to its future interpretation. The issues that arose from the exact meaning, scope, context and application of the principle will continue attracting attention and giving rise to controversy, especially in the crossover between those criteria used in international commerce and those upheld by environmentalists.

[5] Centre of International Development, Harvard University. *Conferencia Internacional: la Biotecnología en la economía global: la ciencia y el principio precautorio*, 22nd and 23rd of September, 2000

The inclusion of the approach in the Protocol has two aspects: firstly, the Introduction to the Protocol reinforced the precaution focus which figures in Principle 15 of the Rio Declaration on Environment and Development., and secondly, the criteria upheld in the Introduction is put into effect in Article 10.6 concerning the correct procedure of decision making and in Article 11.8 which refers to LMOs intended for direct use as food or feed or for processing.

There is a difference between approach and principle[6]. The principle is a guideline in the decision making process. The approach or criteria is not compulsory for the Parties. The precautionary approach presumes that the potentially dangerous effects coming from phenomena, product or process have been identified but that scientific assessment has not been able to determine the risk with enough certainty. The Protocol is based on the traditional precautionary approach, understood in a much broader sense and goes further than damage caused or lack of scientific certainty. It requires the recognition of a range of broader damages, including social and economic damages (art. 26). The precautionary approach includes the idea of seeking alternatives for dangerous technologies, the concept of transferring to those people who propose new technology the responsibility of answering for the safety, clarity and fairness involved in their decision taking concerning technologies.

The Substance Equivalency [7] (SE) is a concept internationally accepted as one of the standard criteria to evaluate the safety of food derived from LMOs (FAO-WHO, 1996; Health Canada, 1994; The Commission of the European Communities, 1997; OCDE, 1992 and 1998). The SE concept considers that if a foodstuff or food ingredient derived from LMOs is considered substantially equivalent to a conventional foodstuff or food ingredient, the former will be considered as safe as the latter. To establish SE the foodstuff derived from LMO must be compared to the food type or food derived from the food type which is as similar as possible. The mere proof of SE does not imply that the food is safe or wholesome.

The final text of the Protocol shows that the precautionary approach, the spearhead of the European Union position, has gained weight. This acts as a hinge in the Health Agreement, which is part of the Uruguayan Wheel of the World Trade Organization (WTO). Point 6 of this document establishes the so-called "scientific principle" which restricts the application of limits to trade, which are not supported on scientific basis. The practical consequences are the introduction of restrictions on seed and grain trade. Exporters will have to have written proof, which shows to what extent their products include transgenic products. It is the exporter who is responsible for the evidence.

The governments will decide to accept or reject the importation of LMOs depending on risk assessment. This assessment will be carried out in a scientific manner, using acceptable known techniques. However, in the case that the pertinent scientific information or knowledge are insufficient, a country may decide to apply the precautionary approach and refuse to allow the LMO to be imported into their territory. The Protocol also recognizes and respects the right of each country to take into

[6] Chávez, Juanita. *El Protocolo de Cartagena sobre Bioseguridad de la Biotecnología.* Work presented in the International Public Forum: Impact of the Transgenic Organisms, The Bogotá Council Ombudsman, 22nd of June 2000.

[7] Belém, M. et al. *Equivalencia Substancial da composiçao de alimentos derivados de plantas geneticamente modificadas (PGM): Procedimentos propostos para o Brasil*. EMBRAPA, Brasilia, July 2000

consideration socio-economic factors, the value of biological diversity and the interest of local and ethnic communities when deciding whether or not to import LMOs.

1.4 The Main Resolutions of the Cartagena Protocol

As from the moment the Protocol enters into force it will provide a framework to deal with the environmental impact of those products of modern biotechnology, which are internationally transboundary. The Protocol will help to protect environment without unnecessarily interfering with the world food market. The Protocol includes[8]:

- The establishment of "The Information Sharing and Biosafety Clearing House" to help countries interchange scientific, technical, environmental and legal information on LMOs.
- The creation of the Advance Informed Agreement (AIA) procedure, which requires exporters to obtain the agreement from the importers before the first shipment of LMOs is released into the environment.
- The requirement that bulk shipments of basic products with LMOs be accompanied by relevant documentation stating that those goods "may contain" LMOs and "it is not the explicit end to intentionally release them into the environment".
- The creation of a process to identify more precisely the basic products with LMOs on the international market.
- The inclusion of a "safeguard clause" which documents that the parties have the intention that the agreement does in no way alter the rights or obligations of those governments in line with the WTO or other existing international treaties.
- Support mechanisms for those emerging countries for capacity-building in the administration of modern biotechnology.

The Protocol marks the difference between the different LMO products, excluding pharmaceutical products which are destined for human consumption, as these products are covered by separate agreements or through the pertinent international organizations; those LMOs in transit; those LMOs destined for any operation to be carried out indoors and which will therefore not be exposed to the outdoor environment.

More flexible procedures will be granted to LMO products destined for direct use as food or feed or for processing. The flexible AIA procedure indicates that the country, which has decided to place on the market an LMO that may be subject to transboundary movement, must inform all the Parties concerned through the Information Sharing and Biosafety Clearing-House (ISBCH). The importing country may inform through this body that it does not wish for the importation of a certain LMO. The system will also facilitate the exchange of technical, scientific, environmental and legal information.

The Protocol does not touch on the following issues: 1) whether foodstuffs are innocuous or not; 2) segregation, during shipping in bulk, of basic products which may contain LMOs; 3) adherence to AIA procedures; 4) detailed identification information for basic products which are shipped in bulk and are subject to future negotiations, and 5) labelling for products destined for the consumer market. The Protocol merely requires documentation to the effect that the bulk shipment of basic products "may contain LMOs"

[8] Convention on Biological Diversity. *Protocolo de Cartagena sobre Seguridad de la Biotecnología del Convenio sobre la Diversidad Biológica*, Montreal, January 2000 CBD Website: www.biodiv.org.

or that "there is no direct intention to release them into the environment", with this shipping documentation the regulations are thus observed.

The Protocol gives countries the chance to obtain information before importing new biotechnologically modified organisms. It sustains the right of every country to regulate organisms resulting from biotechnological engineering in keeping with existing international obligations. It also creates a reference framework to help emerging countries to develop skills to protect biological diversity.

1.5 The Advance Informed Agreement Procedure (AIA)

The AIA procedure [9] requires that the Party of export must obtain consent from the Party of import before the first shipment of the LMOs is released into the environment. From the date of the notification of the exporter, the Party of import has 270 days to make the corresponding decisions concerning the importing of the LMOs for release, based on a scientific risk assessment. The governments must inform the Biosafety Clearing House of their final decision concerning the local use of merchandise containing LMOs within 15 days. Different shipping documentation requirements have been established for different types of LMOs and they will come into force when the Protocol becomes effective.

1.6 Labelling of Products

The Protocol[10] does not stipulate any obligation to segregate transgenic organisms from conventional ones. It only indicates that the shipment of living modified organisms intended for direct use as food or feed or for processing must be clearly identified as "possibly containing living modified organisms". The Conference of the Parties will take a decision about detailed requirements.

Those LMOs that are intended for intentional introduction into the environment must be identified as such, with specific detail of features and traits. The cargo of LMOs must state that the shipment "may contain" LMOs and that they are not for intentional release to the environment. They must specify the point of contact for further information. The Protocol refers to the possible decision of the Parties to elaborate detailed requirements for that end, including identification and any other specific characteristic of the LMOs. Concerning LMOs that are destined for contained use the shipment must be identified as containing LMOs.

1.7 Information Sharing and Biosafety Clearing House (ISBCH)

The Convention on Biological Diversity encourages countries to share information including scientific and socio-economic research results to allow for the effective management of genetic resources so as to guarantee an equal distribution of the benefits from its use. The Protocol channels this issue through the Information Sharing and Biosafety Clearing-House (ISBCH).

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[9] Convention on Biological Diversity. *Protocolo de Cartagena sobre Seguridad de la Biotecnología del Convenio sobre la Diversidad Biológica*, Montreal, January 2000 CBD Website: www.biodiv.org.
[10] See above Footnote 9

In the first meeting held in Montpelier, from the 11th to the 15th of December 2000, the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP)[11] recommended the preparation and launching of the pilot phase of the ISBCH and insisted that the governments present to the Executive Secretary their most pressing priorities with respect to the capacities needed to participate in the pilot phase. The ICCP asked the Executive Secretary to analyse the needs for capacity-building and to create financial backing for those countries, in particular the least developed and small island States, and those with emerging economies. They also expressed their support for those countries, which are centres of origin and centres of genetic diversity to allow them to actively participate in the pilot phase of the ISBCH.

The pilot phase of the ISBCH was launched in April 2001 and has been functioning since. A series of instruments have been prepared to help countries to incorporate information and to establish national data banks. There is general consensus on the need for capacity-building, to improve institutional, technical, human and financial resources for the countries to be able to take full advantage of the Information Sharing and Biosafety Clearing-House. It is also necessary to foresee the way to deal with issues of confidential information and intellectual property rights, which tend to arise when any new information system is created.

The Secretary of the Convention has defined the initial characteristics of the main website and the handling of the pilot phase of the Information Sharing and Biosafety Clearing-House, including mechanisms to register information from a distance. There are still some critical points pending, such as the exact wording for controls and procedures to check and validate registered information.

The organization of the ISBCH[12] was analysed during a Latin American and Caribbean Meeting held in Lima from the 4th to 6th of September 2001. The countries in these regions were offered the chance to air their needs and expectations with respect to the pilot stage. Those Latin American and Caribbean countries, which are also part of the Convention of Parties, were invited. Representatives of bilateral donors and intergovernmental and non-governmental organization were also invited to participate as observers and/or informers.

1.8 Public Awareness

The Protocol[13] recognizes that national measures are vital for their procedures to be effective. Member Governments commit themselves to promoting public awareness ensuring easy public access to information and consulting the public in decisions regarding biosafety. National measures should also be adopted to prevent illegal shipments

[11] Convention on Biological Diversity. *Informe del Secretario Ejecutivo resumiendo la información recibida en respuesta al cuestionario sobre creación de la capacidad*. Open-ended meeting of experts on capacity-building for the Cartagena Protocol on Biotechnology Biosafety, La Habana, 11th to 13th July 2001. UNEP/CBD/BS/EM-CB/1/2.

[12] Convention on Biological Diversity. *Informe de la Reunión Regional de América Latina y el Caribe sobre el Centro de Intercambio de Información sobre Seguridad de la Biotecnología*, Lima, 4th to 6th September, 2001 UNEP/CBD/BCH/LAC. Reg. /1/2

[13] Convention on Biological Diversity. *Protocolo de Cartagena sobre Seguridad de la Biotecnología del Convenio sobre la Diversidad Biológica*, Montreal, January 2000 CBD Website: www.biodiv.org.

and accidental releases of LMOs notifying those affected or potentially affected states should an unintentional transboundary movement occurs.

1.9 Social Aspects of the Cartagena Protocol

The Cartagena Protocol will be of great help to those countries which do not have of yet a regulatory framework for LMOs and are importers of seed and foodstuffs. However the effects of the Protocol are quite different in milder zone countries, which have a lesser biological diversity, or in countries in the tropics. The tropical zone is characterized for its mega-diversity to such an extent that it is worth reflecting on this difference and acknowledging that biological diversity in these regions has a cultural and social foundation.

The regions richest in species and varieties of flora and fauna are those which have social structures based on indigenous and farming communities which know and make use of the richness of these natural resources. However, the acknowledgement of this situation in the context of the Protocol is limited: only Article 26 makes reference to this reality and Article 10 offers the instrument of the precautionary approach as a brake to possible negative effects.

Article 26 establishes that in reaching a decision on import, under domestic measures implementing the Protocol, one may take into account, consistent with international obligations, socio-economic considerations arising from the adverse effects of LMOs on the conservation and sustainable use of biological diversity especially with regard to indigenous and local communities. Thus, the parties are encouraged to cooperate in information sharing and research into the socio-economic effects of living modified organisms concerning the indigenous and local community.

The Protocol on Biosafety recognizes that indigenous and farmer communities must be protected since their resources could be affected by risks from transgenics which are of yet unknown. However, this recognition is purely commercial, without taking into account that for country folk there is a different relationship with nature: a relationship linked more to subsistence and sustainability rather than to commercial aspects. For this reason, the implementation of the Protocol in various Latin American countries requires groundwork into the mechanisms so that the rights of local rural communities are understood and appreciated.

1.10 UNEP-GEF Project on Development of National Biosafety Frameworks

The United Nations Environment Programme (UNEP)[14] launched the programme to advise emerging countries on the benefits and risks of LMO crops. The project is financed by the Global Environmental Facility (GEF) and will help 100 countries to develop the scientific and legal framework to evaluate LMOs. The GEF was founded jointly by the UNEP, the United Nations Development Programme (UNDP) and the World Bank, in 1991.

The UNEP-GEF started working in June 2001, with the mission to help countries develop their National Structures of Biosafety (NSB) so as to be in a position to apply the

[14] United Nations Environment Programme (UNEP) *UNEP-GEF Project on Development of National Biosafety Frameworks*, UNEP Website: www.unep.ch/biosafety.

Cartagena Protocol. The UNEP-GEF will aid 100 countries to organize internal regulatory processes that will be administrated by each country. The global project helps each participant to prepare the necessary tools to handle living modified organisms at the national level, enabling them to comply with the requirements of the Cartagena Protocol.

The UNEP-GEF also has as objectives the promotion of regional and sub-regional collaboration and the exchange of experiences of issues relevant to national structures of biosafety. This should help in the following ways: firstly to use economic and human resources efficiently; secondly, to establish regional and sub regional networks, and thirdly to encourage the harmonization of risk assessment procedures and of regulatory mechanisms, and lastly, to give technical assistance and support to countries during the development of their own national biosafety frameworks.

Every country that wishes to participate in the project must live up to the following requisites, set down by the GEF:

- Sign or ratify the Cartagena Protocol on Biosafety
- Be eligible for GEF funds
- Not to have received any previous aid from the pilot project on Biosafety- UNEP-GEF.
- Have been formally chosen by the GEF National Focal Point to take part in the project.

The development of tools includes: information gathering, analysis, consultancy, training, and the preparing of the project on the national biosafety framework, which comprises legal instruments, administrative systems, risk assessment procedures, systems for public participation and information. The regional Workshops are aimed at increasing understanding of the Cartagena Protocol and monitoring the implications for risk assessment and national decision-making. The sub-regional Workshops are orientated towards the identification of priorities to promote: capacity-building in each country, opportunities for collaboration, mechanisms for sharing risk assessment and management experiences, ways to coordinate capacity-building activities and a computer network for sharing experiences.

The first stage of the project is common to all participating countries and entails: to set down the structure of the project, to prepare a report on the situation of biotechnology within the country, covering programmes, legislation and regulations, regional programmes of harmonization, and national skills in those relevant issues linked to biosafety regulations. After this stage, consultancy workshops will be held with the "stakeholders" within the country, where the results of previous work will be studied to identify needs so that priorities in each field can be chosen. Then training activities will be carried out with selected groups on different issues, and a list of national experts in each field will be drafted. Finally, further workshops with the local stakeholders will be held to identify the main points of the regulatory framework and work out the project for a national regulatory framework of biosafety in biotechnology.

The cost of the Biosafety Project – UNEP-GEF is 38.4 million dollars that include 26.1 million dollars from GEF and 12.3 million dollars from UNEP. The countries participating will cover one third of the cost of their own project in money or in kind.

1.11 The UNDP and the Cartagena Protocol [15]

The United Nations Development Programme (UNDP), which works for the development of national capacity-building to regulate biosafety in biotechnology, fully supports the application of the Cartagena Protocol. The strategy of UNDP is not to increase its portfolio of biosafety projects but to identify possible synergies between the activities of other agencies such as the United Nations Environment Programme (UNEP) and their own traditional vision focused on the development of skills, fighting poverty and the integration of policies.

UNDP is truly willing to help all the signatory countries of the Protocol. The help can be tailor-made for every country, depending on the conditions and needs of each, including the coordination of financial efforts between national, bi-national and multilateral players, the mobilization of technical, human and financial resources, technical assistance, and the promotion of common criteria among the different players and organizations.

UNDP assistance will be destined to those countries that ratify the Protocol. In the period prior to the First Meeting of the Parties [16] the UNDP took part in the Preliminary Strategy of the GEF, in projects developed in Cameroon, Ghana and Poland, as a member of UNEP and the World Bank. They may well take part in two other projects approved by the GEF, to consolidate capacities in Malaysia and Mexico; both of these projects will be assisted by the UNIDO.

The initiatives pool the information gathered by each country in order to put into effect and to strengthen their national biosafety frameworks. From the social viewpoint, this framework includes the creation of jobs and skills, training, professional development, ethics and information enrichment for those people involved in the regulatory process. From the point of view of the system, it works within the political scenario in the institutional, legal and regulatory frameworks, considering the availability of resources within the system. From the institutional point of view, the setting up of missions, culture and structure, processes, resources and infrastructure will receive support.

2.- Application of the Cartagena Protocol in Argentina[17]

In Argentina, the Cartagena Protocol should be seen in a special context, mainly due to the importance that LMO crops have gained in agriculture, making Argentina the second largest transgenic soybean producer in the world. Argentina has made a strong commitment towards biotechnology and this has recently been ratified by the highest authorities in the area of agriculture.

At the FAO World Summit, the Secretary for Agriculture, Rafael Delpech, defended the Argentine stance towards agro biotechnology, putting special emphasis on the fact that " the commercial restrictions imposed internationally on our products constitute an obstacle

[15] United Nations Development Programme: Desarrollo de Capacidades Nacionales para Bioseguridad, Buenos Aires, 8th to 10th May 2002

[16] This date is related to the ratification of the 50th member country, which, in turn will mark the enforcement of the Protocol.

[17] Dellacha, Juan: La *implemenación del Protocolo de Cartagena en Argentina*. Work presented in the Conference: The Cartagena Protocol and the necessary conditions for its implementation in the Latin American countries, CamBioTec, Mexico City. 24th and 25th of June 2002.

to the sustainable development of our economy". He also lashed out at the policy of agriculture subsidies currently applied by both the European Union and the United States of America, as well as the tariff barriers imposed by developed countries [18].

2.1 Institutional Framework of the Activities.

The Institutional framework of the Protocol establishes that each country should designate a National Focal Point (NFP) to be responsible for liaison with the Secretariat and a Competent National Authority (CNA) responsible for performing the administrative functions required by the Protocol, and to be authorized to act on the country's behalf with respect to those functions. A country may designate one single entity to fulfil the functions of both focal point and competent national authority.

Argentina has not yet arrived at any decision regarding this matter. The General Secretariat of Environment of the Ministry of Foreign Affairs is the national representative of the Convention on Biological Diversity, and acts as national coordinator. The technical activities are performed under the auspices of the Secretariat of Agriculture, Livestock, Fisheries and Food (SAGP&A), which is currently housing the Argentine Focal Point of the UNEP-GEF, (Project for the National Development of a Biosafety Framework).

From the 24th to 28th of January 2000, negotiations on the Protocol on Biosafety to the Convention on Biological Diversity came to an end in Montreal, Canada[19] where a consensus text was finally drafted. Argentina signed the Protocol in Nairobi on April 25th, 2000 during the V Conference of the Parties to the Convention on Biological Diversity. From 11th to 15th December, the Committee of the Protocol Implementation met in Montpellier, France with the aim of starting to work on the Protocol implementation. The Technical Coordination Committee of the CONABIA participated in the meeting coordinated by the General Secretariat of Environment of the Foreign Office, in order to reach a consensus regarding the Argentine position, taking into consideration the opinion of both the public and private sectors.

Argentina has formally requested to participate in the project on the national framework of biosafety organized by the UNEP-GEF. The focal point of the GEF is established in the General Secretariat of Environment of the Ministry of Foreign Affairs. The Representative of the Project in Argentina is the Secretariat of Agriculture, Livestock, Fisheries and Food.

2.2 Precautionary Approach vs. Substance Equivalency.

Argentina is prepared to assume the responsibility for developing regulatory structures and capacities to assess risks of biotechnology throughout the world. As a member of the Intergovernmental Committee for the Cartagena Protocol on Biosafety the country contributes to the development of the necessary procedures so that the Treaty can be applied. Internally, the members of the CONABIA, are preparing, together with officials of the Ministry of Foreign Affairs, the documents that must be submitted for this purpose.

During the negotiation stage of the Protocol, Argentina, as part of the Miami Group, held

[18] Newspaper "La Nación" *La Argentina se pronunció a favor de los alimentos transgénicos*.", Buenos Aires, June 12 2002.
[19] National Advisory Committee of Farming Biotechnology, MEMORIA 2000, CONABIA Website: www.sagpya.mecon.gov.ar/programas/conabia

the position that respect for environmental biosafety should not be used as a shield to hide commercial barriers behind. Argentina rejects labelling as it considers it a tariff levying measure. This position has been recently ratified by the country's governmental officials in international forums.

During the Conference on the Precautionary Approach organized by the CIID of the University of Harvard[20] Diego Malpede, of the Ministry of Foreign Affairs emphasized the national benefits of the application of biotechnology and the high quality of the regulatory structure organized in Argentina. He also pointed out a more cautious attitude on the part of the traders of agricultural products since the adoption of the Cartagena Protocol, and the sector's awareness of the need to have differentiated agricultural products to satisfy the consumers' preferences. Malpede underlined that the Argentine government fears that the precautionary approach could be used as a protectionist measure to restrict access to foreign markets. Argentina has only authorized the commercial development of LMO varieties that have been approved by the EU, thus ensuring its international markets. This reflects a certain aspect of the precautionary approach applied to economic conditions.

The achievement of efficient capacity-building in emerging countries is essential for the success of the Protocol. In this sense, Malpede suggested that preventive action is justifiable only in the following circumstances: where the pertinent scientific information is insufficient; on the basis of available pertinent information; through efforts to obtain additional information necessary to make a more objective risk assessment and within a reasonable timeframe for revision. The regulatory guidelines of the approach must consider: the agreed international principles, transparency, rigorous research (especially by independent organizations), no restrictions to trade other than those completely necessary; the recognition that ignorance is not the same as a lack of scientific certainty, and lastly, a reasonable time framework to adopt decisions.

2.3 Continuity of the regulatory system currently in effect

Argentina has not yet made public its official position regarding its interest to modify the current regulatory system, so as to be able to adapt for any hitches generated by the adoption of the precautionary approach. For the record, it is worth mentioning that the Second National Report of the Parties[21] elaborated in May 2001 by the Secretariat of Sustainable Development and Environmental Policies (formerly the Ministry of Social and Environmental Development) refers to the advancement achieved in Argentina in relation to Articles 19 and 20 of the Convention, regarding the Management of Biotechnology and the distribution of its benefits, and particularly, on Decision IV/3: Issues related to safety of biotechnology, and Decision V/1: Working Plan of the Intergovernmental Committee of the Cartagena Protocol on biotechnology safety.

The Argentine Government points out that it considers the application of Article 19 and its decisions as medium priority, emphasizing that the financial resources required to make

[20]Centre of International Development, Harvard University. *Conferencia Internacional: la Biotecnología en la economía global: la ciencia y el principio precautorio*, 22nd and 23rd of September 2000

[21] Secretariat of Sustainable Development and Environmental Policy of the Ministry of Social Development and Environment. *Convenio sobre Diversidad Biológica, Segundo Informe Nacional de las Partes*, Buenos Aires, May 2001. CBD Website

the corresponding investment are not readily available. Regarding Decision IV/3, the report states that the country has signed the Protocol and is ratifying that decision. When asked whether the country has evaluated the need, at national level, to adopt efficient blanket-regulation governing restrictive technologies of genetic uses so as to ensure safety of human health, of environment, safety of food and conservation and sustainable use of agricultural biological diversity, the reply is that such a measure is not necessary due to the fact that current legislation encompasses those areas.

2.4 Chain of Command within the public sector.

The Argentine government as part of the preparatory strategy to adapt to the Protocol is promoting the passage of a law passed by the National Congress so that the institutional areas linked to biotechnology regulations should be within a hierarchical tiered system. The Bill of the Biosafety Law[22] regarding the application of farming biotechnology gives legal support to the current LMO-approval regulatory framework regarding biosafety, the wholesomeness of agro-food, and health and sanitary controls of the markets. The debate on the impact of biotechnology on food derived from LMOs should be on the agenda of every local legislature and authority throughout the country and at the regional scale, reaching the Parliaments of the MERCOSUR in order to build regional regulation on Biotechnology.

In May 2001, the Chamber of Deputies of the National Congress created a Special Commission on Biotechnology. Its main objectives are to analyse and express opinion on the necessary rules to arrange and promote the development of biotechnology, articulating the national legislation with the international commitments undertaken by Argentina, to perform an audit and appraisal of the current international, national, provincial and borough legislations on the issue, and to summon all those involved, at the different levels, to a meeting to draw up draft legislation on the topic.

In the first phase, the Commission drafted a bill on Biosafety in the Application of Farming Biotechnology. This draft has made considerable headway in Parliament, and parallel to its passage process, the issue is also being discussed within the public sectors involved in biotechnology. One of the most positive consequences that should arise from the approval of this Bill is the introduction of a tier system in biosafety management, a reform which is considered advisable for the smooth implementation of the Cartagena Protocol.

The main objectives of the proposed bill are to establish a regulatory framework which update and renovate the tier system and provide legitimacy to the process of incorporating LMOs to the agro-industrial and farming production systems, ensuring biosafety conditions, and to promote the development of modern biotechnology in farming production. This biotechnology should be considered a fundamental strategic factor for the increase of farming productivity and competitiveness, as well as to improve the levels regarding quality, differentiation and aggregate value of food and other products.

The process of incorporation of LMOs into the market will be done after the following three evaluation processes are complied with:

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[22] Chamber of Deputies of the National Congress. *Proyecto de ley de Bioseguridad en la Aplicación de la Biotecnología Agropecuaria*, Buenos Aires, 2001

- Risk assessment and evaluation of environmental benefits originated by LMOs production.
- Biosafety evaluation of food and of other products
- Evaluation of the commercial impact when introduced into international markets.

The Bill expressly prohibits -and considers it a crime – the introduction, experimentation, productions, use, release, commercialisation or any other possible uses of LMOs which have not been duly authorized by the Application Authorities. The Executive Power shall set out the responsibilities and procedures, and regulate the scope of the foreseen evaluations, according to strictly scientific bases and considering the nature of the products.

All information related to the regulatory process and the commercial approval of a transfer should be in the public domain and the Application Authorities must ensure that such information, save those details considered confidential, be permanently and continuously available to all those people interested in the matter.

The Bill names the Secretariat of Agriculture, Livestock, Fisheries and Food of the Nation (SAGP&A) as the Application Authority with the appropriate power to authorize or deny licences to experiment with, to release into the environment and to trade LMOs. To aid the Application Authority in these tasks, an Advisory Body, legally constituted, will provide previous technical advice. The Application Authority is also in charge of establishing biosafety conditions and those regulations which are required to incorporate LMOs into the farming and agro-industrial systems. They are also responsible for the enforcing of said norms.

The Bill endorses the creation of the National Advisory Commission of Farming Biotechnology (CONABIA) according to Resolution N° 124/91 of the Secretariat of Agriculture and Livestock. CONABIA will be an interdisciplinary and intra-active entity, whose members will perform their duties "ad honorem". The Commission will be made up of members selected from competent organizations in the field, under the supervision of the SAGP&A, which will designate the Commission's authorities. The Secretariat of Science, Technology and Productive Innovation (SEC&T), and other representatives from competent organizations, designated by the Secretariat of Sustainable Development and Environmental Policy, will be also members of the Commission. The CONABIA's main functions are firstly, to advise the Application Authority on the current law on the technical biosafety requirements that LMOs should meet before they are used in the farming and agro-industrial systems, by any procedure or method, no matter what form that may take -trials, diffusion, etc.-; secondly, to propose rules and express opinion on matters of their competence; and lastly to coordinate, and authorize subcommittees to deal with specific issues, and to enforce its regulations.

The Bill creates a Technical Advisory Committee on the Use of LMOs[23], an interdisciplinary and intra-active entity, with a President and Coordinator, which will be formed by representatives from the appropriate competent organizations related to the matter. All members will perform their duties "ad-honorem". The Technical Advisory Committee will: put forward the necessary requirements and supervise their application to enable the Application Authorities to give authorization for the use of LMOs; propose

[23] Briozzo, Alberto. *Panel Biotecnología, Economía y Estado*, II International Conference on Biotechnology, organized by the Argentine Seed Producers Association (ASA)

rules and express opinion in issues related to the wholesomeness of LMOs; collaborate with official entities, should they so require, on the current legal norms; coordinate and authorize the dealing of specific matters by permanent sub committees, which will be established in accordance with internal statutes.

Additionally, the Law creates, within the sphere of the Application Authority, a Technical Advisory Committee on Agro Food Markets, which will analyse the impact of access to international markets. It will be an interdisciplinary and intra-active body and will be made up of representatives of public and private sectors related to the subject. The general coordination will be carried out by the National Office of Agro food Markets, and the members of the Technical Advisory Committee will work "ad-honorem". Their main functions will be to analyse the commercial policies developed by the main LMO producer countries, exporters and consumers; evaluate the impact of the commercial approval of a transformation process on entering external markets and pass its internal regulations.

Finally, the Bill creates a Farming Biosafety Fund which will be financed by the proceeds from the levying of tariffs and which will be exclusively used to cover the expenses incurred in carrying out the objectives within the law. The tariffs will be established by the Secretariat of Agriculture, Livestock, Fisheries and Food. The project includes a glossary of technical terms, adopted on the basis of the FAO-OMS Conclusions and Recommendations document drawn up by experts in biotechnology and food wholesomeness in Rome from the 30th of September to the 4th of October 1996.

In the field of farming biosafety legislation, the Bill on Biosafety states that all information related to the regulatory process and commercial approval of a transfer will be in the public domain and the Applicable Authority shall ensure that such information is permanently and continuously available for all people interested in it. The exception to this norm lies with those issues subject to confidentiality. This criterion will be difficult to apply, as it is contrary to those rules that regulate State administration on the whole, which establish that a Bill in passage within the National Public Administration must be treated as confidential until it finally becomes Law.

This legal initiative has received certain criticism from national deputes, and civil servants from the Foreign Ministry and the Secretariat of Environment. The Foreign Office has remarked on a certain incompatibility between the project and the Cartagena Protocol. Argentina must aver the Protocol which will carry legal precedence over the law. There are other initiatives currently in the pipeline, in particular, a Bill in passage in the Environmental Commission of the National Chamber of Senators which is receiving considerable flank from protagonists, both from the private and public sectors in the field of biotechnology in Argentina.

2.5 Socio-Economic Criteria.

Argentina has several years' experience working with the inclusion of economic factors in the evaluation criteria for marketing LMO seeds. This activity, as previously mentioned, is carried out by the National Office of Agro-Food Markets (DNMA), which is part of the Secretariat of Agriculture, Livestock, Fisheries and Food. DNMA intervenes, in the final stages of the regulatory process, in the authorization of the commercial release of crops, and prepares a report on the potential impact that the introduction of the analysed LMO

crop would produce on the Argentine market share in the international grain market.

This Agency uses its own methodology: firstly, it performs an analysis of the international market of that specified crop including the market share Argentina enjoys; secondly, it analyses the commercial policies of the main buyers regarding LMO products, and afterwards, it gathers and studies updated information on the performance of the specified product in other international markets. With these appraisal tools, an evaluation of the potential financial benefits or losses for the country can be carried out. Finally, a report is drawn up which either establishes that there is no negative impact or recommends the postponement of the approval of the LMO crop.

DNMA works with public information obtained from national organizations, from the public sectors of other countries and from international entities. Their reports are mutually independent and are treated as confidential. There is a movement, albeit in the initial stage, to make this phase of the regulatory processes more transparent, by means of the creation of an Advisory Committee[24] made up of representatives of private and public entities involved in international trading of Argentine grain.

2.6 Education and public participation.

There is no official position regarding this issue. As background, it should be mentioned that, within the framework of the United Nations Conference on Environment and Development, in Section III: "Strengthening Key Groups", the governments and the system of the United Nations must require the participation of non-governmental organizations (NGO) in the elaboration of policies and decision-making, related to the Sustainable Development. In line with this commitment, the country has organized the Programme of Promotion and Civil Participation, which depends on the Office of Institutional Relations and Environmental Promotion, of the Secretariat of Sustainable Development and Environment Policy [25]. The programme's overall mission is to design, implement and evaluate public participation in environmental promotional activities, while its strategic mission is to achieve the articulation and support of the country's NGOs.

Notwithstanding the above, the conservation of biodiversity and the necessary measures to be taken to such effect are the not priority objectives on the public education and awareness agenda for the Argentine Government. Some programmes for the conservation of biological diversity including an educational effort are isolated initiatives which are not linked to any National Plan.

2.7 Capacity- building in the respective public areas.

Argentina has developed and presented a project to participate in the first stage of the UNEP-GEF project, which is still in the negotiation stage. In the various meetings held, Argentine representatives have expressed their willingness to cooperate and participate in the ISBCH organization, in return for external technical support and financing.

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[24] Modelled on the Advisory Committee of CONABIA

[25] Office of Institutional Relations and Environmental Promotion, Ministry of Social Development and Environment. *Programa de Promoción y Participación con la Sociedad Civil*, Buenos Aires, CBD Website: www.biodiv.org

Although national priorities should arise from the implementation of the UNEP-GEF project, at first sight, the SAGP&A authorities were able to identify certain shortcomings in the field of the implementation of some points of the Cartagena Protocol which refer to the labelling of commodities.

2.8 Common Policies at Regional level

Among the recommendations of the Cartagena Protocol, the importance of achieving regional common policies on Biosafety in Farming Biotechnology is underlined, being this particularly relevant when dealing with countries such as Argentina, Brazil, Paraguay and Uruguay, which integrate the MERCOSUR block. Bolivia and Chile should also be included with these countries, as, although they have worked hard for more than 10 years to join as members, they have not yet achieved significant advancement on the subject.

This is a very complex issue, and according to those involved in the topic, the countries have very different views on what the scope of the different organization sectors of the MERCOSUR should be, in particular, the Environmental Commission and the Agricultural Technical Subgroup of the MECOSUR. Both of these areas are linked to different national entities which, on many points, have many conflicting attitudes.

The first recorded instance[26] of regional harmony within the field of biotechnology applied to the farming sector was a Workshop titled "Common Policies of Biosafety in the Southern Cone: Supervision of Transgenic Crops" held in Buenos Aires from the 16th to the 20th of November 1992, and organized by the Inter-American Institute for Cooperation in Agriculture (IICA) and the International Service for the Acquisition of Appropriate Agro biotechnologies (ISAAA).

During the 2nd Latin American Meeting on Farming Biotechnology held at Puerto Iguazu from 4th to 9th of June 1995, various technicians of the region agreed on the need to identify proposals in order to establish national rules and mechanisms for supervision in the Southern Cone countries As a consequence, the Meeting on "Biosafety and Commercialisation of Genetically Modified Organisms in the MERCOSUR" was held in Buenos Aires on 19th and 20th of September 1995, organized by the present SAGP&A, and sponsored by the Cooperative Programme for the Farming Technological Development of the Southern Area (PROSICUR). Its main mission was to identify parallel activities to find common policies to base rules and procedures for the supervision of development and commercialisation of LMOs within the region.

Another initiative, in the same field, was the Workshop "Biosafety in Farming Biotechnology: Towards the commercialisation of plants and vaccines genetically modified" which was held in Buenos Aires from the 5th to 7th of March 1996, and organized by the SAGP&A and the Environmental Department of the United Kingdom, and sponsored by PROCICUR, the ArgenINTA Foundation and the British Embassy in Argentina. On this occasion, technicians from the MERCOSUR member countries presented the situation of each country's national ordinances and discussed the possible format of common criteria, including agreements on regional cooperation as well as the design of a standard framework for the environmental release and commercialisation of LMOs and their by-products. These initiatives were merely technical, with very little, if

[26] CONABIA Website: www.sagpya.mecon.gov.ar/programas/conabia

any, impact on national political discussions.

In the field of environmental negotiation, after 7 years, the countries have managed to set up an Environmental Protocol of the MERCOSUR[27]. The main stumbling block for the conclusion of the Protocol was the debate related to biotechnology and the use of genetically modified grains. The Framework Agreement on Environment was approved by Statute of the Common Market Council N° 2/01[28], based on Recommendation Nr. 1/01 of the SGT Nr. 6 "Environment". The mission of the Agreement is the sustainable development and environmental protection through the articulation of the economical, social and environmental sectors, thus contributing to improving the quality of the environment and of the lives of the population. The States averred their commitment with the principles laid out in the Rio de Janeiro Declaration on Environment and Development of 1992, and went further by undertaking to make a deeper analysis of the sub-regional environmental problems, with the participation of both national competent organizations and other civil entities. The text does not consider the impacts on environment produced by the application of biotechnology in the farming sector.

Recently, a new negotiation initiative regarding LMOs safety has taken place based on the points mutually agreed upon within the framework of Agreement "4+1". The key players around the negotiating table were the MERCOSUR countries and the United States of America, and the underlying point of interest was biotechnological regulation. In the first meeting of the representatives of the MERCOSUR member countries which was held in Montevideo, Uruguay, a tentative agenda was drawn up to be submitted to the delegation from the United States of America, including issues related to health, plant sanitary conditions and biotechnology[29]. According to the SAGP&A of Argentina, the need to focus the discussion "in a similar way as the general criteria foreseen by the World Trade Organization" was debated. In this way, "an agenda would be prepared that would address those specific problems arising from access to the markets and would solve them according to international norms".

Finally, it is worth underlining the crucial role that international cooperation plays in this matter. Over the 20 years of Biotechnology history, the countries of the region have received the support from several international programmes of cooperation, organized by different international entities[30]. During the last few years, these programmes have been increasingly focused on problems derived from biosafety, handling of risk and public understanding of farming biotechnology. Let's see some examples:

In 1998, the United Nations University created a Programme on Biotechnology for Latin American and the Caribbean (UNU-BIOLAC) in Caracas, Venezuela. In 2001, the UNU-BIOLAC created the Regional Network on Biosafety (RNBio), to work on human

[27]Farming Environmental Observatory of the MERCOSUR. *La biodiversidad aparece como obstáculos para la norma ambiental del MERCOSUR*. Website of the Latin American Centre of Social Ecology (CLAES) Nr. 12, 19th July 2000

[28] Common Market Council. *Acuerdo Marco sobre Medio Ambiente del MERCOSUR*. MERCOSUR / CMC/DEC. Nr. 2/01.

[29] Agriclipping: *EL MERCOSUR presentará mañana a Estados Unidos su propuesta sanitaria, fitosanitaria y biotecnológica al iniciar la discusión sobre el comercio agrícola.* Buenos Aires, 16th of October 2001.

[30] This issue has been elaborated based on the work of Albornoz, M., Vaccarezza, L., Carrullo, J. and Zabala, J. Public Policies, Social Relations and Scientific Research Guiding in the field of Biotechnology, Final Report of the Project Financed by IDRC, Buenos Aires, September 2001.

capacity-building, and to elaborate guidelines and documents on problems dealing with biosafety, handling of risk and public understanding of biotechnology, with the aim of strengthening the regulatory systems of the lesser developed countries, with those countries of the Andes Pact, Central America and the Caribbean being top priority.

The Ibero-American Programme of Science and Technology for Development (CYTED) has a sub programme III: Biotechnology. The mission of the Ibero-American Multimode Network of Biotechnology Relationship and Development (REVYDET) is to link the scientific-academic sector with the industrial-enterprise one, so as to give greater diffusion of the results of biotechnological research to different companies. Over the last few years, the scope of this Network has been widened to encompass biosafety problems, handling of risk and public understanding of biotechnology in Ibero-American countries.

The Canadian – Latin-American Initiative on Biotechnology for Environment and Sustainable Development (CamBioTec Programme)[31] was promoted by the International Development Research Centre of Canada (IDRC). Its mission is to promote the use of biotechnology to strengthen the development of regional agriculture and agro industry, increasing its competitiveness and sustainability, while preserving the environment. CamBioTec centres its activities in biosafety, handling of risk and public understanding of biotechnology.

During 1999 and 2000 CamBioTec ushered in a project for the Fostering of Biotechnological Development in the Southern Cone, sponsored by the Canadian International Development Agency (CIDA). The main aim of this project was the transference of management know-how from the Canadian public offices dealing with Biosafety, Risk Management and Public Understanding of Biotechnology to their Argentine and Chilean counterparts. The programme included activities in capacity-building, tutorial training courses in the Canadian Civil Services, and public conferences in Argentina and Chile. On the 24th and 25th of June, 2002, CamBioTec held the International Conference "The Cartagena Protocol and the necessary conditions for its implementation in the Latin American countries" in Mexico City, with representatives from Argentina, Canada, Chile, Colombia and Mexico attending.

2.9 National Expertise on relevant subjects

The development of the regulatory process regarding LMOs in Argentina has resulted in the specialization in the different aspects of farming biosafety of experts who belong to public watchdog institutions, university research and development centres, national R&D institutes and the private sector. This appraisal team is considerable in number and well able to meet the national demand as well as making up a reliable source of cooperation for the development of national biosafety frameworks. It is also giving support to other countries in the region.

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[31] Carullo, Juan C.: *El Punto Focal Argentino de la Iniciativa Canadá-América Latina en Biotecnología, Medio Ambiente y Desarrollo Sustentable*, In the First Joint Meeting of the Ibero-American Network for Biotechnological Relationship and Development (REVYDET) and XVI Programme "Gestión de la Investigación y el Desarrollo Tecnológico", both from the CYTED Programme published in the Technology Management Handbook Nr. 35, Núcleo de Política e Gestao de Ciencia e Tecnología da Universidade de Sao Paulo, CYTED, XVI Programme, 1996

2.10 Foreseeable impact caused by the enforcement of the Protocol

The enforcement of the Protocol will bring about changes in the export and international trading of LMOs in the agriculture sector. Given Argentina's position as a key exporter of LMO by-products, the country will definitely be faced with a serious challenge. It is indeed an awesome question considering that 90% of the country's soybeans and an increasing amount of maize have an LMO origin. The agreement has two trigger aspects which will directly affect Argentine commercial interests depending on the specific characteristics of the product in question.

A survey carried out by the Argentine Foreign Office brings to light some aspects which will be key to the future as regards this issue[32]. The authors have carried out a detailed analysis of the overall international grain market and the Argentine market share thereof. They focused their study on the implications of the introduction of transgenics in the soybean harvest, a crop market that United States of America, Brazil, Argentina, India and Paraguay enjoy more than 95% of the world production.

The Argentine soybean harvest targets three clearly different markets: the soybean itself, soybean oil and soybean meal. Exports of soybean reached 4 million metric tons in 2000, soybean oil climbed to 3 million metric tons in 1999, a figure which placed Argentina as the largest exporter in the world, along with soybean meal which was exported to the tune of 13 million metric tons in 1999. The identification ordinances for LMOs and the by-products thereof could well produce considerable modifications in soybean prices resulting in differentiation between the categories "conventional soybean" and "transgenic soybean". It is indeed hard to predict which would be the market leader and what the trading price would be on the Chicago market.

It is worth mentioning here the future market of the Tokyo Stock Exchange. Historically, there has always been an average price margin of 6.7% with a 10% leeway. The backers of LMOs are confident that transgenic products will be bullish in the middle term. But even if this were true, there would still be a negative trend to overcome created by the consumers restricting the access of LMOs to the market. Meanwhile, price fixing could adopt different characteristics either detrimental or beneficial for LMOs.

In the above scenario, those producers, eager to take advantage of the more convenient prices of conventional crops, will have to guarantee the total absence of even the slightest trace of transgenic material. There will have to be important adjustments in the crop-production chain, harvest-storage-freight-marketing, to assure segregation and traceability of the crop putting into effect the process of preserved identity (PI). PI implies higher production and marketing costs, due to extra human labour in all stages of production: growing and harvesting, storage, freight, tests and processing.

The soybean without processing, that is to say, in bean form, is mainly exported to China, (32%) and EU (34%). In this case, Argentina will have to identify the shipments that "may contain LMOs" and the soybeans will be segregated in "conventional" and "transgenic". The same situation will apply to maize which is exported almost always in grain form. A

[32] Ablin, E. and Paz, S. *Productos transgénicos y exportaciones agrícolas: Reflexiones en torno de un dilema argentino.* Argentine Foreign Office, National Office of Economic Negotiations and International Cooperation, September 2000.

turnabout to a larger "conventional" crop-share will only come about if its profitability can compete with the positive benefit margin currently enjoyed by "transgenics". The benefit-margin of soybeans is estimated in U$S 43 per hectare, due to the fact that "transgenic" soybeans can be grown in ground not apt for "conventional" soybeans. The fact that the above margin does not take into account the additional costs of the PI process shows that the return to "conventional" soybean is highly unlikely. The conditions for the return to "conventional" soybean would have to be either that its price soars or that the market prohibits "transgenics" completely.

In the case of soybean meal, two thirds of the exports are destined for the European Union where it is used as feed, the basic diet for livestock production. Unless, there is an unexpected upset in the general policy in the Union, it is difficult to imagine that the European market could do without the Argentine supply due to the lack of "conventional" soybean on the international market[33]. The European Union does not import soybean oil, while the European oil industry needs raw material for their oil manufacturing and competes in other markets as oil suppliers. Three quarters of the Argentine soybean oil production is destined for Asia, the Middle East and some regions of Africa. In those countries, the consumer demand is not going to fluctuate much whether the product is derived from LMOs or not.

The Cartagena Protocol clearly sets out that risk assessment must be carried out in a scientific way based on available scientific evidence. But the parties can adopt stricter measures always when the actions are consistent with the same objectives. The application of the precautionary approach is extended and risk assessment becomes a subjective decision for each party, with the danger that more protective measures are introduced with evaluation lacking any multilateral control.

With regards to the LMOs, which are to be used directly as food or feed, the Cartagena Protocol opens a door so that those transgenic crops which are destined to be part of the food chain must firstly be segregated and secondly may be identified in detail, according to their origin within the framework known as "traceability". Through a combination of a widened precautionary approach and the putting into effect of LMO traceability, a way is provided to make labelling compulsory for all those products which are processed from said raw materials from the import-export market to the supermarket shelf.

It is true that the transformation, which the soybean undergoes when crushed, would break the DNA chain, making identification almost impossible. Thus a shipment of soybean meal or soybean oil cannot be certified as coming from a genetically modified soybean or not. However, considering that in Argentina today, 90% of the available soybean crop comes from transgenic origin, it would obviously be rather difficult to assert that a normal shipment of soybean by- product has come 100% from "conventional" soybeans. The odds of this being true are very low.

Soybean in bean form is exported for crushing for meal and oil at destination and it is not used as feed in the same form as exported. The processed meal becomes one more

[33] More than 50% of the United States of America production is made up of transgenic crops. Even though there is a ban on LMOs in Brazil, it is well known that in the south of this country, where transgenic seed is smuggled from Argentina, there are extensive areas under these crops, so much so, that the Brazilian soybean production is 30% contaminated by transgenic soybean. See Mr. Ablin, E. and Paz, S. ob cit.

ingredient among the diverse formulas of local feed. Of course, it would also be almost impossible to deny that any animal feed produced using Argentine soybean meal as an ingredient is LMO free.

Japan and the European Union protect themselves behind this criterion to introduce internal norms to ensure the identification of food products which contain LMOs in their local markets. The proliferation of national ordinances concerning labelling adopted since the Cartagena Protocol seems to herald the general practice of traceability and preserved identity as well as segregation of LMO crop markets and by-products containing them.

The vast extensions under transgenic soybeans make irrelevant those outlandish claims that products made from Argentine soybean are LMO free. The obligation to identify soybeans, soybean meal, and soybean oil will not affect these products on the Japanese market, as, even though it is an important market, Argentine imports are currently, in effect, banned there. The trading of large quantities of soybean oil in Asia, the Middle East and Africa will also be unaffected. The reaction of the consumer in these regions would be to discriminate LMOs or oil produced from LM soybeans only if there were, in any way, price alterations.

3.- Application of the The Cartagena Protocol in Chile[34]

3.1 Comparative Synopsis between the local regulation and the Protocol

There are very few norms in the Chilean judicial framework which are directly related to the Articles of the Biosafety Protocol. In general, the norms have been adapted from existing legislation as and when required. Here we will deal with the Chilean regulations, which coincide, in some way, to the different articles of the Protocol. First, the corresponding article of the Protocol will be mentioned and then follows a short report of the national regulations or related projects.

Article 2: General Provisions

Chile is currently working on the development of a UNEP-GEF project which aims to create i) a regulatory system of biosafety, ii) an administrative system, iii) a decision-making system encompassing risk assessment and management, and iv) a mechanism for public information. The Centre of Environmental Law (CDA) of the Law School of the University of Chile has developed, jointly with the Foundation for International Environmental Law and Development (FIELD) of the University of London, a research project aimed at establishing a judicial and institutional framework for biosafety in Chile. This research has been backed by a project entitled "Judicial Aspects of Biosafety and its Importance for Environmental Protection in Chile" and is financed by the Department of Research and Development (DID) of the University of Chile [35]

[34] Gil, L. and Martínez, Víctor: *Regulaciones de Bioseguridad en Chile en el marco del Protocolo de Cartagena*. Work presented in the Conference: The Cartagena Protocol and the necessary conditions for its implementation in the Latin American countries, CamBioTec, Mexico City. 24th and 25th of June 2002.

[35] This was a joint project with the Centre of Environmental Law of the Law School of the University of Chile and FIELD (Foundation for International Environmental Law and Development) of the University of London. It was financed by the Darwin Initiative for the Survival of the Species of the Environmental Department, Transport and Home Counties. It was also backed by the Department of Research and Development (DID) of the University of Chile, titled " Judicial Aspects of Biosafety and its importance for the Environmental Protection in Chile"

In March 2002, CamBioTec, the Chilean focal point, launched the OEA-CONICYT project. The study proposes to develop a multinational plan among Chile, Colombia and Peru aimed at training in biosafety. The first phase will be directed at national policy and regulatory system evaluation, the identification of needs and at the carrying out of a series of training workshops on biosafety on a national level. The General Mission is to draw up specific proposals with a high level of consensus towards putting into effect the Protocol of Biosafety in Chile, Colombia and Peru.

Article 3: Use of Terms

Resolution Nr. 1523 from the year 2001, passed by the Agricultural and Livestock Breeding Service (SAG) establishes in Article 1 some definitions of concepts related to Article 3 of the Protocol on Biosafety:

1) Living Modified Organism (LMO) means "the living biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids that offers a new combination of genetic material which has been obtained through the application of modern biotechnology".

2) Modern Biotechnology means "The application of in-vitro nucleic acid techniques including recombinant deoxyribonucleic acid DNA and direct injection of nucleic acid into cells or organelles or the 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"

Article 4: Scope

Resolution Nr. 1523 of the SAG, in Article 2, states that "it shall apply to Living Modified Plant Organisms for Propagation obtained through the use of modern biotechnology, intended for direct use in the external environment and produced within the country or abroad."

In Article 4, the same resolution states that the SAG must authorize any transboundary movements into the country or any release into the environment of these organisms. This authorization will be given once the corresponding risk assessment has been undertaken by a competent authority from the country of origin and the corresponding report has been made which guarantees that any direct environmental release in said country has not caused any adverse effects. It should be underlined that this regulation governs any type of LMOs and not just those that may have adverse effects for the conservation and sustainable use of biological diversity, which is one of the conditions laid down by the Protocol.

Article 5: Pharmaceuticals

There are no specific regulations for pharmaceutical products derived from LMOs, except in the case of products for veterinary use, which fall under the norms of the SAG. It can thus be deduced that the regulations of the Protocol are not applicable to this type of compound.

Article 6: Transit and Contained Use

In Article 3 of the Resolution 1523 it is stated that "Modified Organisms entering the country or in transit through the country must comply with the plant sanitary requisites established for each case by the corresponding Service". Moreover, Resolution Nr. 1007 passed in 1986 (amended by Resolution 49 in 1993) gives the regional directors of the SAG the authority to prolong the length of time transit goods, which are considered a threat to biodiversity, can be kept in Chilean customs. The restrictive use is regulated by Resolution 1523 which authorizes field trials or multiplication of material by the exempt Resolution 3280 which sets out the conditions for plant sanitary quarantine. (Not specifically intended for LMOs but can be applicable).

Article 8: Notification

Concerning the notification of the Party of Export to which reference is made in paragraph 1 of the Resolution 1523, Articles 29 and 30 lay down the background details which should contain the introduction application form (article 29) and the final report (article 30). This final report, obligatory under the SAG, contains part of the information required in Annex I of the Protocol.

Article 10: Decision Procedures

Referring to paragraph 2 of this Article, Resolution 1523, in Article 23 states that the acceptance or rejection of the application for LMO transboundary movement will be resolved by the SAG either within 45 working days of the date of the closing of the public consultancy stage (15 days from the publication of the application in the Official Newspaper) or as from the date the required report has been completed, whichever is first. There is no mention of any time limit for acknowledgement of receipt of notification or to inform the Information Sharing and Biosafety Clearing House.

Article 11: Procedure for Living Modified Organisms intended for direct use as food or feed, or for processing.

Concerning paragraph 6 of this Article the SAG will only authorize transboundary movement of Modified Organisms once the Risk Assessment has been undertaken by competent authority from the country of origin and a favourable report has been submitted. The risk assessment must show that direct use in the environment has not caused any adverse effect (article 4). The time framework for decision taking is established in Article 23 of Resolution 1523.

With relation to paragraph 9, Chile is currently working on a UNEP-GEF project, the Chilean counterpart of which is CONAMA, which as mentioned above, has as its main mission the laying of the foundations for regulation of transboundary movement and use (production, research, marketing, transporting and surveillance) of LMOs. At the same time, efforts are being made to verify the compatibility of Chilean legislation to international instruments on those issues which Chile has enrolled in or plans to do so in the future.

Article 15: Risk Assessment

Given the importance of developing a solid scientific base, which identifies local risk factors, Chile must broaden its scientific, technological and institutional capacity concerning the subject, as well as improving its ability to coordinate multidisciplinary analysis and to take full advantage of external resources. What is particularly relevant is the ability to analyse the eventual impact of the introduction of LMOs on the country's ecosystems, including the effects on cultivated crops and human health. It is also important to evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biological diversity.

The Advisory Council for Transgenic Release (CALT) carries out scientific and technical risk analysis with the aim of authorizing LMO field trials. This analysis is undertaken with molecular biological techniques and attempts to identify possible effects on the environment such as the introduction of aggressive species and cross pollination, among others. It is hoped that the LMOs introduced will not affect the biological diversity and will not be pathologic for agriculture. This analysis is being undertaken by CALT, case by case, and is supported by experts in each area.

Within the legal framework of CALT, Resolution 1523 -articles 28, 19 and 30 (Annex 2)- is included. In these articles, the information required in the application form regarding introduction of LMOs into the environment is indicated, as well as the complementary information to be presented for evaluation by the SAG, and background details that must include the final report regarding the condition of the transgenic material.

Article 16: Risk Management

As regards risk management and decision-making, it is very important to be able to determine and quantify not only the identified risks but also the effectiveness of the adopted measures including the application of the precautionary approach. Thus, in this context, it will be necessary to install follow-up and evaluation mechanisms to supervise and report back on planned and unplanned environmental effects. This implies being able to rely on the technological resources to identify and monitor imported LMOs, that is to say, equipped laboratories and training in the use of analytical techniques. On a lesser scale and expense, will be the task of evaluating the application of risk management instruments in the diverse sectors of biotechnology.

In Chile, it is hoped to combine the national capacity to take decisions and risk management with the regional capacity in risk assessment. This will mean that the different needs particular to each region and stemming from geographical diversity will be dealt with separately. Each centre of origin of species and biodiversity should be strengthened and should generate national coordination capacity on a long term.

Article 18: Handling, transport, packaging and identification.

The Health Regulations for Food set the sanitary conditions which govern production, importation, elaboration, packaging, storing, distribution and marketing of food for human consumption. These norms guarantee the correct food properties and safety standards and hence the general health and nutrition of the population. Apart from the historical details

as in the Health section, with respect to paragraph 2a), as well as article 3 with the preliminary title Regulations mentioned above, the Food Code (Códex Alimentarius) should be mentioned as it establishes a framework for the evaluation of food harmlessness and sets out a criteria for testing the wholesomeness of food coming from LMO crops, which have not of yet been put into effect. The procedure, step by step, examines the following relevant factors:

- Description of new variety
- Description of the base crop and its use as food
- Description of donor organism or organisms
- Description of genetic modification or modifications
- Characteristics of genetic modification or modifications
- Evaluation of Harmlessness
- Expressed substances (substances different from nucleic acids)
- Analysis of essential components
- Metabolites Evaluation
- Food elaboration
- Nutritional modification
- Further considerations

With respect to paragraph 2 b) the Ministry of Health aims to put into effect a "Declaration Form for LMOs for contained use", which provides all the necessary information concerning identification, handling, etc. As regards paragraph 2c), the National Fisheries Service, dependent on the Ministry of Economy, relies on the Supreme Edict Nr. 320/2001, which sets out the Environmental Regulations for the Fishing Industry. This ruling forbids the growing of LMOs unless given the express authorization of the Under Secretary.

Article 19: Competent National Authorities and National Focal Points

The National Commission for the Environment (CONAMA) acts as the Chilean Focal Point on behalf of the Protocol on Biosafety. The main functions of CONAMA[36] are: to propose to the President of Chile the environmental policies for the government, to periodically report on the fulfilment and application of enforceable environmental legislation, to act as a consulting, analysing, communication and coordinating body, in all matters related to the environment, to maintain a national system of regional environmental information for the public, to administer the system of environmental impact assessment on a national scale, to coordinate the process of creating environmental quality standards and set out the programmes for fulfilling them, to work with the corresponding authorities in the preparation, approval and development of media educational programmes aimed at instigating national conscience in environmental protection, the preservation of nature and the conservation of environmental patrimony and to promote citizen participation.

They also carry the responsibility of coordinating the competent authorities in those fields related with international support for environmental projects, and to work alongside the International Cooperation Agency of the Ministry of Planning and Cooperation as a national counterpart in environmental projects with international financial backing, to give

[36] Article 70, Stat 19,300

financial support to projects and activities aimed at the protection of the environment, the preservation of nature and the conservation of environmental patrimony, and to undertake the roles the legislation vests in it.

This institution is responsible for proposing the national environmental policies and to inform the President of the enforcement and fulfilment of all legislation relevant to the environment. The mission of CONAMA is to promote the environmental sustainability of the development process, and to coordinate those activities deriving from the policies and strategies defined by the government on the environmental issue. Some of their main objectives are the recuperation and improvement of the quality of the environment, the prevention of environmental deterioration, the fostering of the protection of the environmental patrimony, and the sustainable use of natural resources. The Organic Law Nr. 119.283 of the Agriculture and Livestock Breeding Service (SAG) states that this organization should certify whether raw agricultural products for export are fit for human consumption. As such, CONAMA should be considered as a national authority competent in determining whether products are suitable for human consumption.

Article 22: Capacity-Building

The project UNEP-GEF, similar to the one carried out jointly by CamBioTec and the OAS, considers, among its objectives, capacity-building in strategic areas.

Article 23: Public Awareness and Participation

Regarding this point, Law 19.300 on Environmental Bases states in Article 4 that "It is the duty of the State to facilitate citizen participation and to promote educational campaigns aimed at the protection of the environment". Article 6, goes on to say that "The educational process, in its different levels, through the transmission of knowledge and the teaching of modern concepts of environmental protection, should foster awareness and understanding of environmental problems. Education should encompass the values and the development of habits and behaviour patterns which lead to the prevention and solving of environmental issues".

Public participation in the Evaluation System for Environmental Impact (SEIA) can be found in detail in Section II paragraph 3 (articles 26 to 31) of the Law 19.300. Even though it does not specifically refer to projects involving genetically modified organisms, they could come under the umbrella of SEIA if they generate the environmental effect described in Article 11 of said legislation. Resolution 1523 contemplates public consultancy within the process for applying for confinement or introduction of genetically modified organisms. For a period of 15 consecutive days, after the date of publication of the application form in an Official Newspaper, observations and comments related thereto can be registered in written form.

3.2 Needs and Opportunities for Capacity-Building

The lack of norms in Biosafety is not the only shortcoming in the Chilean system. There is an urgent need for capacity-building in human resources, mainly in public services, which are in charge of the effective use of legal and administrative instruments. The loan from the Inter American Development Bank considers, within the programme of technological development in the forestry, agricultural and fishery department, a budget of 5.7 million

dollars for the training of human resources in these fields. This shows the deep interest there is to have skilled professionals in the biotechnological sector.

The capacity-building programme undertaken by the UNEP-GEF is yet another example of training activities to which Chile has easy access. Within the activities programmed for the year 2002, there is a series of 12 workshops which will be held in 6 sub regions as from September 2002. The issues to be dealt with are: Risk Assessment, Public Awareness, Regulatory Systems and Administrative Tasks.

The recent new Programme for Technological Development and Innovation 2001-2004 of the Chilean Genoma, aims at tacking problems of social and economic impact, with the development of awareness and technologies in genomics, proteomics, and bio information. One of the missions of the programme is to encourage the interchange of knowledge and capacity among various scientists from different Universities and to create the opportunity for interaction between the academic and business worlds. It is also of utmost importance to be able to rely on experts in risk assessment, associated with LMOs who are capable of identifying the potential risks and benefits of transgenic food.

In the year 2000, it was estimated that the total number of scientists in Chile was more than 4.300, of which only 14.4% worked in biology. This would indicate that, not only is there a need to train public civil servants but also there is a need to guide professionals towards research. It would also seem necessary to broaden the minds of the critical masses towards the development of biotechnology throughout the country. With the aim of improving skills in priority areas, it would be advisable to increase basic training in the fields of genomics and proteomics. It would also be very useful to organize courses, workshops and activities in laboratories, in foreign developed countries, on different techniques, such as transformation, cloning, direct mutant genetics, cell fusion and specific methods within physics, such as the "gene-gun"

3.3 Evaluation of the Existing Biosafety Infrastructure

The main shortcoming in this area is the very weak infrastructure in research and development, mainly in the field of molecular biology and genetic engineering. Various governmental initiatives, with financial backing by the BID, aim to reverse this situation but considering the high sums of investment required, it is fundamental to study alternative financial formulas. The infrastructure destined for biosafety is scarce and sadly lacking. There are very few centres with the necessary equipment and human resources to be able to deal with the high demand stemming from the certification of transgenic content of food. The option that the Public Health Institute authorizes private laboratories with the credentials to act as referees as regards the certification of transgenics required in Chile and abroad should be considered.

The creation and use of a database system is also very deficient. In the case of documents related to biosafety, there is no standardized procedure which allows easy access to data. Furthermore, in some institutions there is not even an electronic register of this sort of data, which makes the passing on of relevant information to the Information Sharing and Biosafety Clearing House almost impossible. It is therefore of primary importance to establish standard procedures for information storage and criteria for registration. To this end, the personnel of each institution should have the electronic know-how and necessary register-handling skills. These measures would facilitate the sharing of information with

the Protocol Secretariat and the other parties of the Convention, as well as ensuring the smooth running of procedures, should immediate action be required under certain circumstances.

The National Commission of Environment (CONAMA), focal point in Chile for the Biosafety Protocol, does not have a task force dedicated full time to this issue. At the moment, the responsibility rests on the shoulders of one single person and, considering the importance of this subject for the future economy of the country, it is imperative that a group be formed to deal exclusively with the point in question.

3.4 The Precautionary Approach and Socio-Economic Analysis

The precautionary approach is a useful instrument for the protection of biodiversity and for its sustainable use; however, its inclusion in biosafety standards is a complicated matter. There is no tradition regarding the use of this approach in Chilean biosafety legislation, neither is there a clear stance concerning the definition of the term. This lack of experience could well lead to an important drawback in international trade when the precautionary approach is incorporated in legislation and if a rigid position regarding the issue is adopted. In this scenario, good evaluation and advice from those countries which have been able to integrate the approach with well-articulated commerce, would be desirable. They would be able to show, from experience, how a precautionary approach while strict enough to protect the existing biodiversity can also be quite flexible in its application.

To conclude on the subject of the Precautionary Approach, it may be considered more convenient to incorporate the concept of precaution into the Chilean legislation as an approach rather than a general principle of law, given that the Precautionary Approach is limited to environmental subjects and does not have such a generalized scope. It is absolutely essential to base the citing of the precautionary approach on previous risk assessment, backed by scientific evidence which allows identification case by case of those risks the effects of which cannot be determined. If there is not enough scientific evidence, exceptional provisional precautionary measures can be enforced and later endorsed subject to review.

The socio economic analysis of the impact produced by the introduction of transgenic crops or marketable goods is yet another neglected area in Chile. At the moment, the lack of a definite methodology to analyse the socio economic impact of those actions is holding up the resolution of the commercial applications handled by the SAG. Consequently, impact analysis is not required when submitting requests for the introduction of LMOs. The SAG does not have sufficient personnel, or resources to be able to conduct such studies. The alternative is to hire a foreign advisory institution which could contribute knowledge and experience in this area. The national body SEIA (Evaluation System of Environmental Impact) could well serve as a base for adopting the proposed models.

3.5 Communication with Society

Another important point on the agenda is to improve public understanding of biotechnology. According to a recent study, Chile is in second place worldwide as regards

a negative public view of biotechnology and transgenic food[37]. This study reveals the most important aspect which should be receiving better information diffusion and shows the need to generate public interest on these topics, given that the scientific community counts on public funding for research. A group programme for effective communication should be established within society. This project should be undertaken by those public bodies related to the issues, universities and private organizations which represent producers and consumers.

It is of the utmost importance to be able to rely on a well-informed consumer who can tell the difference between solid scientific evidence and sensationalist commentaries. In this matter, the mass media of communication plays a crucial role. The published material concerning transgenic food should be objective, presenting both sides of the debate and be previously endorsed by experts. It is not productive to try and convince the public of a certain aspect of biotechnology if not to give them true and impartial information concerning the potential risks and benefits linked to the matter.

Basically, the first and foremost priority is to educate those in charge of mass communication media through courses and specialized workshops. The idea is to create a "scientific journalist" who is able to handle scientific terms and to translate those most important concepts into language that a man on the street can understand. At the same time, the educational institutions, schools and universities, also have much to offer. The subject of biotechnology should be included from the early ages of schooling, with the background theory didactically interspersed with the everyday use of biotechnology.

University career courses should include in their study plans those aspects of biotechnology related to each profession. In this way, the communication amongst the different protagonists will be smoother and more efficient. Within the issue of public understanding, the formation of human resources also plays an important role. The training of civil servants in the field of biosafety should instigate an increase of public trust in the regulatory and fiscal institutions, thus facilitating the spreading of information through governmental communication campaigns.

3.6 Future Tasks

Chilean biosafety legislation is at a stage of full development and the studies, which have been carried out to gauge the current situation, have been extremely beneficial in identifying the main shortcomings therein. This aspect should be solved as soon as possible so as to be able to rely on a solid framework which would allow progress in areas such as infrastructure, capacity-building and formation of human resources. Foreign consultancy is seen as the most practical and feasible means to aid the setting up of national frameworks which would hence allow the country to work independently.

Chile is far from fulfilling the basic requirements for the effective implementation of the Biosafety Protocol, but the increasing importance given to the subject on the governmental agenda and other initiatives, such as those from the Centre of Environmental Law in the University of Chile and CamBioTec, reflect that efforts are being directed towards the foundation of a national policy in biotechnology. This policy should include political,

[37] Gil, L and Irarrázabal, C. (Editors): "*Organismos Genéticamente Modificados: Producción, Comercialización, Bioseguridad y Percepción Pública*" CamBioTec, Chilean Focal Point

social, ethical, health, and environmental aspects and should be set within a Biosafety regulatory framework in keeping with the Cartagena Protocol.

4. Application of the The Cartagena Protocol on Biosafety in Colombia[38]

4.1 Comments on Biosafety Legislation in Colombia

Colombia has a great many norms which are directly or indirectly related to the issue of biosafety. The majority of these norms are not specifically or concretely aimed at regulating the topic in question, if not exactly to the contrary, they are the results of isolated ordinances which seek basically to regulate other areas related to environmental issues and to biological resources.

The dispersion and fragmentation of current legislation means that it is extremely difficult to enforce. Many of the dictates are not carried out given the confusion rife amongst those who are responsible for the keeping of the ordinances. There should be integration among those sectors involved: health, agriculture, environment, industry, foreign trade, etc. At present, regulations are divided by each of these areas in an isolated and unconnected way, which leads to restricted application in each sector. This situation tends to create gaps which in some cases are filled by new ordinances which are added to the ever-growing list of regulations on the subject. The same unorganised situation can be found in the definition of terminology and concepts, given that each sector defines terms depending on their own biased interpretation and according to the context. There is often, therefore, an overlap of expressions and interpretations of the same term, which causes misunderstanding and greatly impairs efficiency.

The term biosafety is not clearly defined in Colombian regulations. The only definition is restricted to the effects of the Resolution C3492 of 1998 "through which procedures are regulated and established for the introduction, production, release and commercialisation of LMOs". This Resolution refers only to the handling of plant LMOs in agriculture.

Over the recent years, international pressure and commitments have led to the reviewing and updating of certain ordinances. Resolutions have been established with the objective to guarantee development in keeping with the normal international framework. Such is the case with Agreement 0013, which created the National Technical Council (NTC) for agricultural biosafety; the Resolution C3492 which governs the LMOs for agricultural use, and the enforcement of the new Colombian Penal Code, which in Article 330 refers to the handling and experimentation of these organisms. Since October 2001, biosafety regulations for LMOs have been in force for the fisheries sector. The country is responding to biotechnological advances and to international commitments.

In specific relationship to the Cartagena Protocol, the regulations for the creation of the National Technical Council (NTC) and the ordinances related to the use of LMOs in agriculture and fisheries contemplate and follow, in general terms, the articles of the Protocol, especially in aspects such as aims, general guidelines, procedures, and risk

[38] Hodson de Jaramillo, E. and Forero Ruiz, A.: *Regulaciones de Bioseguridad en Colombia en el marco del Protocolo de Cartagena,* Work presented in the Conference: The Cartagena Protocol and the necessary conditions for its implementation in the Latin American countries, CamBioTec, Mexico City. 24th and 25th of June, 2002.

assessment and management. Some points not considered in current national legislation, such as the issues related to information sharing, capacity-building and other general international aspects should be dealt with aside at another opportunity.

4.2 Comparative Synopsis between the Protocol and the Colombian Regulation

General considerations, aims and general guidelines covered by the Cartagena Protocol can be found in the Colombian legislation: in the Political Constitution of Colombia, Articles 80 and 81; Penal Code/01, Chapter VIII; Statute 2811/74 Code NRNR; Law 999/93 MMA Article 1.5; Law 101/93 Development Agriculture and Fisheries; Law 165/94 CDB, Article 8, 9; Law 299/96 (flora), Article 10; Statute 1753/94 modified by Resolution 655/96, environmental licence; Agreement ICA 0013/98, Resolution C3492/98 LMO agriculture.

The Scope of application: even though it is described in each ordinance, and even though the general guidelines and the definitions are linked with the Cartagena Protocol, care should be taken that the articulation among the different sectors (Agriculture, Environment and Health) be as smooth as possible, without leaving gaps.

Competent National Authorities and National Focal Points: these are clearly defined for the agricultural and fisheries sector (ICA). Other sectors still lack definitions.

Transit and confined use: this is clearly set out for the Agricultural and Fisheries sector (Colombian Institute for Agriculture and Fisheries – ICA)

Advance Informed Agreement: this is mentioned in Article 19 Law 165/94 related to the Convention on Biological Diversity; considerations and procedures can be found in the current regulations of the ICA.

Notification: this is mentioned in ICA Procedures

Decision procedure: Law 165/94 Article 10, Chapter V ICA Procedures

LMO intended for direct use as food or feed or for processing: this can be found in ICA Procedure Article 16.

Risk Assessment and Management: Articles 8 and 9 of the ICA Regulations, Law 165/94 deal with this point.

Unintentional Transboundary Movements and Emergency Measures: this point is contemplated in the Regulations of ICA. Definition is lacking in other sectors.

Handling, Transport, Packaging and Identification: (labelling) this is mentioned in Regulations of ICA, articles 11 and 27 for agricultural use. Definition is lacking in other sectors.

Confidential Information: Articles 17, 18 and 19 of the ICA Regulations, covers this issue.

Illegal Transboundary Movements: Section XI of the Penal Code, Regulations of ICA, Articles 23 and 24 deal with this issue.

Socio-economic considerations: this is covered by ICA Regulations - Articles 14 and 15.

Liability and Redress: Law 99/93, Articles 1, 84 and 85 as well as ICA Regulations, Article 24 deal with this topic.

4.3 Aspects of the Cartagena Protocol not included in regulations

The main aspects of the Cartagena Protocol not contemplated by the Colombian legislation or ordinances are the following:

- Bilateral, regional and multilateral agreements and arrangements.
- Information Sharing and Biosafety Clearing House
- National Focal Points
- Capacity-building, education, public understanding and participation
- Financial mechanisms and resources
- Non Parties
- Conference of the Parties
- Subsidiary Bodies
- Secretariat

4.4 Aspects of the Cartagena Protocol included in regulations

The main aspects of the Cartagena Protocol, which are included in the Colombian legislation or ordinances, are the following:

- Advance Informed Agreement
- Precautionary Approach
- Regulation for introduction, transport, use, handling, production, release and commercialisation of LMOs for use in agriculture and fisheries.
- Case by case risk assessment.
- Labelling

5.- Application of the The Cartagena Protocol on Biosafety in Mexico[39]

The adaptation of Mexico to the Cartagena Protocol poses a very particular situation. From the point of view of biodiversity, Mexico is one of the richest countries in the world. Within its borders, there are five ecosystems, 9 of the 11 different habitats and 51 of 191 eco-regions which exist on earth. Of all known earth plant species, 10% can be found in Mexico and it also has the largest diversity of reptiles. In the world, it rates second in different mammal species and fourth in amphibians. Mexico enjoys great biological diversity, a great deal of the species found in the country are exclusively local to that region. The country is the place of origin and diversification of many crops, in fact, today

[39] Saad, Isabel: *Las repercusiones para México del Protocolo de Bioseguridad de Cartagena*. Work presented in the Conference: The Cartagena Protocol and the necessary conditions for its implementation in the Latin American countries, CamBioTec, Mexico City. 24th and 25th of June, 2002.

in Mexico, 259 different species of agriculture crops are cultivated for commercial benefits, while 300 more are in initial stages of development. This Central American country has been endowed with 100 different native species of edible wild plants and an accompanying reservoir of useful genes which are indispensable for the conservation of those species. The cultural diversity is also exceptional, with more than 50 different ethnic peoples living there.

The climatic, biological and cultural diversity is reflected in Mexican farming, where there are three very different agricultural sectors with very diverse cultures, needs and interests. Firstly, the traditional Mexican farmer using old fashion farming technology, sowing local varieties and depending on natural climatic cycles; secondly, an intermediate sector, which uses farm techniques from the "green revolution", such as artificial irrigation and improved seeds, and lastly, a sector using high technology, aimed at high-economic-yield crops with productivity and quality standards compatible to the first world. This sector buys seeds with high technological back up on the foreign market and has access to international credit.

An important part of Mexico's future lies in its ability to acquire, adapt, develop and take advantage of new products and processes stemming from biology. Mexico has a double challenge, to conserve the enormous biological variety within its territory, while, at the same time, reaping full benefits from this diversity. As a country with a mega-diversity of native plants and a rich genetic source for cultivated crops, it must tread very warily when contemplating which LMOs to import and which are to be produced within its frontiers, developing specialized skills needed to handle and control them. Mexico cannot afford to turn its back on LMO technology.

Even though the Protocol chiefly deals with international commerce, it obviously does have some repercussions on internal regulations and LMO control, because most of the transgenic organisms and their by-products reach Mexico from abroad. In keeping with Protocol commitments, Mexico must establish a complete biosafety legislative framework, and delegate the corresponding authority to competent organizations so that they can put it into practice. A national centre of biosafety information must be created and general regulation policies concerning the handling of LMOs established. The success of the above rests on two basic premises: firstly, public consensus in favour of the use of LMOs in Mexico, and secondly, human and institutional capacity -building.

5.1 Paving the way for the implementation of the Protocol

Mexico must define its position regarding the following points related to aspects of the Protocol [40]:

- Which institution will be the National Focal Point?
- Which will be the National Authority competent enough to be in charge of administration aspects?
- Will the procedure for application be ruled within a national ordinance framework, or under the procedure set down by the Protocol?

[40] See above footnote 39

- In its role as a centre of genetic origin and diversity of crops, will Mexico expect some kind of preferential treatment (stricter legislation, longer terms, technical support, and /or financial backing for special research)?
- Will Mexico be seeking financial and technical aid for the creation of specialized institutional and human capacity-building?
- Will Mexico be expecting the importer to cover risk assessment costs?
- How will the precautionary approach and socio-economic analysis be put into practice?
- What will be Mexico's position with respect to the points of the Cartagena Protocol which still have to be defined? Furthermore, how will national viewpoints be consolidated?

5.2 Characteristics of current biosafety legislation

In Mexico, biosafety regulation is still in the pipeline, and the gaps, which are caused by lack of legislation, tend to hold up the use and marketing of certain products which are required by various industries. In some cases, there has been rigorous risk assessment while some activities have been overlooked, without effective control, thus putting in risk the ecosystem balance as well as human and animal health. An obvious example is that of the use of micro organisms for bioremediation of land and continental water bodies, there is no legislation to impede indiscriminate spraying or spreading nor is it clear which is the competent authority to deal with this issue.

The biosafety legislation does not set out a coordinated regulatory code, rather a series of unrelated independent processes based on various different approaches. This results in procedures with very different requirements, bureaucratic paper work, limits and prohibitions, and vague aims and objectives, which are, as such, wide open for diverse interpretation. Perhaps, the best way to tackle this situation would be to work on a double track. On one hand, complete and amend existing legislation in each regulatory area, where and when necessary, while at the same time, create a general biosafety ordinance which would lay down general guidelines, mark out the jurisdiction of each of the different federal governmental agencies, set out an overall code of infringements and sanctions and establish a basic system of information coordination. Finally, a competent regulatory authority would be instituted.

The general guidelines for the elaboration of biosafety legislation should not forget that members of advisory committees must receive economic benefits and enough free time to be able to carry out evaluations. Financial resources must be designated to the system taking advantage of institutional capacities, the experience of the existing human resources, and assuring motivation of all sectors involved.

5.3 The gaps in regulation

The enforcement of the Cartagena Protocol on biosafety in Mexico will require the elaboration of three types of ordinance: the nomination of competent authorities in each of the corresponding sectors and an institution to represent Mexico which should endorse, in each of the administrative areas, the pertinent decisions after previously informed consent

and socio-economic study, the official drafting of Mexican norms to regulate contained trials and the marketing of those products which have been evaluated in field trials.[41]

There should also be regulations over products destined for agricultural use (symbiotic micro organisms, biological control agents, bio pesticides, bio fertilizers and plant hormones, etc.) It would be a good opportunity to regulate the following issues:

- Field trials and the marketing of transgenic animals
- Veterinary products (vaccines, hormones, feed supplements, medicines, etc.) including import and export.
- Micro organisms and plants used in environmental bioremediation, including the transboundary movement of these products.
- Statutes which specify how precise the information, which is presented by the applicant, must be.
- Ordinances referring to labelling of products in the areas of transgenic plants, transgenic animals, products for agricultural and veterinary use, and products for bioremediation.

Health regulations already specify that permission must be obtained prior to importing biotechnological products and the corresponding time limits are governed by the Protocol. In the agricultural area, it is also necessary to have prior certification. The main problem lies in those areas which still lack the necessary regulation, that is to say, animal health and the use of micro organisms in environmental bioremediation.

The precautionary approach has always been a follow-up in those areas where regulation exists. The problem, once again, arises from those aspects not covered by applicable legislation. In order to determine the scope that such regulation should have in each of the corresponding areas it is crucial to establish general policies. While this happens, Mexico could temporarily adopt the articles of the Protocol. Given that the country has the characteristics of a centre of biological diversity, it is convenient that it has its own legislation to authorize or not the importing of LMOs into the country.

5.4 Competent National Authorities

In Mexico, there are two types of institutions in charge of biosafety. Firstly, the offices of the Secretaries of Health, Agriculture and Environment, which are in charge of the administrative paper work involved in the evaluation of LMOs. They strive for environmental balance, and the upkeep of human, animal and vegetal health-standards laid down by federal and general laws and regulations. Secondly, the Inter-Secretarial Commission on Biosafety and Genetically Modified Organisms (CIBIOGEM) which is a federal commission created by presidential decree in November 1999 [42]. The job of the commission is to coordinate the federal administration policies, concerning the biosafety of Genetically Modified Plant Organisms (LMOs), their products or by-products. This

[41] There is a Mexican Draft Bill of Law NOM—FITO/ECOL-2001, Requirements for the transboundary movement and introduction to the environment in pilot programmes of genetically modified organisms destined for agricultural use and for commercial ends.

[42] The Official Journal of the Secretariat of Agriculture, Livestock and Rural Development. Agreement by which the Biosafety and LMO Inter Secretariat Commission was created. Friday 5th of November 1999

includes movements (whether transboundary or internal) reproduction, consumption, use and exploitation.

The specific tasks delegated to the CIBIOGEM through the presidential decree are:

- Draw up national policy on the subject
- Update judicial framework
- Budget official regulations
- Lay down the adequate criteria for the requisites to obtain licences, permits and authorizations.
- Make out a system of registration of LMOs
- Promote alongside the CONABIO studies of distribution of wild species, directly related to cultivated crops,
- Establish mechanisms of evaluation and monitoring of the impact that open-air release, production and consumption of LMOs may have on the environment, and /or human, animal and plant health.
- Recommend criteria for public diffusion
- Recommend research projects of national interest
- Propose programmes of technology transfer
- Designate, with the cooperation of the Foreign Office, the delegates and representatives for Mexico in the field of biosafety.
- Promote the systemization of relevant information, nationally and internationally.
- Establish their own self-governing regulations and the Statutes of the National Advisory Council of Biosafety.

CIBIOGEM, created by a presidential decree, has three backup organizations: the Biosafety Advisory Council, comprising outstanding scientists, a Technical Committee [43] of competent civil servants, chosen by the Ministers of the different Secretariats, and Technical Sub Committees created to deal with specific issues. The Technical Committee is coordinated by an Executive Secretary who must be a specialist on the subject and nominated by the Inter- Secretarial Commission.

5.5 The Socio-economic impact

The ordinance of the Cartagena Protocol in relation to socio-economic considerations to be taken into account in the decision-taking process about the LMOs can be found in only one article, Article 26. In this respect, there are three relevant aspects that countries should consider when reaching a decision on import: the decision must be compatible with international obligations, special attention must be paid to the interests of ethnic and rural communities, and finally the socio-economic factors must be kept in mind.

What is not very clear is how these ordinances should be put into practice. The text of the first paragraph seems to be dealing with economic effects of the impact of LMOs on the biological diversity. However, it is hard to believe that this is the intended meaning of this text, because the direct impact on the ecological balance would only provide a reason for denying permission for the import of any organism. The text should be read as referring to the economic effects per se, involved in the importing of a transgenic organism.

[43] The Technical Committee was established on the 10th of February 2000

The mention of ethnic and rural communities reflects that there is an intention to consider how the impact of the introduction of transgenics could affect social groups, and there would seem to be special consideration for those sectors which are the most vulnerable. In terms of equity and social justice, one of the main problems is that those poor country people who live on the margin of development do not have access to new technology.

Apart from the considerations regarding safety of products, there cannot be a special legal code for biotechnology and another for the rest of the other technologies. Those licences to produce and trade goods, produced by means of other technology anywhere in the world do not take into account what would be the economic area of impact. This should not be the interpretation of Article 26 of the Cartagena Protocol. All technologies, whether biological or not, when utilised are bound to affect vested interests. While some businesses are affected, others appear and in the long run they become stable.

The introduction of biotechnology can doubtlessly lead to new industries, creating new jobs and new opportunities for trade, thus bringing prosperity to a country in the long term. Being isolated and not having taken any active role in the international community, has made it harder for Mexico to be able to solve the country's technological problems. The progress in agro research and development has been driven by investment in the private sector.[44] To block the import of new biological technology on the grounds of social injustice would put Mexico at a grave disadvantage on the worldwide free-trade market place. It would also widen the gap between Mexican technological capacity and that of the developed world; even more so, if one considers that the internal biosafety legislation encompasses not only imported products, but also national biotechnological breakthroughs.

The development of a technology also depends on the socio economic context in which it occurs[45]. Apart from the technical facet biotechnology carries a social aspect which is reflected in the technological development objectives it wishes to foster. Socio economic data should only come into play for the authorization of imports, release into the environment and the introduction into the market of those LMOs which would bring clear benefits for the country overall.

The use of living modified organisms, and their introduction into the environment, will always involve a certain risk, especially if the planned location of release is a centre of biological mega diversity and origin of species and has a wide variety of crops. Such is the case of Mexico. Notwithstanding, during the experimental stage, if there is no evidence of harm to human health or to the ecological balance, risks can be taken if two indispensable conditions are met: there must be, firstly, true handling skills, including human and institutional capacity with adequate infrastructure, and secondly, broad social and/or economic benefits.

As Mexico is a centre of diverse biology and an emerging country, resources should not be spent on evaluating the impact on the environment or on human health of those LMOs which are not indispensable for the country or those not required by a certain Mexican production sector. The socio economic evaluation of any project should be carried out first, and then, only if it is meaningful for the country, should the risk assessment be made. The final word on whether to import, to authorize external release and/or to trade LMOs

[44] Visser B. (1998) Effects of biotechnology on agro-biodiversity. Monitor. Nr. 35, June
[45] Biotechnology and Development Monitor. Nr. 35, June 1998.

lies on the risk/ benefit ratio. As such, authorization will only be granted when the benefit is greater than the possible risks; if there are no benefits, then there will be no authorization.

Risk management is an important factor in the decision-taking process that should be considered along with such questions as the economic implications and cost/benefit analysis. Decisions should be taken on a case-to-case basis. Recently, there has been increasing consensus to take into consideration social, cultural and ethical aspects in the decisions concerning risk management.[46]

Whether it is convenient to use LMOs or not depends to a great extent on the institutional capacity to effectively carry out the following tasks: to evaluate each product, to monitor field trials, to oversee facilities, production procedures, research and trading, to ensure the fulfilment of current legislation, and to be able to deal with unforeseen emergency situations. In Mexico, there are very good biotechnologists, molecular biologists, genetic engineers, geneticists, ecologists, but unfortunately, there are very few biosafety experts.

The ability and efficiency to handle LMOs largely depends on institutional capacity-building in three main areas: the development of viable procedures and hands-on experiences, the drafting of a complete and workable ordinance, and human and technical capacity-building. The first two areas should be based on an interactive process construed from the experience and the interaction of the players.

The socio-economic study requested in the Cartagena Protocol should contain, in the case of Mexico, enough information to be able to compare the situation of the country prior to the adoption of technology, with that of the immediate future (1 to 3 years) after its implementation[47]. Information that could be included in these studies involves:

- The mock-up of different scenarios within a future socio-economic context.
- A description of the phase of technological development of those industries involved.
- Identification of technical, social and economic barriers towards the use of said technology.
- Identification of the areas that may receive positive or negative impact due to the introduction of the technology.
- Identification and description, on a quantitative scale, of short, medium and long term effects in certain areas.
- Identification of possible courses of action to enhance the positive aspects of technology and to minimize the negative ones.

5.6 The right to know

One of the most important features of the evaluation process is that it should assure the public as well as the importing countries that all the relevant aspects of analysis are being

[46] Byrne, J. (1995) Dealing with Socio-economics Surrounding Biotechnology in the Canadian Federal Government. In: Assessing the Impacts of Agricultural Biotechnology's Canadian-Latin American Perspectives (Herbert-Copley, B., ed). International Development Research Centre, Canada, pp 79-91.

[47] Burnquist, H (1995) Biotechnology and Agriculture in Brazil: Social and Economic Impacts. In: Assessing the Impacts of Agricultural Biotechnologies. Canadian-Latin American Perspectives (Herbert-Copley, B., ed.) International Development Research Centre, Canada, pp 79-91

considered. It is very necessary to have on hand the relevant data of field trials which have been carried out, that is to say, who requires them, which are the species involved, which are the new characteristics, and the general results of the studies undertaken. All this implies efficient information gathering and analysis processing, with the respective software and skilled personnel to take advantage of the infrastructure to the full. Information should be gathered in a national information sharing and biosafety clearing-house. A feasible alternative would be to name the CONABIO as the said authority, as it currently represents Mexico before the Convention on Biological Diversity and it has a data bank on biological diversity in Mexico. In that way, the infrastructure and experience of this entity would be used to its full capacity.

6.- Use of the UNEP Programme of technical assistance: the case of Bolivia[48]

6.1 Objectives and Development of the Project

The project was aimed at encouraging the participation of the institutional players in the sectors directly involved in the management of biosafety and biotechnology, coordinating their work with the scientific capacity available in Bolivia. Through this project, a diagnosis of the situation and safety of biotechnology in Bolivia was made, thus bringing to light the potential pros and cons of establishing a National Strategy on this issue. From the institutional viewpoint, a National Committee on Biotechnology and the Bolivian Biotechnology Network were organized, with the support of international experts from Argentina, Cuba and United States of America. A case-by-case risk assessment system was established, and specific protocols for each case were drafted.

Various workshops were held on evaluation criteria and on the identification of priorities and needs for risk assessment. The first meetings of the National Committee on Biosafety were held. These events triggered discussions on these issues at national levels, with public participation. However, it was not possible to establish a legal institutional framework, nor give continuity to those activities. It is hoped that future efforts to adapt the country's regulation to the Cartagena Protocol will enjoy greater support and participation.

6.2 Some pertinent comments

The main difficulties encountered were in the field of human and institutional resources, where there was a lack of national capacity regarding technical and legal matters for the management of biosafety. Another stumbling block was the inopportune change of government at a time when the structure for biosfaety management had not then been consolidated. The main lessons to be learnt are: a) good management of biosafety requires a high technical capacity in molecular biology and risk assessment, b) close coordination among the institutions involved, such as Environment, Agriculture, Industry and Commerce, Health, Foreign Affairs and Universities.

In conclusion, the process of the application of a national norm on biosafety has found new strength, and the gaps and weaknesses have been identified, thus facilitating future

[48] Zapata Ferrufino, Beatriz: UNEP Pilot Biosafety Enabling Activity Project: Bolivia Enabling Activity 1998 – 1999, General Office of Biodiversity, Ministry of Sustainable Development and Planning, Buenos Aires, 8th to 10th of May 2002.

progress. A preliminary diagnosis of the situation of biosafety and biotechnology has been made, a National Strategy on Biosafety has been approved as part of the National Strategy on Biodiversity, the different tiers of the decision-making process are aware of this issue and a little capacity-building within the critical mass directly involved in the management of biotechnology has been achieved.

By starting off on the wrong foot, the public perception of biotechnological biosafety can hardly be said to be optimal due to the distorted information which was given to the public in general and to farmers in particular. It should be noted that the acceptance of the people is fundamental; and therefore more emphasis should be given to the spreading of information and transparency within management. The exchanges of experiences on the regional level have been positive.

Bolivia will continue to work in the implementation of the National Biosafety Framework of Bolivia, and will submit the second phase of the project to UNEP-GEF and to other donors, such as FAO. This new stage requires the re adaptation of the national ordinance according to the regulations laid down by the Cartagena Protocol, which was ratified by Bolivia in 2001. Activities will be directed to the interaction of the sectors involved, such as environment, agriculture, health, and foreign trade, thus strengthening regional cooperation with the countries of the Andes Pact and other countries as well.

7.- Regional Network on Biosafety (RNBio - UNU-BIOLAC).

In 2001, the Programme on Biotechnology for Latin American and the Caribbean of the United Nations University (UNU-BIOLAC) created the Regional Network on Biosafety (RNBio) directed at the countries of the Andes Pact, Central America and the Caribbean. The creation of this Network and the area it covers aims at supporting those countries of the region which, having signed the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, require capacity-building and experience in the agro-biotechnology and biosafety.

7.1 Vision and Mission

The main objective of the RNBio is to train professionals who belong to public research institutions related to regulatory entities and to develop their knowledge and capacity in the evaluation and commercial use of Living Modified Organisms (LMOs). The mission is to contribute to the development of the legal framework and to the implementation of a regulating system to guide risk assessment and management in the commercialisation of by products from modern biotechnology, within the agricultural and agro food sectors of those countries that form part of the Region.

It is thus the aim of the RNBio to develop knowledge and skills in those professionals involved in policy making and regulations and who are working in public and private technical and research institutions, in the Andes Pact countries, in Central America and the Caribbean. Through these trained professionals the implementation of regulations and the necessary criteria for the evaluation and trade of products derived from LMOs in the fields of agriculture and agro food will be ensured. Moreover, new skills will be developed to promote biotechnology in society.

The main mission of RNBio is:

- To assist in the making of public policies on biosafety, regulations and public understanding of agro biotechnology.
- To cooperate with professionals of public organizations in the drafting and implementation of biosafety regulations for LMOs.
- To train and mould scientists, technicians and people involved in issues related to biosafety regulations on LMO by-products in those countries covered by the Network.
- To create an electronically accessible database for the Region, with information on the current regulations on biosafety in each different country and on the public understanding of agro food biotechnology.
- To prepare printed material, to hold workshops and courses concerning biosafety issues and the public acceptance of agro biotechnology.
- To work in cooperation and perform joint activities with international and regional Networks and Programmes which share common visions.
- To undertake any other activity of interest to promote the work of the Network under the auspices of UNU-BIOLAC within the Region.

7.2 RNBio Activities

In March 2001, an introductory course was given in the Institute of Advanced Studies in Baruta, Venezuela which covered the following items: to name the future regional authorities in the posts of scientific advisors, legal counsellors and those in charge of the handling of public understanding; to determine the needs regarding information and documentation in order to create a biosafety working schedule for the region, and to obtain a general description of the biosafety system, including the professional staff required and the procedures for checking guidelines, and operational norms and feed-back mechanisms.

In June 2002, at the same venue, a course entitled “Biosafety in Agro Biotechnology: Risk Management and Public Understanding”, was held. The objective of the course was to build professional capacity in the areas of agriculture, molecular biology, genetics, ecology, food technology and the civil service related to agriculture, health and environment. Twenty-eight professionals from Argentina, Bolivia, Costa Rica, Mexico, Peru and Venezuela attended the course of whom ten received scholarships.

7.3 Scholarships for Personal Development

The RNBio has organized theoretical and practical capacity-building workshops in the Biotechnology Laboratories of the National Institute of Technology for Agriculture and Fisheries (INTA- Castelar) where professionals from Venezuela, Costa Rica, Ecuador and Colombia received training in the different techniques required to be able to develop skills in the approaches to and organization of LMO biosafety systems. These professionals received financial support from the Personal Development Scholarship programme of UNU-BIOLAC

7.4 Capacity-Building Handbooks

Within the projected diffusion programme, specifically related to educational material, the Handbook "Public Understanding of Science: the case of Biotechnology" has been published. This work analyses the problem of public understanding of biotechnology within the broader context of the public awareness of science and technology in modern society. It includes concepts and studies from the international scene and Latin American countries.

7.5 RNBio Website

The Network will be launching a website with pertinent information concerning biosafety and public understanding of biotechnology. It will have a dynamic interactive format and will be easily accessible to the scientific and regulatory communities of Latin America and the Caribbean. The website address is www.rnbio.net and will be available as from August 2002.

8.- To sum up

The Cartagena Protocol is the result of long arduous international negotiations and as such reflects the different interests of the players involved. The Protocol leaves a very grey area, with respect to the relationship between the regulated commerce of LMOs and the environment. It also poses numerous questions one of which that particularly stands out is the need for the implementation of international norms and procedures governing liability and compensation for damages. Today, it is not yet known on whom the responsibility lies, whether it be the company involved in the production of LMOs, the country that exports or imports them, the farmers that uses them, or even none of them at all. Other pending issues to be tackled are those concerning efficient mechanisms to monitor, fine and deter illegal movements of transgenic organisms.

Perhaps, the most polemic debate stems from how the Precautionary Approach should be applied. One viewpoint suggests that the criteria should be applied as broadly as possible, a viewpoint shared by the European Union and the Codex Alimentarius Mundi Commission (CAMC). This scenario would require that all risk analysis on LMOs, the combination of LMOs and their by-products be carried out before shipment. The risk analysis should encompass assessment, handling and Advance Information. A time limit for these studies has not been specified.

The alternative point of view is based on the application of Article 5.3 of the WTO Agreement on Health and Plant Sanitary Conditions, within the General Agreement on Merchandise. This ordinance dealing with the Precautionary Approach states that "on applying the Precautionary Approach pertinent economic factors should be taken into account". The WTO Agreement on "Technical Barriers of Commerce" lays down that each State may establish preventive measures which should be temporarily legislated and be based on: substitution, proportionality and chance. In other words, there must be a direct relationship between the national restrictive ordinance and the general desired aim. The measure should be appropriate and not excessively biased towards that aim.

It is very easy to see that the Cartagena Protocol could directly clash with the WTO provisions, and especially over Health and Sanitation ordinances. If those countries

encouraging the use of broad precautionary criteria begin to impose preserved identity, traceability and labelling on their products, then these barriers will end up being dealt with in the same way as other multilateral trade controversies are dealt with. In that case, other member countries of the World Trade Organization, such as the United States of America, will exert pressure to clarify the issue.

As was mentioned in page 8, the Protocol[49] has been ratified by 21 countries in June 2002 it is hoped that the European Union will give its support, thus leading to the possible ratification by its 15 member countries. The 50 signatories shall be obtained albeit later than was expected.

The broad precautionary criteria incorporated in the Cartagena Protocol may well create future problems for those products derived from LMOs and destined for food, feed or processing. The obligation to identify those products destined for feed, forage or future processing with the words "may contain" could well lead to the next step being that those food products already processed should bear the words "may contain LMOs"

In scientific and business circles it is generally believed that science itself will eventually solve this issue by creating transgenic products that are so beneficial to the customers that all products, whether traditional or modified will be treated alike. Ecological organizations are driving other countries to sign the Protocol as soon as possible, so that it comes into effect in 2002, and thus the exporting of LMOs, which they consider potentially negative for the environment and human health, will be banned.

Biotechnology offers to various countries in the region the chance of offering differentiated products and, hence, be free from the traditional commodity[50] market. This is why long-term policies are crucial. These policies should be state-instigated as they apply to agriculture which is the key to the future world marketplace. Conditions must be established to allow for smooth and flowing contacts among the technological sources, the investment market and the judicial regulatory framework for intellectual property and biosafety.

The application of the Protocol could bring with it the adoption, throughout the world, of the Precautionary Approach in its broadest and general sense. Such a situation could create pressures, although the very defensive wording of the Protocol text imposes limits. According to the text (Annex III) risk assessment should be carried out in a scientifically sound and transparent manner and should consider the acknowledged technique of assessment to determine and evaluate the possible adverse effects of LMOs for the conservation and sustainable use for biological diversity taking also into account risks to human health.

In those countries with a strong social link stemming from ethnic heritage, as in the case of Mexico, Peru and Guatemala, there is a very particular outlook with regard to biodiversity. Not only do they firmly believe in the conservation of the different species, but they also feel that the biodiversity belongs to them. This is due to the importance of

[49] INAI News: *Segundo Encuentro del Comité Intergubernamental del Protocolo de Cartagena*, Nairobi, Kenya, 1st to 5th October, 2001.
[50] Trigo, Eduardo. *Biotecnología. Economía y Estado. La necesidad de afianzar marcos regulatorios y jurídicos.* Biotechnology Panel, Economy and State, II International Conference on Biotechnology, organized by the Argentine Seed Producers Association (ASA).

cultural differences and territorial rights. The international community must acknowledge this idiosyncrasy especially when applying the biosafety Protocol by putting cultural emphasis on the protection of biodiversity. Considering the precarious situation of agriculture in numerous Latin American countries, a special approach should be adopted to those sectors which are most vulnerable, introducing new research and programmes for the transference of technology[51].

Amongst the recommendations of the Cartagena Protocol, the harmonization of Biosafety policies in Biotechnology for Agriculture and Fisheries within regional context is of utmost importance. This harmony bears special relevance to Argentina, Brazil, Paraguay and Uruguay (current members of the MERCOSUR block) as well as Bolivia and Chile, who are on the threshold of entering. The negotiations on biosafety issues within the MERCOSUR are an example of the difficulties to be faced when dealing with different approaches based on the particular policy of each country. After more than ten years of talks, Argentina, Uruguay, Paraguay and Brazil, all food-producing countries have been unable to find a common stance regarding this issue and have decided not to regulate transgenic foods until the negotiations with the Codex Alimentarius have ended.

[51] Mexican Focal Point, ob.cit.

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