

DEVELOPMENT OF
THE NATIONAL
FRAMEWORK OF
SECURITY OF
BIOTECHNOLOGY FOR
PARAGUAY

Final Report

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DEVELOPMENT OF THE NATIONAL FRAMEWORK OF SECURITY OF BIOTECHNOLOGY FOR PARAGUAY

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Presentation

Biotechnology, moreover, genetic engineering, has been developed in a very rapid way. Thus, nowadays there are Living Modified Organisms (LMOs) products genetically up to the fourth generation, which provide some solutions to the food production, so it could be thought that the biotechnology is the panacea for the world feeding. Nevertheless, it has to be recognized that human health and biodiversity could be affected for consequences that the same biotechnology could produce.

In the face of the urgency of these paradigms from the contemporary world, the world community conceived the Biological Diversity Agreement (BDA), where the biological diversity conservation is focused in a holistic way, the sustainable utilization of natural resources and a fair participation of the benefits originated from the use of genetic resources.

It is important to highlight that the mentioned agreement recognizes and conciliates among its articles, two aspects with the same strength, such as:

- the necessity to protect the human health and the environment against the adverse aspects of the modern biotechnology products; and
- the great potential of the biotechnology to promote the human welfare and satisfy food, agriculture and the sanitation care needs.

Likewise, in other articles of the BDA the access to technologies, including biotechnology and its transference is considered pertinent to the conservation and sustainable utilization of the biological diversity. Also, it guarantees the development of adequate procedures to improve the security and to reduce all the possible threats against the biological diversity and risks for the human health.

On the other hand, the Cartagena Protocol (CP) has as an objective “to contribute for guaranteeing an adequate level of protection to the sphere of a secure transference, manipulation and utilization of the living modified organisms resulting from the modern biotechnology that can have adverse effects for the conservation and the sustainable utilization of the biological diversity, also having into account, the human health risks, focused concretely in the transboundary movements”. Paraguay, respectful of its assumed compromises, has been a signatory of the CP since May 3rd. 2001, whose subscription was ratified by the Law Nr. 2.309/03, that had validity from June 2004.

It has to be highlighted that the definitive adoption of the CP has been praiseworthy because it provides an international normative framework, where the commerce protection and the environment needs reconcile in the biotechnology industry. With this, a surrounding is created for the application of biotechnology, in such a possible way to obtain the maximum benefits of the vast potential in biotechnology and, at the same time, to reduce to the minimum the environment risks.

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Executive Abstract

The present document is the product of an institutional interaction of work and consensus, with the aim of giving a solution to the issue in of the use of genetically modified living organisms in Paraguay.

Biotechnology in Paraguay is used for the micro propagation of plants, in the production of animal vaccines and in molecular markers regarding the genetic improvement of soy and the detection of LMOs. Biotechnology is also used for the detection of gluten in food and in investigation of the “mal de chagas” disease, the leishmaniasis and the tuberculosis. However, it has to be recognized that its use in agriculture, specifically in the transgenic soy, exceeded all the predicted expectancies, converting Paraguay into a mega producer of such grain. The cotton Bt was already authorized for its experimentation. Even though, the country does not have yet a normative according to reality, and less than that, a National Policy on Security of Biotechnology.

This reality led to define as the objective of this Project, the identification of the basic guidelines for a National Policy of Security of Biotechnology. For that, the Secretary of Environment, by Resolution Nr. 1.957/05, assumed the execution of this Project, constituting an institutional and management structure when it decided to name a National Coordinator of the Project (CNP), conforming a National Committee of Coordination (CNC).

Later, the Terms of Reference were elaborated for consulting of the studies that involved an analysis on: existing juridical instruments, impact of the commercial release of events, harmonization of procedures and mutual acceptance; besides, a consulting office for the design of an information and participation of the public mechanism.

After that, in order to give participation to the engaged stakeholders in the use of LMOs, regional seminars-workshops took place in five cities, representatives of the country side, where the necessities of each region were into a consensus, to, finally, carry on a national seminar-workshop in Asunción, in order to consolidate a proposal from the country about guidelines to identify the basic terms that a National Policy of Security of Biotechnology should have.

It is important to remark that during this process, it had the valuable contribution of the members, representatives of the National Committee of Coordination, who with its technical installed capacities in the engaged institutions, assumed the serious compromise to orientate and advise on the actions of the Project, as well as to do the pertinent adjustments and corrections to the studies and to the present document to be presented to the United Nations Environment Programme (UNEP).

Hopefully, the top level national authorities, the Executive Power as well as the Legislative Power, when they consider the right time, take the pertinent considerations for the basic guidelines be part of the elaboration of a National Policy of Security of the Biotechnology, and then it could be translated in a normative in keeping with the national reality and necessity in the use of LMOs in the country.

Acronyms and Abbreviations

APROSEMP	:Asociación de Productores de Semillas del Paraguay (Seed Producers Association of Paraguay)
APS	:Asociación de Productores de Soja, Oleaginosas y Cereales del Paraguay (Soybean, Oleaginous and Cereals Association of Paraguay)
ADN	:Acido Desoxirribonucleico (DNA- Deoxyribonucleic Acid)
AFP	:Acuerdo Fundamentado Previo Previous Foundation Agreement
Bt	: Basillus thuringiensis
BHC	:Biosafety Clearing House (Information Center of the Cartagena Protocol)
CAP	: Coordinadora Agrícola del Paraguay (Agriculteur Coordinator of Paraguay)
CAPECO	: Cámara Paraguaya de Exportadores de Cereales y Oleaginosas (Paraguayan Chamber of Exports of Cereals and Olaginous)
CDB	:Convenio de Diversidad Biologica (Convension on Biological Diversity)
CIISB	: Centro de Intercambio de Información sobre Seguridad de de la Biotecnología (Information Exchange Center on Security of Biotechnology)
CNC	: Comité National de Coordinación (National Committee of Coordination)
CNP	: Coordinador National del Proyecto (National Coordinator of the Project)
ComBio	: Comisión de Bioseguridad (Biosafety Commission)
CONACYT	: Consejo Nacional de Ciencia y Tecnología (National Council of Science and Technology)
CONAM	: Consejo National del Ambiente (National Council of Environment)
CP	: Cartagena Protocol

DDV	: Dirección de Defensa Vegetal (Plants Defense Department)
DIA	: Dirección de Investigación Agrícola (Agricultural Research Department)
DIPA	: Dirección de Investigación de Producción Animal (Animal Production Researching Department)
DISE	: Dirección de Semillas (Seeds Department)
DNA	: Dirección Nacional de Aduanas (National Customs Department)
DNVS	: Dirección Nacional de Vigilancia Sanitaria (Nacional Sanitary Control Department)
DOA	: Dirección de Ordenamiento Ambiental (Environment Regulations Department)
DPE	: Dirección de Planificación Estratégica (Strategic Planning Department)
DPNVS	: Dirección de Parques Nacionales y Vida Silvestre (National Parks and Wild Life Department)
ENPAB	: Estrategia Nacional y Plan de Acción para la Conservación de la Biodiversidad del Paraguay 2004-2009 (National Strategy and Action Plan for the Conservation of Biodiversity in Paraguay 2004-2009)
FAO	: Food and Agriculture Organization
FSA	: Facultad de Ciencias Agrarias (Agrarian Sciences Faculty)
FECOPROD	: Federación de las Cooperativas de la Producción (Production Cooperatives Federation)
GEF	: Global Environment Facilities
GMO	: Genetically modified Organism
IICS	: Instituto de Investigación de Ciencias de la Salud (Health Sciences Research Institute)
INAN	: Instituto Nacional de Alimentación y Nutrición (National Institute of Food and Nutrition)

INBIO	: Instituto de Biotecnología Agrícola (Agricultural Biotechnology Institute)
INTN	: Instituto Nacional de Tecnología y Normalización (National Institute of Technology and Regulations)
MAG	: Ministerio de Agricultura y Ganadería (Ministry of Agriculture and Livestock)
MERCOSUR	: Mercado Común del Sur
MIC	: Ministerio de Industria y Comercio (Ministry of Industry and Commerce)
MNSB	: Marcos Nacionales de Seguridad de la Biotecnología (National Frameworks of Security of Biotechnology)
MNSB Py	: Proyecto Desarrollo del Marco Nacional de Seguridad de la Biotecnología para el Paraguay (Development Project of the National Framework of Security of the Biotechnology for Paraguay)
MODIT	: Modalidad de inserción y pago de tecnología (Modality of insertion and payment of technology)
MRE	: Ministerio de Relaciones Exteriores (Ministry of External Affairs)
MSPBS	: Ministerio de Salud Pública y Bienestar Social (Ministry of Public Health and Social Welfare)
NGOs	: Non governmental Organizations
OFAT	: Oficina Fiscalizadora de Algodón y Tabaco (Controller Office of Cotton and Tobacco)
ONE	: Organismo Nacional de Ejecución del Proyecto (National Organization of Project Execution)
PAN	: Política Ambiental Nacional (National Environment Policy)
PCR	: Polymerase Chain Reaction
PP	: Principio Precautorio (Precaution Principle)
RR	: Round up ready (toleration to Glyphosato)

SEAM	: Secretaria del Ambiente (Secretary of Environment)
SENACSA	: Servicio Nacional de Salud y Calidad Animal (National Service of Animal Health and Quality)
SENASA	: Servicio Nacional de Saneamiento Ambiental (National Service of Environment Sanitation)
SENAVE	: Servicio Nacional de Calidad y Sanidad Vegetal y de Semillas (National Service of Quality and Sanitation in Plants and Seeds)
UNA	:Universidad Nacional de Asunción (National University of Asuncion)
UNICOOP	: Central Nacional de Cooperativas (Cooperatives National Center)
UNDP	: United Nations Development Programme
UNEP	: United Nations Environment Programme
WTO	: World Trade Organization

**Note of Translator: The Acronyms of local organizations were maintained in original language and translated the meaning for a better understanding. International Acronyms and Abbreviations were translated into English.*

I. Introduction

The National Project “Development of the Security National Framework of the Biotechnology in Paraguay” (**MNSB PY**) is a joint action between the Secretary of Environment (**SEAM**) and the technical cooperation of the United Nations Program for the Environment (**UNEP**) financed by the World Fund for the Environment (**GEF**), with the administrative support in Paraguay of the United Nations Program for the Development (**UNDP**)

It is important to remember that the Project **MNSB Py** comes from the **World Project for the Development of National Framework of Bio security**, that was designed by **UNEP-GEF** to help countries to develop their bio security national frameworks and in this way, fulfil with the requirements of the Cartagena Protocol (CP), which is an international tool legally binding about the Security of Biotechnology of the Convention on Biological Diversity (CBD), that were approved by the National Congress through the Law **Nr. 253/93**

DEVELOPMENT OF A NATIONAL FRAMEWORK FOR PARAGUAY

A NEED FOR A NATIONAL FRAMEWORK

It is clear that Paraguay belongs to a region considered as of a major biological diversity of the planet, as it is evidenced in the existing native wild flora. On the other hand. In Compensation , nowadays it has an agriculture production which already includes live organisms genetically modified as the soybean RR (Glycine Max) and, lately, the Cotton Bt. Even though its experiment has been authorized, there are plots of land of this crop without the administrative formal steps fulfilment and of the essential risk analysis.

It cannot be left apart the existing unbalance between the strength of modern biotechnology and the country limited capacity in its political , economic and social structure to administrate such situation.

We should add to this that the global international context urges and press for a greater commercial liberalization of LMOs in a country where there is no developed biotechnology, but it does have the possibility of being a user of it expanding new markets and opportunities of funds (currencies)income from abroad.

In this context, is evident that to establish a Security National Framework of the Biotechnology in Paraguay is of an urgent necessity. Moreover, when there is already a LMOs production and commercialization in a world scale (Soybean RR), and representative international companies submit applications to be authorized for new events (Cotton Bt), supporting at the same time a clandestine entry of “white bags” whose real origin is unknown, and there is no certainty about their phenologic characteristics.

PRINCIPAL OBJECTIVE OF THE DEVELOPMENT OF THE NFSB Py PROJECT

The principal objective of the National Project is the evaluation and the revision of the national context to define Basic Guidelines for a National Policy on Security of the Biotechnology, that strengthen the national institutional capacity with the purpose of developing the propitious conditions for adopting decisions on a secure transfer, manipulation and utilization of modified live organisms, in accordance with the CP.

The Project, at its end, should count with standards about:

- 1.- lawful system as a juridical instrument to support legally the security activities concerning the biotechnology;
- 2.- a strengthened and organized administrative system to access manage the risks, and thus to fulfil with the obligations took Against the CP;
- 3.- a system to take decisions , with a capacity to evaluate risks and take measures; and
- 4.- a mechanism for the participation and information to the public.

CHARACTERISTICS OF THE PROJECT UNEP-GEF FROM PARAGUAY

Duration and Financing

NFSB Py Project with the present coordination, started formally in July, 2005, considering at the beginning a duration of 12 months that was extended to 24 months, and concluded on June 30th., 2007.

The financing obtained was of USD 163.000, being provided as local counterpart by the Government of Paraguay the amount of USD 50.000.

National Execution Entity

SEAM, through the Strategic Planning Direction (SPD), with the International Affairs Department and the Office of Biosafety conform the entity in charge of the Project execution for the Cartagena Protocol(CP) in the framework of the Convention on Biological Diversity (CDB) .

Phases of the NFSB Py Project

According to the design of the World Project on Biosafety National Frameworks, the NFSB Py Development Project consist of the following phases:

Phase 0: Where the project is designed according to the national reality, its principles, establishing the institutional structure and the management for its implementation;

Phase 1: Where the studies are made and where the inventories of the sectors involved with the biosafety and the biotechnology in the country are prepared, including them in the national data bases.

Phase 2: Where the stakeholders are identified and consulting, analysis and necessary training to identify priorities and parameters take place in order to draft de Security National Framework of Biotechnology; and,

Phase 3: Where the writing of the Security National Framework of Biotechnology draft, with the identification of national capacities and weaknesses to be suitable for the Cartagena Protocol.

Institutional Structure of MNSB Py Development Project

The basic structure is integrated by:

- A- Project Execution National Entity (ONE),
- B- Project National Coordinator (CNP) and
- C- Coordination National Committee (CNC).

The functions of the Project components are:

A.- ONE. It is the legal entity in charge of the Project execution. Its function is considered essential for the effective performance of the National Project, being its major task to coordinate the entire participation of all governmental bodies with mandates related to the Cartagena Protocol on biotechnology security.

B.-CNP. It's the person in charge of the management, coordination and supervision of the project, as well as of the supervision and presentation of progress reports on the basic guidelines development for a Security National Policy for the Technology; and ,

C.-CNC. It is the institutional structure consultative body, established for ONE to orientate and advice in the basic guidelines preparation for the Security National Policy for the Biotechnology.

The LMOs and the Paraguayan Society

There are very little studies in relation to the citizens perceptions on the live organisms genetically modified. Nevertheless, initiatives such as ENBAB 2004 Project, TCP/PAR/166 Projects on Strengthening of the Biosafety system, and the TCP/PAR/3.001 for Supporting the formulation of a Biotechnology National Policy, enable to express that besides the stakeholders directly engaged in the production and commercialization of transgenic products, the consuming population in general unknow the real nature of the LMOs, a bit predisposed toward the rejection of such products.

In reality, the Paraguayan society cannot be excluded of the world debate that exists about the use or not of LMOs. In the middle of the controversy that generates this issue, some strong and conflicting positions are found as well as others more sensitive, through which the biotechnology's benefits are recognized but alerting on the precautions to be taken for the utilization of LMOs.

There are then, on one hand, the civil environmentalist organizations that according to their principles, reject completely the LMOs utilization and, on the other hand, the huge agriculture producers and the academic sector (of searching) eager for the use of new technology through which they can increase their profits and scientific capacity as well.

It is important to mention that the present productive economic model in Paraguay is mainly based on the agriculture and livestock (export of raw material), so the commercial

introduction of seeds genetically improved (up to now only first generation) represents a valid and undeniable possibility for the socio-economic development of the country.

The Executive Power, the LMOs and the Biotechnology

Nowadays, there is not a defined national policy on the use of biotechnology nor on the biotechnology security. Even though some institutional initiatives in certain sectors appeared, that with help from international organizations have started, in the country, a national policy formulation process on biotechnology, it was not approved by consensus yet. However, these initiatives, in certain way, have given the chance to institutional sectors of the government which are engaged in detecting certain capacities in regards the LMOs administration in the country.

This is very important, since this was useful for this administrative capacity to be part of the CNC of the NFSB Py Project that unobjectionably made possible to obtain the criteria that serve as support elements for the political guidelines and to concrete in this way the foundation for the National Policy about the Security of Biotechnology in Paraguay that make possible clear procedures for a responsible and transparent use of LMOs.

Presently, The Executive Power, through SENAVE and the Biotechnology Commission (COMBio), receive the applications for authorizing of agriculture events (LMOs) and for the liberation inside the country with a limited participation of the environmental sector. Nevertheless, it is important to mention that the juridical situation of this Commission is under re-structuring for a better adequacy to the present situation, since there are involved institutions that were absent before such as SENAVE and SEAM whose roles are not well defined.

The Legislative Power, LMOs and the Biotechnology

Many drafts bills related with the use and utilization of the LMOs were presented to the Legislative Power (the Congress). However, from all of them the only one that continues under study is the "Biosafety Draft Bill", presented by the Ministry of Agriculture and Livestock (MAG).

If the Law about Security in Biotechnology were passed, this should translucent the guidelines or foundation of the national policy, for the biotechnology development as well as to permit procedures or instruments necessary for its control and a responsible and transparent use, with relevant aspects concerning the promotion and development of their scientific capacity (academic –of researching). It means, an appropriate regulation through which the potentialities structures and were not wasted, and at the same time, the country could benefit with the economic opportunities that biotechnology offers (exports of soy, cotton, etc.) guaranteeing an acceptable environmental risk level management.

Inside the legal context of the regulatory framework regarding security of the biotechnology, it is necessary to start from the text of the National Constitution and its later adequacy to the actual rules, being these national or international, that succeeded it in an inferior range in relation to its accomplishment.

The Constitution of the Republic of Paraguay determines in its Art. 8th-the necessity to regulate and take precautionary measures of the activities tending to protect the

biotechnology in all moment, from its manipulation up to its commercialization and final placement in the market, protection the production as well as the final consumer.

Once contextualized, the different regulations can be identified, those that are part of the juridical body in force in Paraguay, to implement then the necessary reforms and to demarcate the national regulatory framework concerning the security in biotechnology, identifying realities and generating proposals for its effective implementation, according to the global requirements which the country is committed with.

Consequently, it is pertinent to affirm that, from the definition of basic guidelines for a national policy, a national legal ordering could be visualized for a frame law (Security of the Biotechnology) where the roles and competencies of involved institutions are to be identified, according to their regulations with a major linking and relevance concerning security of the biotechnology.

The Judiciary, the LMOs and the Biotechnology

Few experiences related to the Judiciary, specifically the Public Ministry let see acts and procedures based, moreover, on the fact that LMOs seeds have an illegal origin (smuggling) or are from an irregular administrative situation, and not on the condition of being “transgenic” which might alter in a bad way the ecosystem. It is like this because the transgression to the penal law must be contemplated in an explicit way in the violated regulation in force, due to its restrictive nature.

In that sense, such procedures transcend in an administrative way only, without very significant results.

KEY CONCEPTS AND USE OF TERMS

Modified Live Organisms

As far as the present report and the Cartagena Protocol are concerned, the following punctual concepts were developed: any biological entity which is able to transmit or replicate genetic material, including sterile organisms, viruses.

Modern Biotechnology is the application of:

- 1.-techniques in vitro of nucleic acid, including recombinant deoxyribonucleic acid (DNA) and the direct injection of nucleic acid in cells and organelles; and
- 2.- the fusion of cells besides the taxonomic family that goes beyond the natural physiological barriers of the reproduction or the recombination and that does not consist of techniques utilized in reproduction and traditional selection.

Bio security is the safe use of biotechnology or the application of measures that contribute to decrease or avoid the environmental risks and of public or animal health associated to the biotechnical applications.

II.- Cartagena Protocol about the Security in Biotechnology

2.1. Paraguay and the Meetings of the Parts from the Cartagena Protocol

Paraguay is Country Part in the Agreement on the Biological Diversity that were approved by Law Nr. 253/93. It is also signature of the Cartagena Protocol on Security of Biotechnology from May 3rd., 2001, fact ratified by the National Congress through Law Nr. 2.309/03.

The CP has as an objective “to guarantee an adequate level of protection in the transference sphere , manipulation and safe utilization of modified live organisms resulting from modern biotechnology, that can have adverse effects for the conservation and a sustainable utilization of the biological diversity, having also into account the risks for the human health, focusing specifically in the trans frontier movements.”

III. Governmental Position with respect to the Cartagena Protocol

Having approved the Cartagena Protocol through a Congress law, Paraguay is associated juridically to fulfil its objectives. However, there are still some points and/or Articles of the CP that were not approved by consensus between the Parties. Nevertheless, Paraguay's position, even in a sectoral way, responds to the great national interests that should be embodied in a *National Policy of Security of the Biotechnology*.

Position of the sectors bodies in relation to the Cartagena Protocol.

- Environmental Sector SEAM

SEAM, created on July 26th, 2000 by Law Nr. 1.561/100, has made a monitoring of the events about the LMOs since before its creation, when it was only the Sub Secretary of Natural Resources and Environment, depending on MAG (Ministry of Agriculture and Livestock). In that moment, it was part of ComBio, created through Decree Nr. 1.848/97, by the agriculture, livestock and forestry sector.

On the other hand, the guidelines and strategic basis for the elaboration of an environmental policy on the sector biotechnology and the security of biotechnology are defined in the Project "National Strategy and Plan of Action for the Biodiversity Conservation (ENPAB).

Meanwhile, SEAM, as Focal Point of CDB, executes the present Project, trying to fulfil the obligations acquired by the country regarding the CP in Security of Biotechnology, ratified by the Law Nr. 2.309/83. Besides, it has, as institution, the legal instrument of the Law of Environmental Impact Evaluation in case of liberation of transgenic events.

It has to be mentioned that SEAM as well as SENAIVE, the MAG and the MIC participate actively in the Meetings of the CP Parties.

- MAG Sector (ComBio-SENAIVE)

The Ministry of Agriculture (MAG), being the entity that authorizes the entry of vegetable material with experimental purposes, was the first institution from the country who received requests from international companies to make experiments and tests with live organisms genetically modified. The government, indeed, understood the necessity to legalize the entry and liberation of LMOs in Paraguay.

That is why, the MAG through Decree Nr. 18.481/97, created the Commission of Bio Security (ComBio) integrated by representatives of institutions from the public and private sectors where based on national and regional normative, certain technical requirements forms and pertinent procedures are set for the entry and liberation of LMOs in Paraguay. It is a prerequisite the presentation of an environmental license previously to any activity amenable of producing significant impacts in the environment and the human health.

Years later, with the creation of SENAIVE, the roles and functions of the institutions involved in the introduction and traffic of LMOs from agriculture source were not well defined, so the juridical actualization of ComBio is an unavoidable necessity, and the MAG is destined to it right now.

In the sector of the MAG there are three different instances directly related with the entry and release of LMOs.

1.-The National Service of Quality and Sanity of Vegetables and Seeds (SENAVE) is where the DDV, the DISE and the OFAT got together. It has a Biotechnology Coordination as part of its organizational structure, which is in charge, among others, of advising, supporting and attending the management of activities related to biotechnology and bio security, specially focused on authorizations of releases to the environment and the commercialization of vegetables genetically modified which were originated for agriculture activities. It is also involved in the definitions of policies, the design of specific rules and the broadcasting of activities of the SENAVE about this topic. It acts as a receive counter for the entry of LMOs. Fresh food for human consumption are also registered, authorized and/or controlled by this institution.

2.- Department of Agriculture Researching (DIA): is the entity which is in charge of the agriculture investigation centers, with high-qualified personnel and places where there are the best and main scientific-technological capacities that the country has in the field of agriculture. The evaluation and risk analysis for the entry and commercial release of the LMOs concerning agriculture are performed, basically, by this institution.

3.- Department of Researching on Animal Production (DIPA): is the one in charge of everything concerning the improvement of the livestock and fishery production, promoting, also, the broadcasting and adoption of technological acknowledges generated through investigations papers for the different animal species.

4.- National Service of Animal Health and Quality (SENACSA): is an autarchic entity in charge of the animal health, being its principal task to provide the pertinent Records and Authorizations for food, drugs and biological veterinarian products.

It has to be highlighted that all actions that MAG performs in relation to the regulations for the use, manipulation, commercialization and trans frontier movement of LMOs and/or products resulting from the modern technology, are ruled, in general by what was established in the CP about Biotechnology Security.

– **Health Sector -INAN MSBS**

In the health sector, it has to be considered the National Institute of Food and Nutrition (INAN) entity in charge of looking after the quality and innocuousness of processed food for human consumption, while for those that are consumed fresh, the control is made by SENAVE. The Ministry of Public Health and Social Welfare (MSPBS) is represented in ComBio through the INAN.

This entity is ruled by the Law Nr. 836/80 of the Sanitary Code, the Codex Alimentarius, the SGT 3 Technical Regulations – Food from MERCOSUR, that take part of the technical committees such as Latin Foods (Latin American Network of Food Composition), LEGALIM/Spain (Paraguayan System of Food Regulations), ComBio, the National Committee of Food Quality and the National Technical Committee for the Elaboration of Paraguayan Regulations.

– **Academic Sector: UNA (The National University)**

Referring to biotechnology generation and investigation in the field of phyto improvement, the Faculty of Agrarian Sciences (FCA) has a Biology Department, where micro-grafts techniques were developed in lab, mainly to clean the citric fruits from viruses and other infectious, to select varieties and sanitary certifications through laboratory proves.

In the ground of the National University of Asunción (UNA) and in the field of human health, the Institute of Health Sciences Investigation (IICS) is located, whose activities in last years were focused in the researching related to tropical medicine, diagnosis, epidemiology and social sciences. It has a Molecular Biology Department, where molecular techniques such as cloning , polymerase chain reaction (PCR), hybridation with non-radioactive probes and production of recombined proteins.

IV.- Regulatory Regime in Bio security

Present situation

This section integrate the juridical context of the specific regulatory regime that rules in certain direct way everything concerning security in biotechnology.

It tries to identify the regulations in force in relation to biotechnology security, following the priority order identified in the National Constitution of the Republic of Paraguay. This is, starting from the text of the National Constitution, continuing with the ratification of international treaties about biotechnology security and the later adequacy of national laws.

National Constitution of the Republic of Paraguay

The National Constitution sanctioned in 1992, in its dogmatic part as well as in its organic aspects, contemplates all modalities juridically protected that the Government determines concerning biotechnology protection.

It is important to highlight that for the first time in the constitutional history of Paraguay, a specific chapter for the environment protection is included, being in the same importance range that the Life Rights,. In this way, the National Constitution places in the same range of importance both legally protected possessions: Life and Environment, over the protection of the other juridical properties and moreover, over the other laws.

The Government's responsibility is to promote and guarantee the quality of life of its inhabitants through plans and policies that recognise determinant factors, fostering at the same time the investigation of factors or population and its links with the socio-economic development, the preservation of the environment and the life quality of its population, expresses the text of the Magna Carta, which responds to the international treaties and agreements subscribed by the Paraguayan government assuming effective commitments for the environment protection.

On the subject of biotechnology security, the text of the National Constitution establishes that the State “will regulate the genetic resources traffic and its technology, protecting the national interests” (Art. 8th).

The incorporation of the Environment Right as diffuse interest recognizes in a constitutional range the quality of human right for the third generation, creating an extension in the vast protection range that reaches different institutions in a trans-national range. Health is recognized as a fundamental right of people and of interest of the community, promoting a Health National System that executed actions and programs from the public and private sectors. The State is responsible for the quality control of the food, chemical, pharmaceutical and biological products in their production, importing and commercialization stages.

In the Education Sector, the conditions through which the State will control the fulfilment of the fostering plans for education and scientific investigation at a university level are regulated, generating in this way funds for researching concerning biotechnology.

The international commerce is protected to promote the effective incorporation of national products to the foreign markets, into the framework of free circulation but always regulated to protect the security of all the involved sectors and the economic, financial, social and even

environment interests of the Republic. In this field, the intellectual property is guaranteed and protected by the law.

Other important aspect is the agrarian reform and the rural development, that can serve as reference for the creation of the National Security Framework of the Biotechnology, which are described in the Magna Carta through the regulation of the taxation system founded in social criteria and of the development of small and medium-sized rural properties, regulating the use of the land and of the farming practices in the promotion of agricultural and livestock intensive and diversity production, but always respecting the environment protection criteria.

Providing farming and livestock loans and creating the agriculture insurance, among others, are part of the constitutional premises that should be the parameters for the other rules, above all in reference to the biotechnology security.

The evaluation on the environmental impact is another issue that becomes mandatory when is related to activities which tend to protect the environment without taking out the incentive the human activities or the development of the country.

The Magna Carta prescribes that the international treaties celebrated in a valid way, approved by a Congress law and whose ratification instruments were exchanged or deposited, are part of the legal internal order even over the internal laws of the Republic, but always below the National Constitution.

Cartagena Protocol

Concerning the recognition of this international treaties as part of the national legal regulation over the own positive laws of the Republic, there is the basic and framework document concerning security in biotechnology: the **Cartagena Protocol (CP)**, which is composed by 40 articles and three appendixes from where our actual investigation break down.

This protocol determines the parameters over which the rules of inferior importance/range must be established for the effective implementation of the National Framework of Security for the Biotechnology, determining the roads over which the pre-existing rules should be adequate and those rules which might be eventually created to complement the policies towards bio security.

Likewise, it establishes the compromises of contracting States concerning biotechnology in order to take special measures to maintain the biological diversity. “Each contracting party will establish or maintain the necessary resources to regulate, administrate or control the risks derived from the utilization and release of modified live organisms as a result of the biotechnology that might have some negative environmental impacts that can affect the conservation and sustainable utilization of the biological diversity, having also into account the risks for the human health”(Art.8th Law Nr. 253/93).

The CP is the first international agreement that regulates the transference, handle and use of modified live organisms by means of the modern biotechnology, and that is used as a guide for the application of the National Security Framework of Biotechnology through uniform security measures and in accordance with the consumers and industrial sector entrepreneurs, and particularly with the environment.

The importance of the protocol is shown in the necessity of revising the development, even the date, of the legislations on biosafety in order to check if they correspond with the guarantee principles in it and to formulate the pertinent appreciations.

Its objective is to contribute to guarantee an adequate level of protection in the transference sphere, safe manipulation and utilization of the modified live organisms resulting from the modern biotechnology, that can have negative effects for the conservation and sustainable utilization of biological diversity, and also taking into account the human health risks, and centralizing specifically in the trans frontier movements.

It is recognized in this document the rapid expansion of the modern biotechnology and of the increased public concern about the possible negative effects on the biological diversity, taking into account the risks for the human health. However, the modern biotechnology is also seen as a mechanism that regulated in a reliable and efficient way, will contribute to the human welfare and the environment care.

This protocol defines terminologies considered modern, inclusively in the field of genetic engineering and regulates the States' commitments in relation to this matter in order to determine the mechanisms for its application.

The Precaution Principle is its foundation, with the purpose of protecting the environment, previewing the danger of serious or irreversible damage, and determining that the lack of absolute scientific certainty must not be used as a reason to postpone the adoption of efficient measures in function of costs to avoid the environment degradation. This demonstrates a wide vision, that it not reduced only to the living organisms subjected to the Previous Foundamented Agreement (AFP), but it is extended to the whole scope of this international instrument.

The protocol regulates also the AFP, which is the central mechanism, constituting itself in an instrument of environmental management of the States respect to the chemical products, the pesticides or dangerous waste and the general principles by which the risk evaluation is ruled.

Other international organizations and other regulations on this respect complete what it is established in the National Constitution and the Cartagena Protocol and its PFA. This is the way in this present work we can refer to the contribution of the "Summit of the Land" of 1992, that took place in Rio de Janeiro (Brazil), where some documents of vital importance are ratified such as the **Agenda 21** and the **Agreement on Biological Diversity** that is the foundation of the Cartagena Protocol, besides de **Declaration of Rio**, where the environmental principles are consecrated as the one on Sustainable Development.

Declaration on Biotechnology by the FAO and the REDBIO

It also has to be analysed the contribution of the United Nations Food and Agriculture Organization

Codex Alimentarius

The Codex Alimentarius rises as an instrument that looks for the protection of the consumers' health. The adoption of regulations with scientific and technical basis to fulfill with said objective is what determines its quality as an organization in charge of the international

harmonization of regulations related to the food innocuousness, with a double aim: to protect the consumers' health and to facilitate the international commerce of food.

The UPOV

Other document to be evaluated is the Act of the Union for the Protection of Obtaining Vegetables (UPOV), created by the Paris Convention in 1978, that recognizes exclusively the rights of obtainer specifically on the seeds.

MERCOSUR

The incorporation of Paraguay to the Common Market of the South (MERCOSUR) is other mechanism that rises in the subject of harmonization of regulations and politics related to the biosafety, and in particular, respect to the biotechnology applied to the agriculture and livestock regime of the States parties and their associates.

In level of countries that conform a part of the regional bloc, several are the antecedents on the procedures for a coordinated regulation among them, inclusively, previous to the conformation of the bloc.

Several meetings, like the one that took place about "Biosafety and Commercialization of the Organisms Modified Genetically into the MERCOSUR" leaded in many cases by Argentina and Brazil representatives, generated not few divergences on this matter, showing a grade of concern from the different governments for its incorporation or not in their countries.

In level of MERCOSUR, after several tries, national and regional committees are integrated. Even a commitment is generated, in relation to go deeper on the studies related to technology in modern biosafety, and over all, accepting that the agricultural and livestock sector is the one that demands almost urgent measures.

Under this context, the Framework Agreement on Environment was created, which was approved in Asunción by the MERCOSUR Council on June 22nd., 2001, and it is in force from July 22nd. of the same year. In Paraguay it was ratified though the **Law Nr. 2.068/03**, "That approves the Framework Agreement of the Environment for MERCOSUR".

The cooperation among States is the convergent point of this agreement to protect the environment and for the sustainable utilization of the natural resources, in order to reach a better quality of life and an economic, social and environmental sustainable development, with participation of the civil society in the protection of the environment, valuating the cooperation among the States parties with the aim of support and promote the implementation of international commitments concerning the environment, observing the legislation and the national policies in force.

This agreement refers to the Sustainable Development as the final purpose of the regulation, and affirms that commercial and environmental policies have to be completed to assure it, establishing that only one effective judiciary framework will achieve the protection of the environment and the sustainable use of natural resources from the States parties.

The Regulation is complemented by a commitment from the States parties of a priority and integral treatment of the causes and sources of environmental problems and the promotion for the internalization of environmental costs through the use of economic and management regulations instruments.

The Law Nr. 2.760/05 approves the Additional Protocol to the Framework Agreement of the Environment for MERCOSUR concerning the cooperation and assistance against environmental emergencies. This document creates mechanisms for the States can report emergency cases given in their territories, requesting regional actions to minimize or avoid the possible environmental impacts.

This is the context of the international and regional regulations that rule in a certain direct way the present situation of the security in biotechnology.

OTHER REGULATIONS IN FORCE

National Law

On their own part, different national regulations previous and some of them subsequent to the constitutional reform in 1992, rise to regulate sectional aspects about biotechnology.

Law on Seeds and Protection of Crops

Among these regulations, there is the Law on Seeds and Protection of Crops Nbr. 385/94 that established the compulsory to create the National Regime of Protected Crops, preventing or providing with precautionary to the farmer and the researcher in their tasks through the regulation of the “Privilege of the Farmer”¹ and the “Privilege of the Researcher”², trying to avoid the monopolies that can affect to farmers and consumers, to the continuity of the process of phyto improvement and to the biodiversity in general.

The referred regulations in the previous paragraph tend to stimulate long-term investments on investigations to obtain vegetables and to support these investments in the private sector. In relation to the protection of genes or genes sequences in Paraguay, this topic is related with the recently issued Law of Patents, **Law Nr. 1.630/2000**.

Law of Evaluation of Environmental Impact

Other legislation concerning environment is the **Law Nr. 293/93** of Evaluation of the Environmental Impact in respond to the necessity of regulation of what was specifically considered in the constitutional text. This law is regulated by the SEAM, entity created in 2000 by the **Law Nr. 1.561/00** that creates SISNAM, CONAM and SEAM, establishing the attributes and the organization of these departments, focusing always in the compromise of establishing environmental policies in accordance to the regulated principles through the ratification of different agreements and international treaties.

Law of Phytosanitary Protection

¹ Where the right of the farmer to produce and utilize seed of protected varieties without permission of the person who got it otherwise it is assigned to its own sowing and not the sold to third parties.

² Right that permits that a third party can use the protected variety for the development of a third variety.

The legal ordering is complemented by the **Law Nr. 123/91** that adopted new regulations on the phytosanitary protection, which regulates the control of vegetable plagues, the utilization of pesticides, and the waste that can be present in vegetables, as measures to protect the population's health and to preserve the environment.

This rule regulates the diagnosis and control of plagues that affect or may affect, direct or indirectly, the vegetable production, and control in the phytosanitary aspects, the transport, storage and commercialization of vegetable products that might carry noxious agents for others. For that, it authorizes the pertinent authority to determine and control the fulfillment of phytosanitary conditions that the vegetable origin merchandises should have and also any material that enter or leave the country that may disseminate plagues to the vegetable production.

Law of Wild Life

A relative new law, since it raises together with the present National Constitution, is the **Law Nr. 96/92** on Wild Life that covers all the numbered objectives in the CBD, it means, it protects with conservation criteria, the sustainable utilization of biodiversity and the regulation of the genetic resources associated to it.

The present law regulates all what is concerned to the flora and fauna that belong to the national territory, being the national containers of genetic material of each of the species that compound them and the essential elements of the ecosystems. It covers the protection, handling and conservation of wild life, and also its incorporation to the national economy including the faculty provided to the respective authority to publish lists of species that are excluded from their protection environment.

Law of Protected Wild Areas

The **Law Nr. 352/94** of Protected Wild Areas is other rule that provides a confine of wide protection to this areas identified as well by the appropriate authority. On this respect, it creates the National System of Protected Wild Areas which is conformed by the conjunction of these protected areas which are considered of social interest and of public benefit.

The present law divides the Protected Wild Areas in handling categories, according to the type of restrictions, in order to coordinate the management and administrations actions of them, under the public as well as the private domain.

Law on Forest

In reference to the forest resources, **the Law 422/733 on Forest**, is complemented with different regulations related to the management, commercialization in all forms and protection of these resources. Its authority of application is the MAG, through the National Forest Service.

This law promotes the rational utilization of the resource, in public as well as private lands, and establishes as objective the preservation of certain environmental services provide by the forests and lands suitable for forestry, where it foresees, in case is necessary, the

expropriation with a constitutional foundation according it is regulated in the present by the National Constitution.

The forest integrity protection includes the preservation of the flora and fauna, associated consequently with the plagues control, the public health care and the national defense, classifying the types of forests according to the use the law provides.

Sanitary Code

In the Health sector, the security of the biotechnology is complemented with the constitutional text of the **Law Nr. 836/80** of the Sanitary Code, which regulated the functions of the State in relation to the integral care of the population's health and the rights and obligations of people, integrating the sector to all public and private institutions which are related with the population's health by its direct or indirect action.

This law, because its antiquity, does not refer specifically to genetic manipulation, or to the activities that derive from it. Nevertheless, it establishes that the National Policy on Health and Social Welfare will be established through health and social plans and programs according to global objectives, policies and strategies based on economic and social development.

Law on Defense of Consumer and User

The **Law Nr. 1.334/98** on Defense of Consumer and User helps the consumer to protect his/her health and security, preserving his/her life and integrity against consumption accidents, besides, protecting the producers investments in a market with clear competitiveness rules, generating guidelines on physical security that can also be applied to the security in biotechnology, attending the economic interests of consumers.

Decrees which regulate the Issue

These legal procedures are complemented with ministry's regulations, up to the points that the principal regulation that rules the biosecurity of the agricultural and livestock sector is contemplated in the **Decree Nr. 18.481/97**, "that creates and regulates the Commission of Agriculture and Livestock Biosafety", assigned to the MAG and the MSPBS.

This decree creates an inter institutional Commission on Biosecurity in order to take care, analyze and recommend everything related to the introduction, field testing, research and release of transgenic plants to the environment. This is the only authorized institution to control and evaluate the field testing that are being made, monitoring transgenic plants which are being experimented in the country.

From this decree on, it is established the obligation that any person interested in producing this type of material must fill a form specially prepared on this respect and present it to the technical secretary of said commission located in the SENAVE at the present.

With this procedure, the other decrees are complemented, like the one that regulated the entry and circulation of any vegetable material under the international traffic regime for the national territory, with the purpose of conditioning the entry of vegetable products in international transit regime though the national territory.

It is a requisite for the transit of the mentioned products , the phytosanitary certificate for exporting and re-exporting issued by the competent phytosanitary authority , with its correspondent loading manifest that consigns information about the treatment conditions of them, the entry and leaving points with its circulation routes, terms and place of permanency in the national territory.

The **Decree Nbr. 10.661/00** prohibited the utilization with commercial purpose of materials and organisms genetically modified during the agricultural campaign 2000/2001, due to the commercial implication derived from the use of transgenic materials, which showed the preoccupation of public and private institutions all over the country.

It is important to consider that the exporting of grains and their industrial by-products represent a high percentage of the national GDP, that can cause a serious damage to the Paraguayan economy. This decision is showed again in the following campaigns.

This regulation has as finality to prevent the future market of national products and specially the one related with soy, in view of the commercial interests of the country in medium and long-term in response to the position of the agro exporter and productive sectors to minimize the risks and to maintain the country free of transgenic materials.

The MAG has promulgated also the **Resolution Nr. 554/99** which regulated the utilization of genetically modified organisms in the agricultural campaign 1999/2000, consigning the prohibition of commercial farming of transgenic soybean, cotton and corn, but not the entry with experimentation purposes³.

Giving a general vision of the most important regulations concerning security, we propose against this vision in Chapter III a perspective of the judiciary situation in force, with the purpose of outline the guidelines on biosecurity and biotechnology.

This situation is reflected in the present document that shows the superposition and the failures of these regulations as well as the identification of Security Policies on Biotechnology in its different governmental sectors or divisions.

There are rules and sectors policies that should be revise and adequate in order to create a National Framework of Security for Biotechnology since the Policy on Security for Biotechnology cannot be sustainable on juridical instruments that prohibit the use of modified live organisms, but cannot forget either the other commitments to assume the protection of the environment, the economy, the commerce and so on.

At the present, the Executive Power is in the process of analyzing the Project of the Law for Biosecurity. Even though this document already took a lot of time being studied, a little was debated in a legislative level about the issues of regulation, investigation, testing, development, manipulation, transport, traffic, storage, production, commercialization, importing, exporting and utilization of modified live organisms were from vegetable or animal origin.

³ In relation to the release of transgenic plants with experimentation purposes, the Biosafety Commission authorized the experimentation of new varieties of transgenic soybean which tolerates the Round up pesticide, Soya RR, for the 1999/2000 campaign requested by Monsanto Paraguay.

The incorporation of these measures through a regulatory framework will have to have a uniform structure that avoided contrapositions or blanks and that, over all, it were adequate to the national reality.

Starting from these concepts, what it has to be obtain is discharging potential conflicts between the commercial regulations and the global biosecurity regime with national existing regulation, and between this last one and the regional and international regulations in order to conciliate all this juridical infrastructure as a whole with different sequences or cogs that must function in a harmonic way for a safe utilization of the biotechnology.

It is necessary to accept that it is not always seen a road or solution toward a food security in the biotechnology, since this practice clash constantly with ethical, environmental, social and health reasons when developing genetic manipulations that, even they occur gradually since various decade, it is now when huge advances took place concerning the transgenic production, induced genetic mutations, etc.

It often clashes with environmental principles which are recognized by the States as the one of Precaution, which is one of the corollaries of the Principle of Avoiding Damage, that advocates that in case of scientific uncertainty on an activity is or not pernicious for the environment, it should be applied the aphorism *in dubio pro natura*.

As the manipulation of LMOs is considered, in scientific terms, of recent origin, the ghosts created in this context are several, ones more reasonable than others. However, this aspect is important in the valuation of present realities of direct agents to perceive over which points the juridical security should focus on, so that the legislation which regulates the matter can serve as catalyst of fears that circulate and as a guaranty against possible dangers demanded by this activity.

The effective regulation will depend, in this way, on the adequate identification of activities that is based on processes which imply the utilization of biotechnology, on the responsible ones to carry on this tasks, on the existing regulations and on the moment that it is born; in spite of some lacks, the contrapositions or blanks always respond to a national juridical structure.

It is the momentum to identify the present reality in the Republic of Paraguay concerning the regulation about biotechnology and the security of the biotechnology in order to be able to evaluate the scope of what already exists, the inconveniences that present, the **adequation** or not to the national reality, applicability, limitations and other adjectives that can be found to finally make an analysis that can provide recommendations about failures or lacks of the present tool on this issue, with the collaboration of the involved sectors.

The aim is clear: the establishment of National Frameworks on Security of the Biotechnology in Paraguay that should be adequate to international exigencies to fit in the international community in activities such as commerce, researching or other activities in a complete way, without unnecessary obstacles or pernicious positions. Besides, it has to be according to the national reality as it was affirmed previously since any regulation is effective if it does not reflect the necessities of people in the issue that regulates.

Critical Revision of the Normative in Force

The Republic of Paraguay is in the initial phase of the drawing of guidelines about biosecurity and biotechnology, although it assumed its commitment against the international community to release bureaucratic obstacles that difficult an international commerce of transgenic products.

The development of the biotechnology in Paraguay is necessary, considering the biological diversity that this country possesses as a genes source , that provides it a competitive advantage in respect to other countries that can focus their interest in the Paraguayan territory, as well as the legal conditions were clear and adequate to the international exigencies.

However, the reality of the country places us in a complex position in relation of producing transgenic crops, with emerging consequences from technical aspects, and from political and economic interests, besides the environmental ones, that are mandatory issues conforming established the National Constitution.

Identification of the reality of the Present Regulation

From the identification of the regulations, covering the National Constitution, international treaties and agreements, laws in the strict sense, and administrative regulations that complement the present reality about biosecurity, reinforced realities are identified with the comments from the different governmental and private entities that provide their experiences to criticize that will enable to reduce bureaucracy and make effective the activities that tend to a major competitiveness of the country on this matter.

The principal regulation on this matter is under the cover of a ministerial disposition, the **Decree Nr. 18.481/97**, that creates a Commission on Biosafety whose functions are subscribed in an exclusive way in relation to vegetables but not animals.

In virtue of this decree, this commission that meet representatives of different sectors, public and private stakeholders, has the role of advisor for the Ministry or Agriculture and Livestock, but it is not an authority of application on this matter. For this commission to be adapted to the existing scenario, it should strength its attributes and capacities to act in an effective way for the protection and security of biotechnology.

The Law of Wild Life that regulates the live organisms, does not include microorganisms and does not specify the obligation to evaluate the environmental impact in the terms of the Law Nr. 294/93.

The Law on Seeds and Protection of Crops does not establish a clear and precise regulation on the release of LMOs in the environment, covering only transgenic products of vegetable origin. Not being coherent the access to genetic resources with the recognition of rights of intellectual right resulting from these cases.

This law, also, regulates the transport of vegetable products inside the national territory, as well as the entry and leaving of vegetables products through the frontiers of the country, according to what is established the international instruments on this matter. This is of vital importance for the regulation for the entry of transgenic products into the Paraguayan territory,. However, there is a big blank on respect of livestock products.

On the other side, a double regulation is observed between the Vegetable Defense Law and the one that regulates Seeds and Protection of Crops in the relation to the seeds exporting and importing procedures. Even though the Law Nr. 385/94 requires for the seed importing a previous fulfillment of the regulation of phytosanitary protection, the presence of two authorities with different criteria about protection can eventually lead to contradictory results, situation that can be more serious in relation to the environment.

The Art.14th. of the **Law Nr. 1.561/00** mentioned the SEAM as the authority of application of all the dispositions of the laws. However, this cannot be the case of the Law 385/94, which has areas of responsibility beyond the environment. Any way, its place should be in the Art. 15th. As, indeed, it is the Law Nr. 123/91 even this did not occur.

What is the most remarkable aspect is that there is not a regulation, with legislative range, to regulate and unify similar policies and criteria to be coordinated for the involved institutions. The absence of a Law on Biosafety, that confronts all these questions in a global and coherent way, hinders the application of the Cartagena Protocol in Paraguay.

Identification of Governmental Policies of Security on Biotechnology

Part of the analysis is the identification of policies of different governmental institutions from each of their departments for the eventual creation of a national level policy, which is the National Framework of Security on Biotechnology.

In this framework, ratifying the Cartagena Protocol of Security on Biotechnology, Paraguay recognizes a different quality in the LMOs that justifies a particular treatment for the internal positive right of the Republic.

It is important to remark that the Policy of Security on Biotechnology cannot be sustainable on juridical instruments which prohibit the use of modified live organisms, since even the CP recognizes in its preamble the risks and benefits associated to biotechnology, it submits textually that “the modern biotechnology has great possibilities for the contribution to the human welfare if it is developed and utilized with adequate security measures for the environment and the human health”.

This unable to open the market to these products without taking the necessary measures tending to protect the environment where they are going to circulate. But this behavior should be regulated from the ratification and inclusion in the national juridical ordering, even above the laws in a strict sense, as a tool to regulate the use of LMOs, with previous evaluations and other procedures that might be required.

It is expected from Paraguay that the adopted policies by the different governmental institutions who are linked with the utilization of genetic engineering in all fields were unified and impose restrictions which will not be irrational in the use of LMOs. This is, in respond to the CP that affirms that its objective is to guarantee an “adequate level of protection in the spheres of transference, manipulation and secure utilization of these organisms”.

Consequently, the national decisions should be carefully evaluated in order to avoid conflicts with the commercial regulations, since the agreements related to commerce and environment should support mutually with the intention of achieving a sustainable development of the

Paraguayan territory, considering the important economic dependence on the exporting of raw materials and some derivatives of agriculture that Paraguay has.

Not only the policies are going to be unified in only one national action, but a unifier criteria should be looked for the other national and international legislations, in order to create rules of competitiveness which permit to protect our genetic resources without driving away the international market.

At the present, the Tentative Plan for the Law of Biosafety is on the Congress but even though it already has much time of study and it is under consideration of the Senate, it was debated very little in the legislative level.

According to this tentative plan, this law will regulate the investigation, testing, development, manipulation, transport, traffic, storage, production, commercialization, importing, exporting and utilization of the modified live organisms, being of vegetable or animal origin.

Likewise, it will prevent the surrounding, protecting and regulating the way of release to the environment, the elimination and final disposition when it proceeded; and it will have three application authorities: The Secretary of the Environment, the Ministry of Agriculture and Livestock and the Ministry of Public Health and Social Welfare.

Conclusions

Part of the analysis of this document is the identification of policies from the various state institutions from each one of its dependencies for an eventual creation of a national scope policy, which is the National Framework of Security for the Biotechnology.

The obligations acquired by Paraguay in the framework of the Cartagena Protocol demand that the country defines a national policy about the LMOs.

The existing propositions in the National Congress are presented in a sectorial way or are very detailed that make impossible their implementation, therefore their processes are standstill.

The normative which tends to regulate the actions of the Paraguayan State and of the private sector should manage the present reality which obstructs the development of biotechnology, such as the economic situation of the country, the poor investment from the State and also from the private sector in scientific investigations, the lack of communication between these two sectors and the limited experience in integration and inter institutional communication which is demanding in modern times against so complex aspects the present has.

Nowadays, there is no unified State policy concerning the biotechnology since the contributions are by sectors and strongly focused on the agriculture sector, with huge blanks in all the others.

The clear policies with respect to LMOs must establish serious commitments from all sectors, without leaving aside the possible impacts in human and animal health, in the environment and commerce.

Paraguay should adopt a protection framework, always taking into account the Preventive Principle or Approach, regulating what is contemplated in the Cartagena Protocol which is a positive legislation in the Republic.

Consequently, and before the assumed commitment by the ratification of the Cartagena Protocol in the context of the Framework Agreement on Biological Diversity, many of the legislations must be revised and modified, besides creating a framework law or reference which regulates as principles and as a general law the course of the security on biotechnology.

All this should also respond to assumed commitments before other international organizations and institutions that have participated previously, elaborating and complementing gradually of regulations, rules and decisions on this subject, such as the Codex Alimentarius, subsidiary entity of FAO and the WHO (World Health Organization), in risks evaluation for biotechnology derived food consumers.

The access system to genetic resources should be adequate for a national and international reality, having a simple and low bureaucratic composition but not for this, considering the national interests will be avoided. In this way, it will provide juridical security to the interested people favoring the internal as well as the external market.

Said system should also assign an only permanent inter institutional entity, represented by all the involved sectors but with certain decisive autonomy, in order to be authorized to negotiate and provide access to the genetic resources and represent the interests of those eventual stakeholders.

Consideration for an Eventual Legislation

The national juridical order is just only one tool to be evaluated for the implementation of a national framework in the subject of biotechnology security, but it is precisely in this tool where other aspects should be identified so they could be effectively protected, in order to be able to accomplish with the assumed commitments at an international level in a competitiveness range that today becomes mandatory but always adequate to national reality.

The compiling of existing normatives let us evaluate exhaustively Paraguay's present position concerning the protection of genetic resources that possesses, and the criteria for their utilization with development purposes that the State has at the present. This compiling is originated in the constitutional text, pass through CDB, the CP about Biotechnology Security and other international documents related to this issue, and it is completed with internal national regulations of civil, commercial, environmental origin among others.

In order to establish the National Framework of Security on Biotechnology is necessary the unification of the biotechnology legislation, to include in it the contemplated principles in the CDB and the established procedure in the CP.

This regulation should contain also an organic section to create an inter institutional entity which will be decisive for the policies and actions of the Paraguayan State concerning the security on biotechnology, in a way that all the linked institutions had their representation in this organization and not be taken apart, due to the technical demand or exigency of the decisions that should be taken from this permanent entity.

Presently, the commission that is conformed has only a temporal and not decisive status and the unification of criteria has difficulties because of its consultative and non ponderous characteristic.

The consolidation of ComBio is necessary from the confirmation of the members of different institutions which at the present are part of the National Committee of the Project Coordination, besides the participation of other private organizations with the purpose of creating an inter institutional entity which would define the policies of the Paraguayan State.

The regulation of the National Framework of the Security on Biotechnology must contemplate Basic Guidelines for a National Policy of Biotechnology which includes each of the public institutions as a responsible entity in the process of its decision, as well as in the starting up process of the framework with the effective collaboration of the private sectors which are the engine of the industry and commerce of the country.

The national legislation which arises from the treatment of this project, founded in the national sovereignty about genetic resources which is already recognized by the CBD, should promote in Paraguay 's internal confines an equal distribution between public and private sectors of the economic benefits which derive directly for the commercial use of genetic resources without leaving apart the financial, scientific, social and over all environment benefits.

This regulation should contain the general principles of environmental protection and the rational utilization of natural resources, regulating and conditioning, concerning the precaution principle, the circulation of LMOs in all its forms, which is more and more imminent.

The raw materials derived from the natural resources of this country, used or imported by physical or juridical persons in the international confine, for different purposes, should be protected through this general regulation that should determine unified criteria for all the other normative that may arise from the MAG, MSPBS, SEAM, DNA and other confines about the use of the genetic resources of biotechnological development.

The identification of a national framework in this matter should be coordinated with the institutions and in-force laws strengthening in order to continue and adequate the policies of the different entities in an only framework. This does not mean necessarily an unique legislation or a unique institution either but only the coordination of the tasks performed among them for not being overlapped and less to oppose unnecessarily in order to put in operation the CP.

V. System for the Decision Taking

Present Administrative Procedure for the decision taking

In Agriculture

There is a wide consensus regarding the environmental repercussion of the transgenic crops and other modified live organisms, for example, transgenic seeds have to be accessed using procedures for risks evaluation with scientific basis and case by case, according to the specie, feature and the agro ecosystem they are about. Scientists also agree that the release of transgenic organisms in the environment must be compare with other agricultural practices and technological choices.

In Livestock and Hydroponic Crop

In this sector, the Research Department on Animal Production (DIPA), through the Technical Service Department, is the responsible to issue the registrations and authorizations regarding food, drugs and veterinarian biological products.

Requirements for the registration of any veterinarian product are established in the legal framework rule by the institution. In this legal framework, there is the **Law Nr. 667/05** which is about the registration and control of veterinarian products, as well as the companies that elaborate such products. This law cites, which products should be registered to be able to commercialize through a sworn statement form.

The companies to be registered should count with a technician advisor. Some details are also specified, for example, the information that should contain the labels, what is understood by veterinarian use products, it talks about production, commercialization, importing, etc.

The Decree Nbr. 891/98 internalizes the resolutions of the MERCOSUR which rules this matter. Such resolution speaks very specifically about the forms that are used as requisites for the registration of the veterinarian products. There are form for biological products, for animal food and for drugs. This decree also establishes the minimum conditions a veterinarian product elaboration laboratory should count with.

Other documents that should be presented are: The power of attorney the elaboration company representative should have and the Origin Sanitary Registration Certificate, also the already mentioned product registration form (formulation, pharmaco kinetics, pharmaco dynamics, its way of administering, possible unfavourable effects, supported by a correspondent bibliography) previous to all this requisites, the company should be registered as a company (Enterprise Registry)

As a result of this process the registration of the product is obtained, which has a validity term. Once it is approved a number of registration is provided. This registry has a validity of 10 years and is subject to a annual payment.

There is a quality control laboratory where the samples of the three types of products, food, drugs and biological are send. For example, in the case of food, minimum necessary test are made such as protein tenor, humidity, dry material, etc.

In the case of biological items, those who are used in the prevention or eradication campaign of sicknesses that affect animals and human beings (epizooties) totalling eight. Lots which are imported are analyzed previous to their commercialization.

Particularly the drugs are assigned with a provisory registry for six months. During this period, with the first import samples should be presented for analysis even though not all products can be analyzed.

The laboratory is ready to analyze a list of active principles of the products that with the first import or elaboration are sent to the laboratory.

In health and food

There are valid procedures to evaluate the innocuousness of food and the Commission of the Codex Alimentarius. FAO/OMS offers an international forum for the elaboration of innocuousness guidelines of food related to transgenic food.

In the environment

There are no guidelines or regulations internationally agreed to evaluate the environmental impact of the transgenic organisms.

The technicians, that have some relation with the topic, agree that methodologies and harmonized regulations are needed in an international and regional level to evaluate the environmental impact in different ecosystems. The normative entities from different countries use to demand analogical database for the evaluation of the environmental impact but differs in their interpretation and in the determination of what environmental risk or danger is.

The technicians differ also about what is the appropriate base for the comparison, with the present agriculture systems and/or with the ecological reference data. An expert consultation for the FAO (2004) agreed that the effects of agriculture on the environment are much more important than the measurable effects of change of production from conventional crops to the transgenic ones, that's why the comparison base is important.

There is no agreement either among the technicians about the value of the laboratory and field tests in small scale, their generalization in large scale. Any of the methods or models of elaboration that incorporated data of geographical information systems would be useful to forecast the effect of the modified live organisms on different ecosystems. The productive and academic community recommends to do further investigations over the subsequent effects about the entry of transgenic crops.

It is also needed an orientated follow up more specifically after the commercial release of the crop and better methodologies for such follow up.

VI. About Harmonization of Evaluation Rules, Mutual
Mutual Acceptance, Results Validation and Risk Management in the
treatment of LMOs. Technical Regulation

Finally, it can be said that in Paraguay the international regulations, instruments and procedures for the risk evaluation are applied, as well as the criteria of studies case by case and step by step, does not have with general instruments for the risk analysis. Consequently, it should be recommendable and necessary to move forward a legislation that incorporates in only one instrument the policies, mechanisms and procedures that must be applied in the process of entry, evaluation, release to the environment and commercial production of the genetic transformation events, which are of interest of the country.

RISK ANALISIS

In the Paraguayan case, the Art.7th. of the **Decree Nr. 18.481/97** establishes that the evaluation of risk will exclusively correspond to the Commission of Biosafety. Likewise, it establishes the general principles through which it has to be done, respecting the following considerations:

- a) the ecosystem where the field test of the genetically modified organism will be done;
- b) the biological characteristics of the organism;
- c) the existence of plants related and localized in active germ plasma banks of the area;
- d) the consequences of the establishment and persistency of the ecosystem in the area, and probable damages over other organisms of the environment;
- e) the infectiousness, toxicity and allergies for the human beings and other organisms; and,
- f) the capacity to transfer the genetic material and the potential diffusion routes.

VII.- Mechanisms of Participation and Access to Information about Biosafety

General Context

The public access to the information is a fundamental base for the public participation, being one of the tool that can help to understand the benefits and to avoid the risks of modern biotechnology.

The Art. 23rd. of the Protocol of Biosafety establishes a number of obligations in relation to the public awareness and participation. It obliges the parties, among others, to:

a) to foster and facilitate the public awareness, education and participation concerning the security of the transference, manipulation and utilization of LMOs in relation to the conservation and sustainable utilization of the biological diversity, having also into account the human health risks. For that, the Parties should collaborate, accordingly, with other States and international organizations.

b) to try to secure that the public awareness and education include the access to information about LMOs that might be imported; and,

c) to consult the public in the process of adopting decisions about LMOs and notify the results, respecting the confidential information according to its laws and rules respectively.

The protocol provides the countries the opportunity of obtaining information before the importing of new organisms generated by biotechnology, and recognizes the right of each of the countries in ruling the organisms generated by biotechnology, subject to existing international obligations.

It is noticeable that through the active participation of the citizens, it is looked for the consolidation of the legitimacy of the issue about security of biotechnology and of the MNSB, that requires certain knowledge about the topic to obtain agreements and consensus, inclusive to create mechanisms which allow to influence at a political level and in the decision making at a country level and guarantee an adequate protection level o in the area of transference, manipulation and secure utilization of the modified live organisms resulting from modern technology, having also into account the human health and environment risks.

It is fundamental that citizens understand and participate in the national decisions concerning the LMOs, for that, it is indispensable that diverse sectors from the society participate of this complex task in an active way.

It is necessary to convene and make broad public consultation addressed to all the interested sectors including the different organizations, users and consumers, in order to establish clear policies with respect to the MLOs mainly in agriculture, and not forget the possible impact in human and animal health, in the environment and in commerce, considering the great economic dependence of the exporting of raw material and some derivatives from agriculture that Paraguay has, taking into account the Mediterranean situation.

The CP about Biosafety, in its Art. 23rd. requires that the Parties foster and facilitate the public awareness, education and participation with respect to security of biotechnology. It also requires the compulsory public consultation and to allow the consultations results in the the making decision process as well. The legislation and its application procedures are almost unknown for a great sector of the population, due to the limited diffusion and forecasting. The national capacities in the existing biotechnology and biosafety areas are scarce and the media controls communication in a superficial way.

In this context, the implementation of diffusion, informative and of sensitization campaigns in the usage of LMOs is a real necessity and have the consensus of the actors as well as the formative workshops and study plans analyses in the different educational levels for articulating science, biology and health areas in the national educative system with a pedagogical approach and with an inter discipline and transverse character.

In respect to the mass means of communication, these manage the information in a superficial way and few develop a critic policy (a few hours a week in spaces address specifically to a public related to agriculture, early in the morning and on Saturdays and Sundays), of consciousness broadcast, becoming channels with poor sensitivity and information facilitators . So, it is urgent to count with the presence of the involved environmental institution to incorporate to the action plans, chats and awareness workshops, information and training addressed to the representatives of written, radio and television press of the country, from urban and rural areas, about different issues on biosafety. Their objective will be provide adequate tools and information to understand more efficiently the issue, assuring with it the monitoring through the means of communication of the problems that are debated worldwide on the MLOs, the production, productivity, the food chain and the human health.

Being Paraguay eminently agricultural and with a economy that relies on the production of great extensions of soybean, wheat and cotton in a priority way, certain scenarios of great challenges are presented in the public participation with respect to “how to reach” the general public sectors who are involved and need to know the benefits and risks of MLOs, specially the small farmers and consumers in general.

The society requires of reliable, equilibrated and with scientific basis information about biotechnology and furthermore, accessible to the general public. The professionals, doctors, teachers and technicians from the involved public entities (MAG, SEAM, DNA, SENAVE) jointly

With entrepreneurs and producers, should interact and articulate awareness and training actions since they constitute the facilitator sources of information more credible by the public.

The public and mainly the consumers’ perception in the country about MLOs or food derived from them is rather of confusion or indifference. There are few those who question about the advantages or disadvantages of consuming transgenic products or originated from MLOs;; they do not demand or put conditions. There is, indeed, one in a while a campaign organized by environmentalist groups in local means of communication, focused against the transgenic products.

On the other hand, any enterprise has developed a diffusion or advertising campaign in favour of the biotechnological products, with the exception of cereal and oleaginous producers who do press a lot for the transgenic products to be released into the country. The agro exporting sector, specially that of soybean and lately of cotton, it is anxious of more technical

information about the different modified varieties in order to evaluate the convenience of applying this technology.

Basically the fact of being a neighbour country from Argentina, where the production was released for some transgenic products and the illegal entry of transgenic soybean seeds are factors that have disturbed the public opinion generating a set of debate so that respect and demanding the governmental institutions (MAG, MSPBS, SEAM) to open debate forums on the use of transgenic seed in the country.

Diffusion and Sensitiveness in Biotechnology

In relation to the priorities of public sensitiveness, participation, information and communication we found the necessity of promoting sensitiveness campaign; training workshops; curriculum programs revision of formal education system; extension to the non formal education, with emphasis in topic related to agriculture and transgenic food; the biotechnology applications to medicine, pharmaceutical industry, those related to the environment and of ethic characteristics., crating materials according to the different involved sectors and actors' reality, especially those who are more vulnerable, in a simple and precise language, as well as in indigenous languages. The proposed ways of communication are diverse and clearly show the necessity to develop tools addressed to specific publics.

Among the strategic actions of the plan are highlighted: the intersectional approach for the environmental performance with community participation; the population auto-responsibility; the promotion of local community actions, the public and private co-operation; and the preventing emphasis.

Concerning the political participation, it becomes necessary to reach the governmental, producer, entrepreneurship, industrial, commercial, educational, research centres sectors, as well as to social, community and consumers organizations, etc. and to work together in the information and communication processes if what pursued is to achieve a responsible and well-informed participation in the decision-making process, focused to a sustainable development with equity, social responsibility and welfare for the whole population.

The Means of Communication

Every campaign orientated toward expanding population groups foreseen the use of the means of communication, as roads to arrive and convince. Its incorporation permits to assure a broad repercussion and massive reach to multiple sectors of public opinion. At the present, there are radio programs that provide spaces to talks about transgenic crops, that represents an excellent opportunity to reach to wide community sectors as well as newspapers that devote a few pages a week to topics like agriculture, but not with the required emphasis. At the national level, the television has opened gradually some spaces to "ecological" programs and sometime it is possible to find people interested in sponsoring punctual campaigns.

Public Perception about Biotechnology

Nowadays, in the legal framework of the Biological Diversity Agreement, is foreseen the regulation for the release of LMOs with commerce purposes. This situation facilitates the country to maintain or improve the situation of the exporting food producer against

international markets. In 2004, The Paraguayan Chamber of Cereal and Oleaginous Exporters (CAPECO), The Seeds Producers Association of Paraguay (APROSEM), The Agricultural Coordinator of Paraguay (CAP), The Production Cooperatives Federation (FECOPROD), and the Soybean Producers Association (APS) expressed their desire to demonstrate due responsibility against the legal exigencies and consequently they are ready to take all the necessary actions and initiatives for the adoption of new technologies. They consider that the access to new biotechnological products will be the key to assure productive increase and sustainable development in a long-term. "A loss in the quality of our products, as a result of technological advances produced in other producing countries, will affect seriously our economy in resting competitiveness in the international market" they excerpt.

According to a report published in January 2007, in Paraguay approximately 2 million hectares of transgenic crops are registered, and that area represents in the present 90% of the total cultivated surface of soy in Paraguay.

This scale production, which is intense in the use of technology and land, has a significant impact on the reduction of the manpower occupation. "The country of Soybean", in its years in force in the country, did not show social sensibility up to now.

In this stage of scientific-technological advances, of adoption and adaptation toward the modern technology, the concepts and practices that have been developed specially in the agro and livestock sector, are new for the Paraguayan population, who in general has scarce or limited knowledge about biotechnology and biosafety. It is not either informed, or trained for the adaptation to the biotechnological changes and its applications, benefits and risks in production, or its effects on the environment and human health.

There is a general lack of sensitivity and knowledge about Biodiversity and what the CDB and other international conventions demand regarding the environment. This absence should be treated by the competent institutions with sensitivity materials, addressed to concrete publics in order to expand the knowledge of the biodiversity role when is the time to support the development as well as the requests from the international conventions on the environment.

In relation to the environmental education, formal as well as informal or non formal, the national educational system does not reveal the expected impact, neither prioritizes the biotechnology inclusion in the study programs, and this is not included in the teachers training curriculum or other university careers. At a superior level, in spite of certain efforts of some universities, there is still a great gap between the importance of the issue and the human resources training to attend the present demand according to the advances we are living nowadays.

Even if it is possible to integrate biotechnology to all disciplines at the elementary, intermediate and superior levels, it is not contemplated in a formal way in the curriculum systems of public or private education. Only some educational institutions, like the ones related to health assistance, of research and a few companies consider under their operative plans, projects including topics related to biosafety, specially in the labour sector (employees' health) without any pedagogical basis.

Some actions regarding training of short duration on biosafety are implemented principally in hospitals, universities and public health laboratories, with contents that contemplate

prevention and negative effects control on health caused by the occupational risks traditional agents.

The Project MNSB Py perceives the absence of implementation of diffusion, informative and sensitivity campaigns, training workshops and study plans analyses at different educational levels, to articulate areas such as science, biology and health into the national educational system, with a pedagogical approach of inter disciplinary and transversal characteristics.

All over, the training of the professionals concerning the topic of biosafety, principally in the involved environmental institutional and academic sectors, will permit to have a more committed presence into a society which demands, more and more, security, quality and the environmental care, guiding this toward a sustainable development.

VIII.- Guidelines for the Basic Terms of a National Policy of Security on Biotechnology

Antecedents

It is undeniable that in the definition of the National Policy on Biotechnology, the execution of the Project TCP/PAR 3001 of Support to the Formulation of a Biotechnology Policy, of the MAG and FAO, is the most significant effort of the country on this matter. Even this initiative has a slant orientated toward the forest agricultural production, this does not dent on it, moreover considering that economically the country depends on, in great measure, on the raw material agro-exporting.

It has to be highlighted, also. That the Project provides supplies that help to consolidate criteria to identify the country's needs, concerning the responsible use of the LMOs in the forest agricultural sector.

On the other side, in the political-institutional ordering it is important to mention the National Council of Science and Technology (CONACYT), which is the organism in charge of the science, technology and innovation activities promotion inside the country, and that involves the biotechnology as a priority area. It has to be mentioned that, even though this instance has a reduced assigned budget, it foresees, for next years, a significant economical support from the international organizations, being this subject to the pertinent laws promulgation.

It has to be highlighted, in the same way, inside the MAG system, the Quality and Vegetable Sanitation National Service (SENAVE), created through **Law Nr. 2.459/04** which is in the process of consolidation concerning its human resources and its budget.

Then, there is the ComBio in the biosafety area, which was created by Decree Nr. 1.848/97 and has the great responsibility of caring, analyzing and recommending everything related to the introduction, field testing, research and release of transgenic plants. But it is of consultant nature without having a legal and up-dated normative test. It is ad hoc and it does not have an structure or administrative methodology to the LMOs problems.

By its side, SEAM, even it counts with a biosafety office, this is still in the process of organization and consolidation, since there are not specialized human resources in biotechnology or in security on biotechnology. Thus, the execution of the present Project MNSB Py makes possible a quite interesting projection in the fulfilment of the CP, principally in what it does with the inter institutional coordination and the public perspective about the necessity of a national policy about the security on biotechnology, in the context of public participation mechanisms, to be embedded with the Biosafety Clearing House Project (BCH).

It has also to be considered the MERCOSUR context, where national and regional committees were created as well as the commitment to deepen the studies related to technology in relation to modern biosafety, accepting that the agro livestock sector is the one that urge almost urgent measures.

Methodology

In order to have the consent for the basic guidelines for a National Policy of Safety on Biotechnology, a methodology was developed as is described below:

a.- A circuit of **getting in touch** began with the Secretaries of the Environment Departments from different governmental bodies and engaging stakeholders in the use of LMOs, with whom meetings were carried on in a personalized way about the characteristics of the MNSB Py Project and the existing relation with them.

This activity was made with the intension of engaging the mentioned stakeholders and that concepts on biotechnology and safety of biotechnology start “to decant” among them, due to the high specificity of the topic.

b.- Once the “getting in touch” was performed and having as focal point the different Secretaries of Environment, a set of regional workshops were carried on in the following districts:

- Loma Plata: covering the Boquerón, Presidente Hayes and Alto Paraguay Departments.
- Villarrica: covering the ones of Caaguazú, Caazapá y Guairá
- Concepción: covering the Amambay, Canindeyú and Concepción Departments
- San Juan Bautista: covering the Itapúa, Ñeembucú and Misiones Departments.
- Ciudad del Este: the Departments of Amambay, North Itapúa and Alto Paraná.

During these seminars and regional workshops technical concepts on biotechnology were debated with an orientation towards the genetic engineering. The speakers were Dr. Rosa Oviedo de Cristaldo (FIA-UNA) and Agr.Eng.Edgar Alvarez (DIA-MAG). There were also speeches about safety of biotechnology, in charge of Agr. Eng. Victor Santander, coordinator of ComBio. During these regional workshops the studies prepared by the Project MNSB Py consultants were presented, obtaining from the participants some conclusions about the interest from the regions in order to be included in the Basic Lineaments for a National Policy about Security of Biotechnology.

c.- A **National Workshop** about Safety of Biotechnology took place in Asunción, where the representatives of each regional seminar previously made participated as well as the engaging stakeholders, in order to consolidate and validate the conclusions of all regional seminars, and be able to consolidate the national conclusions on the guidelines a National Policy about Safety of Biotechnology should have.

For the elaboration of the present document “Basic Lineaments for a National Policy of Safety on Biotechnology” was ruled through a resolution SEAM Nr. 1.957/05, the National Committee of Coordination (NCC), with the following institutions : Ministry of Industry and Commerce, Ministry of External Affairs, Ministry of Public Health and Public Welfare, National Service of Quality and Vegetable and Seed Sanitation, National Institute of Technology and Normalization, National Institute of Food and Nutrition , National Council of Science and Technology, Institute of Investigation in Health Science, National Customs Department and Biosafety Committee.

Several meetings took place with the NCC and the members of the Project revising, correcting and adjusting the studies made by the different consultants in order to enrich the information of regional workshops that were carried and validating this documentation later.

Productive Private Sector

By the way, it is important to mention the Agricultural Biotechnology Institute (INBIO), which is a new non profit civil association, whose aim is the promotion of the safe incorporation of biotechnology and biosafety in the agricultural sector, as key factors for the modernization of the agriculture and the consolidation of sectors competitiveness. This membership is integrated by the most representative productive sectors of the country (CAPECO, APROSEMP, CAP,APS,FECOPROD and UNICOOP Ltda.).In said context, the majority agree with the conclusions of the seminars regional workshops made.

Nevertheless, it is highlighted that:

- They agree with the greater participation of the decentralized instances in the decision taking about local release of LMOs. But, in practice, it could be very difficult to implement the restriction to the diffusion in case the biotechnological events were demanded at the producers level. Even among countries of the same region, the attempts to restrict its diffusion were fruitless, among regions inside each of the countries or among countries as well;
- They do not agree with the affirmation that technological events benefit only the great producers. According to the domestic and international experience, the small agricultural families are the principal adopters of varieties of LMOs, at least in the most important products for our country such as, soybean, cotton, corn, sunflower, canola, etc.;
- “assuring national varieties” could become in a responsibility for the public sector through the conservation in situ and ex situ of the conventional varieties which are displaced by the diffusion of LMOs in competitive sectors; and ,
- The application of the regulations established in the CP will make possible to ensure the risks assessment of each biotechnological event of LMOs type, to avoid the potential damage in health and environment. Regarding biodiversity, this is an issue that might belong to the management of wild areas, due to the great alteration introduced by the agriculture. In this last confine, is where the agricultural LMOs would be introduced.

Finally, they consider that the majority of the proposals bore in the results of the workshops coincide with the outlines of the programs of this entity.

On the other side, it is important to mention the existence of a framework agreement about the incorporation of agricultural biotechnology, agreed among the members of INBIO and MONSANTO about the soybean in particular. This event engages a payment of royalties through a payment system (MODIT) of the soybean producers for the use of technology (it is supposed) to its owner. Part of what was collected (10%) it is assigned for a development and investigation fund.

During the socialization of the MNSB Py Project in CONADERNA recommendations were given in the sense that the value of the genetic fund of the Paraguayan varieties should be rescued and develop a biotechnology according to the national limitations and needs.

Regarding the environmentalists organizations their engagement is well known in such a way that even they are invited to express their position in the present document, they reject “in limine” any analysis or consideration about the use or regulation of LMOs.

IX.- Recomendations for a National Policy on Safety of Biotechnology

It is important to recognize, that the conclusions mentioned before agreed in great way with the National Environment Policy (PAN) understanding that this considers as indispensable condition that national policies should look for a global and local balance among the economic, social, cultural and environmental objectives.

Likewise, the principles of PAN in the sense of sustainability, precaution, integrity, gradualism, responsibility and subsidence are also respected.

And, in relation to the specific objectives of PAN, is coherent concerning the generation of conditions for the welfare and improvement of the life quality of the people, preventing the degradation of habitats, the application of a precautionary principle engaging actively the population in taking decision and in the environment management, as well as monitoring the international agreements and treaties. Besides, the trend to foster the building up of strategic alliance continues with the articulation of the other governmental policies., understanding that the joint action ensures the political and social feasibility, making viable the attainment of the objectives of a sustainable development.

On the other hand, even in Paraguay the National Policy on Safety of Biotechnology is not shaped or written as a document yet, the engaged institutions which conform the governmental stratum tend to behave in a separate way by sectors, but concomitant when the national interests are at stake. This is more clearly evidential in the protagonist role of national institutions during the meetings of the States Parties of the CP.

For that, it has to be understood that there is an application in force of a National Policy on Safety of Biotechnology, but it is not still consolidated like it should be, staying only as a necessity. This is what it is tried to put in the present document in the definition of basic guidelines or lineaments for a National Policy of Safety on Biotechnology.

Although this National Policy on Safety of Biotechnology should consider the necessary instruments for the control and safe use of LMOs (biosafety), it has to be careful about not obstructing the characteristics regarding fostering and enhancing the scientific capacity (biotechnology) of the country.

It means, it has to be a policy orientated towards a pertinent regulation where the country could get benefits through economic opportunities of biotechnology (exporting of soy, cotton, etc.) but where the evaluation of the environment risks and the management of an acceptable risk level were guaranteed.

This National Policy must provide a context in which it can be decided, for example, the convenience or not of using certain type of transgenic material and the conditions of its eventual use. This will facilitate the engaged institutions for the effective application of actions from the State jointly with the private sector.

This National Policy should be reflected in an organic generic and dogmatic law, strengthening in this way the effective institutions which have been working in a gradual way in the management of an investigating field of technology provided by the genetic engineering.

In this sense, and having the appropriate support documents, it can be inferred the recommendations which are detailed as follows:

9.1 About the juridical instruments to support the activities for the safety of the biotechnology

- To establish a juridical framework norm for Safety of Biotechnology which should include clear and precise procedure rules?
- To establish an expedited and simplified procedure with presence of the State.
- Juridical instruments with a technical-scientific basis.
- To consult the private sector engaged in the ordering of the topic on the decision taking.
- The supervised experimental tests for authorization or release should be opened to the private sector too.
- The juridical framework should guarantee the conditions for food safety with traditional species.

9.2 About an administrative system on an organized structure to assess and manage risks.

- Updating and improvement of the organizational structure of ComBio and the institutions which conform it for assessment and control of risks.
- Organization in a departmental and national level (decentralization).
- Planning of activities in a national scope.
- Training of the national and local stakeholders about the biotechnology, biosafety and other similar topics.
- To promote and strengthen regional committees for the risk analyses and commercial release of LMOs.
- Engaging of other public local instances such as: municipalities and governing sectors, and private as: producers or farmers, consumers associations in the ComBio.
- ComBio or similar instance with power of decision directly entailer and autarchic.
- To submit the release mechanisms of LMOs (laboratories, experimental tests, field testing, commercial production, etc.) and its commercial products to the assessment procedures of the environmental impact.
- Development of local technologies to research about LMOs.
- To ensure national varieties, national genetic material and food security.

9.3 About the system for the adoption of decisions

- To present a project on institutional strengthening to the CONAM and incorporate it in the PAN.
- To promote a harmonic living or of the different crops systems (LMOs , conventional, organics) in order to mitigate the potential adverse effects that each of these activities might generate.
- To expand to the universities the possibility to study and experiment with LMOs in their laboratories and investigation fields.
- To consider the local socio-cultural aspects, principally of the small and medium size farmers.

- Security systems in adopting decisions for the manipulation and safe use of the LMOs, for the environment as well as for human health.
- Biotechnology is presented as a present alternative to be competitive in the international market.
- To ensure the development of critical events as, for example, tolerance to water or salinity stress, which may be interesting in special conditions.

9.4 About the mechanisms on the participation and information to the public

- To train the national, regional and local authorities, as well as means of communication, in aspects related to the safe use of biotechnology.
- Inclusion of aspects related to teaching, training and diffusion of LMOs in formal and non formal education.
- Utilization of an appropriate language in keeping with the academic level of the public.
- To rest on the use of the traditional means of communication and computing support (Web system and/or national and international network) for the diffusion.
- The use of other non massive means of communication (for example, use of brochures).
- Connexion with the Consumer Law.

X.- Recommendations and Comments of the National Committee of Coordination, about the Guidelines or Basic Terms for a National Policy on Security of Biotechnology

The CNC agrees mostly with the conclusions collected from the regional and national seminars workshops, but annotate the following:

10.1 About the juridical instruments to support the activities on security of biotechnology.

It has to be a gradual growth of the juridical regulations in order to fulfil what was established in the CP.

Is a regulated activity, but the application instruments should be modernized or adequate them to the dynamic change of the activity.

Consulting Mechanisms should be design for the private sector about the use of LMOs.

The implementation of experimental tests executed by the academic sector with supervision of the government should be made in a gradual way.

The Government Fiscal system must be strengthened according to the permanent evolution of the modern biotechnology.

10.2 About an administrative system with an organized structure to evaluate and manage risks.

The existing proposed law presented by the Executive to the Congress should be treated. If this does not take place, it will be convenient to modernize the decree through which the ComBio is created.

Responding to a genuine aspiration, it is convenient to establish a strategy in relation to the activities schedule all over the country.

A national capacity should be created in all scopes and levels, emphasizing its incorporation to the educational curricula.

That Paraguay should be the seat of regional workshops of the GEF projects about the issue.

A consulting mechanism for the commercial release of LMOs should exist.

A transference and creation of a genetic engineering capacity should exist in order to generate or promote LMOs' generation.

Use of genetics to be adapted to local agro systems.

Using of modern biotechnology for the conservation of national varieties through strategic alliances with the technology owners.

10.3 About the system of adopting decisions.

Coexistence of crops (conventional, organics and LMOs)

10.4 About the mechanisms for participation and information to the public

Effective implementation of the Mechanism of information exchange

Production of booklets about modern biotechnology.

10.5 Other Comments of CNC

It should be convenient to put in force the project of harmonization of the Consumer Law with the Biosafety Law which is in the Congress.

A well consented opinion is that there is an urgent necessity to put in force the CP due to the pressing situation.

There should be a real engaging of the environment and health sectors in the use of LMOs issue.

XI.- Contributions of the UNEP-GEF Project

Even though the fundamental objective of the Project MNSB Py is the identification of guidelines already explained, which will make possible the definitions of the basic lineaments for a National Policy of Security of the Biotechnology in Paraguay for the manage and use of the LMOs, is important to mentioned that certain contributions that the UNEP-GEG Project has achieved during its development.

- 1.- The consolidation of the incipient capacity inter institutional from the State-country in the processing about the use of LMOs in Paraguay.

In a country like Paraguay, where the biotechnology and the security of biotechnology were not developed yet as the rest of the world, but, however, it became a user of the biotechnology products, the institutional intellectual capacity in certain way tries to administrate the economic pressure which represents the use of LMOs in agriculture. For that, the strengthening of the existing human resources through this project was useful for the engaged institutions to take into account in an exact way of their limitations, as well as of their potentialities, to face satisfactorily the use of LMOs in Paraguay. It has to be considered that this institutional intellectual capacity had already existed before the Project MNSB Py, through other initiatives related to the transboundary movements of LMOs, moreover, having the unavoidable commitment of the application of the CP of Security of the Biotechnology.

- 2.- The complementation of information and diagnoses with other initiatives for the formulation of the National Policy of Security of Biotechnology in Paraguay.

The Project MNSB Py was useful for, through an institutional coordination, the existing projects were not repeated or duplicated, as happened before with other previous initiatives, but, by the contrary, for this information to be complemented, based on the dynamics developed in the country, according to the recommendations of UNEP and FAO, which were coherently advised by the National Committee of Coordination of the MNSB Py Project.

- 3.- The technical and institutional potentialities and limitations concerning biotechnology and security in biotechnology should be strengthen in the country.

Evidently, the governmental institutions in Paraguay, like the other Latin American countries, have had the bad habit of acting as close and stagnant entities, with an institutional myopia of acting only to fulfil the administrative law from whom they are the application authorities and with the consequent overlaps, blanks and hindrances among them that cause an awful public service. However, this Project has permitted to demonstrate that the institutions should consider their commercial interests in favour of the national interests; moreover, when it is talked about the use of hi-tech technologies which is the case of LMOs in the country. Consequently, as the engaged institutions be worked in a coordinated way, socializing concepts, criteria and needs in managing LMOs, the inherent difficulties of this activity will be administrated in an effective and in parallel way. This will be useful to strengthen of the academic, technological, intellectual and institutional capacities of the country.

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XIII.- Annexes

RESOLUTION FOR THE CONSTITUTION OF THE
NATIONAL COMMITTEE OF COORDINATION (CNC)

SECRETARY OF ENVIRONMENT

Resolution Nr. 1.957/05

WHEREBY, IT IS ESTABLISHED THE NATIONAL COMMITTEE OF COORDINATION “CNC” OF THE PROJECT FOR THE DEVELOPMENT OF A NATIONAL FRAMEWORK OF SECURITY ON BIOTECHNOLOGY FOR PARAGUAY, IN THE FRAMEWORK OF THE WORLD PROJECT OF UNEP-GEF

Asunción, November 25, 2005

WHEREAS: The necessity to establish the National Committee of Coordination “CNC” of the Project for the Development of a National Framework of Security on Biotechnology for Paraguay, in the Framework of the World Project of UNEP-GEF, and,

WHEREAS: That, in virtue of the prescriptions of Law Nr. 1561/00 “That creates the National System of Environment, the National Council of Environment and the Secretary of Environment, in its article 11 establishes that the Secretary of Environment has as an objective the formulation, coordination, execution, supervision of the national environment policy, and,

That, likewise, in the article 12 of the same Law, it is ordered: “The Secretary of Environment will have as functions, attributes and responsibilities the following: a) To elaborate the national environment policy ... b), c), d) To determine the criteria and/or environment principles to be incorporated in the formulation of national policies, e), f), g) To coordinate and supervise the management of public bodies with competence in the environment issue and the benefits of natural resources... h), i) j),”

That, likewise, in the Article 15 of the said legislative body says: The Secretary of Environment will exercise authority on the issues concerning its scope of competence and in coordination with the other competent authorities in different laws, and,

That, the Secretary of Environment “SEAM” and the United National Environment Programme UNEP, on date July 1st., 2005, have subscribed the document for the implementation of the Project for the Development of a National Framework of Security on Biotechnology for Paraguay, in the Framework of the World Project of UNEP-GEF, and,

That, in accordance to what was stipulated in the Paragraph “Functions and Responsibilities”, of the document of the previously mentioned Project, the Secretary of Environment is the National Body of Execution “ONE” and therefore responsible for the execution of the National Project.

That, in a different Section of the same document, it is stipulated that the National Body of Execution “ONE” is the entity in charge of and authorized to establish the National Committee of Coordination “CNC” .

That, on the same way in the Annexe I of the mandates, it is stipulated that “ONE” will establish the National Committee of Coordination “CNC”, and ,

(signatures and steals)

SECRETARY OF ENVIRONMENT

Resolution Nr. 1.957/05

WHEREBY, IT IS ESTABLISHED THE NATIONAL COMMITTEE OF COORDINATION “CNC” OF THE PROJECT FOR THE DEVELOPMENT OF A NATIONAL FRAMEWORK OF SECURITY ON BIOTECHNOLOGY FOR PARAGUAY, IN THE FRAMEWORK OF THE WORLD PROJECT OF UNEP-GEF

That, the National Committee of Coordination “CNC” is established to give orientation and advising in the preparation of a National Framework of Security of the Biotechnology “MNSB”. In said Committee should be included representatives of governmental entities with pertinent mandates for the Cartagena Protocol about Security of Biotechnology, likewise, representatives from the public and private sectors should be included. The Committee will be of multidisciplinary and multi-sector type in areas which are pertinent to the Cartagena Protocol about Security of the Biotechnology, and,

That, the Secretary of Environment is a specialized institution, being its scope of action the national level and the functions that develops should take it to be the articulator axis of the public administration’s efforts in order to satisfy the demand of an appropriate, efficient and effective public service, through a policy that ensure the full validity of the legacy principle and specially, the one concerning the juridical security of events and acts related to the environment, and,

That, in agreement to the mentioned legal norms, it arises the necessity in establishing a National Committee of Coordination “CNC” of the Project of Development of a National Framework of Security of the Biotechnology for Paraguay, and,

That, according to the Art. 18 inc. g) of said Law “That creates the Secretary of Environment”, it is responsibility of the Executive Secretary to dictate all the Resolutions that were necessary for the consecution of the goals of the Secretary, making possible to establish the internal regulations necessary for its functioning.

THEREFORE, In exercise of its legal faculties;

THE MINISTER OF THE SECRETARY OF ENVIRONMENT RESOLVES:

Art. 1st.: To establish the National Committee of Coordination “CNC” of the Project for the Development of a National Framework of Security on Biotechnology for Paraguay, in the Framework of the World Project of UNEP-GEF, in conformance to the considerations of the present Resolution;

Art.2nd .: To establish that the National Committee of Coordination “CNC” functions as a deliberative and consultant body in its limit of competence, established in the present Resolution;

Art. 3rd .: To decide that the National Committee of Coordination “CNC” will be conformed of the following Institutions:

Art. 6th.: The National Committee of Coordination "CNC", will assume the functions and responsibilities established in the document of the National Project.

Art.7th.: The National Committee of Coordination is authorized to dictate an Internal Rule.

Art. 8th.: To communicate to whom it might concerned , and once fulfilled to File

Agr. Eng. ALFREDO MOLINA

ACT OF APPROVAL OF THE REGULATION OF THE NATIONAL COMMITTEE OF
COORDINATION (CNC)

3rd. MEETING OF THE NATIONAL COMMITTEE OF COORDINATION (CNC) OF THE
MNSB Py PROJECT

December 29, 2005

ACT

In the City of Asunción, Cerro Corá Neighbourhood, at eleven thirty of the date twenty-ninth of December of the year two thousand five, in the Trebol Room in the Secretary of Environment (SEAM), in virtue of the notice of a meeting by the National Coordinator of the Project (CNP) Agr. Eng. Walter Nieto Tarazona, Secretary of the National Committee of Coordination (CNC), meet together Agr. Eng. José Schwartzman (National Council of Science and Technology-CONACYT), Agr. Eng. Liz Carmen Rojas (SENAVE from the Ministry of Agriculture and Livestock-MAG), Agr.Eng. Victor Santander (Biosafety Committee from the Ministry of Agriculture-MAG), Eng. Aida Romero (Ministry of Industry and Commerce-SSEC), Agr. Eng. Crisanta Rodas (from the Cabinet of the Ministry of Agriculture-MAG), Dr. Gloria Vega de Rojas (National Institution of Food and Nutrition-INAN from the Ministry of Health and Social Welfare-MSP y BS), Dr. Veronica Patricia Acosta (National Department of Sanitary Control from the MSPyBS), Chem.Eng. Cristina Torres (ONE-Secretary of Environment-SEAM) and Dr. Graciela Russomando (Institute of Researching of Health Science-MSPyBS). All of them members of the National Committee of coordination (CNC), with the aim of proceeding with the study and analysis of the Regulations of the mentioned Committee.-----

The Presidency, in the present Meeting of CNC is being ad interim by Agr. Eng. Victor Santander, as per a phone request by the President Agr. Eng. José Schwartzman, who arrived later to the Meeting. Then, it is continued with the analysis and stud of the Internal Regulation of CNC, reaching to the agreement to approve it in terms of the corrected version during the present Meeting, stipulating the delivery of such document to the SEAM, to be put in force through a Resolution. -----

To finish, it was put under consideration of the present people a copy of the Annual Schedule of Work of the MNSB Py Project, standing its treatment for the next meeting of the CNC, fixed for Thursday, February 2nd. 2006. After that, and being one o'clock in the afternoon, the meeting has been finished, attesting it through the signatures of the presents.-----

(signatures)

INTERNAL REGULATION OF THE NATIONAL COMMITTEE OF COORDINATION
(CNC)

**INTERNAL REGULATION OF THE NATIONAL COMMITTEE OF
COORDINATION (CNC) OF THE MNSB PY PROJECT
December 29th, 2005**

NATURE, ESTABLISHMENT AND GOALS

ARTICLE 1.- The National Committee of Coordination- CNC established by virtue of the Resolution SEAM Nr. 1957/05 in the context of the Project: “Development of the National Framework of Security of Biotechnology (MNSB Py) is the consultant body and of advising of the operative structure of the Project. It will have a multidiscipline and inter institutional character, being able to modify its composition as far as the Project be implemented.

APPOINTMENTS OF REPRESENTATIVES

ARTICLE 2.-

- a) For being official members as alternates of the CNC, the institutions and/or the organizations, public and private, must deliver the designations of their representatives, which will be endorsed, through a Resolution of the Juridical Entity responsible for the execution of the Project, Secretary of Environment, SEAM.-
- b) In first instance, the National Committee of Coordination will be conformed by public institutions which have linking with the Cartagena Protocol. In second instance, the representatives of other engaged sector of the civil society will be integrated, according with the advance of the program and activities of the Project.

RESPONSABILITIES OF THE REPRESENTATIVES

ARTICLE 3.- The representatives have the following responsibilities:

- a.- The working team has to meet in an ordinary way each month and/or in extraordinary way, when the situation be required.
- b.- To supervise the planning, follow-up and evaluation of the activities and results of the MNSB Project.-
- c.- Orientate and advise about the Work Schedule proposed by the National Coordinator of the Project (CNP).-
- d.- To provide the available data and knowledge in the institutions represented through the adequate flow of information among the parties for the execution of the project.
- e.- To offer general orientation about the national policy for the execution of the National Project.-
- f.- To ensure that the generated information be forecasted to the local and national authorities of the represented sectors.-

- g.- They will be able to elect and/or be elected to preside the meeting.-
- h.- To attend the meetings to those they were called.-
- i.- To have voice and vote in decisions not taken by consensus.
- j.- To know and approve by consensus the Annual Work Schedule, as well as the advance of the Quarterly Program of the Project.

TAKING DECISIONS

ARTICLE 4.- Decisions will be taken considering the priority and magnitude of the tasks to be done and will be resolved by consensus among the members. By the contrary, it will be resolved by simple majority of votes (more than 50% of the presents with voting right). It is considered one vote per institution which is present, with the exception of the President, who will vote only in case of draw.

REDACTION AND APROVAL OF ACTS

ARTICLE 5.- In every Act should be recorded:

- a) Place, date and hour where the meeting took place.-
- b) Who chaired and who were present.-
- c) If there was a regulated quorum and remarks about the previous Act.
- d) Discussed Agenda.-
- e) Motions put under consideration.-
- f) Reading of previous Act for its approval.-

SESSION AND/OR FULL MEETING OF CNC

ARTICLE 6.- They have to meet in an ordinary way each month; people would be called and confirmed with a 48-hours-anticipation, by the Secretary of CNC. The extraordinary meeting will be made according to the necessities with fixed agenda and when the situation requires so, in coordination of the members of CNC with the Secretary of CNC. The National Coordinator of the Project will exercise the position of Secretary of the CNC.

ABOUT METINGS

ARTICLE 7.- Meeting will be composed of the following stages which are the following: “Approval of the Act of the Previous Meeting”, “Order of the Day” and “Debate”.-

ARTICLE 8.- The quorum required for the meetings to be valid is the half plus one of the representatives at the first call, and with the present members in the second call. The calls will be made in the same day of the notice to the meeting with an interval of 30 minutes at most.

OF THE PRESIDENCY AND THE EXECUTIVE SECRETARY

ARTICLE 9.-The President will exercise his functions of moderator of the meetings. Any member of CNC will be able to be elected by simple majority. The position of President will have a duration of three months, being able to be elected and/or re-elected each three months, up to the end of the project, based on the criteria of the Full Meeting of the CNC.

ARTICLE 10.- The Executive Secretary will have the following responsibilities:

- a) To call for the meetings.-
- b) To elaborate the preliminary agenda
- c) To elaborate the Act of meeting.-
- d) To communicate the reports to the Regional Coordinator
- e) To present to the CNC the directions of the Regional Coordinator.-
- f) To present the advance reports about the execution of the Project.-

VALIDITY, APPROVAL AND MODIFICATION OF THE REGULATION

ARTICLE 11.- The present Regulation will be able to be modified according to the scope and consolidation of the CNC and with the consensus of the 75% of the members with a right of voice and vote..-

ARTICLE 12.- The present Regulation is approved by the CNC, according to the Article 7 of the Resolution SEAM Nr. 1957/05 and will be put in force with a Resolution of the SEAM.-