Gobierno de Reconciliación y Unidad Nacional

El Pueblo, Presidente!

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Nicaragua Gana con Vos!

FINAL REPORT
MARENA/UNEP BIOSAFETY PROJECT
IN THE FRAMEWORK OF THE CARTAGENA PROTOCOL ON BIOSAFETY FOR LIVING MODIFIED ORGANISMS

Ministerio del Ambiente y los Recursos Naturales

Km. 12½ Carretera Norte, Frente a Corporación de Zonas Franca
(505) 2631994

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EXECUTIVE SUMMARY

Biosafety is an issue of outmost importance for Nicaragua, a country that imports pharmaceuticals, food and agricultural products: this flow of products exposes the country to a diversity of risks, in the sense that elements stemming from Living Modified Organisms (LMO's) could be introduced into the country. For this reason, it was a priority for Nicaragua to implement a system to address the issue in a safe manner, in order to provide a correct response to LMO-related cases and avoid risks to human and animal health and to the national biodiversity.

In 1992, Nicaragua signed the Convention on Biological Diversity during the Earth Summit in Rio de Janeiro, Brazil, which was then ratified by the Nicaraguan National Assembly on October 27,1995, through Legislative Decree No. 1079, published in the Official Gazette Journal No.215.

Subsequently, during the celebration of the V. Conference of the Parties to the Convention on Biological Diversity, the Cartagena Protocol on Modern Biosafety was signed, in compliance with the commitment made by article 19 paragraph 3 of the CBD; in conformity with the national legal system, the State of Nicaragua then proceeded to approve and ratify the Cartagena Protocol, through Legislative Decree of the National Assembly No.3248 and through the Executive Decree issued by the Presidency of the Republic for the approval of the ratification instrument, dated March 21, 2002 and June 28, 2002, and published in the Official Gazette No.56 and 121 respectively.

With this background, Nicaragua could formulate Project No. GFL/2716-01-4319 (PMS: GF/6010-01-01), Subproject No. GFL/2716-02-4554 (PMS: GF/6010-01- 88), proposing itself the objective to prepare a National Regulatory Framework in line with relevant provisions of the Cartagena Protocol on Biosafety, which outlines the following elements as strategic pillars for its functioning:

- A Regulatory System
- An Administrative System
- A Decision-Making System that includes risk management
- A mechanism for public participation

In addition, the project aimed at creating a database of information based on the following objectives:

- Specification of the existing Institutional Framework and future perspectives of governmental and non-governmental agencies in Nicaragua in order to comply with the provisions of the biosafety protocol
- Determination of the current status and future perspectives for the scientific personnel working on technical aspects of of biosafety, both in government institutions and the scientific community
- Identification of the current state and future perspectives of the infrastructure and / or the equipment of the institutions involved, to allow for a proper management and risk assessment under the Biosafety Protocol
- Identification of training needs and expertise in the governmental sphere and outside the government of Nicaragua, in order to ensure that qualified personnel is enabled to implement the Biosafety Protocol
- A list or "Directory" of institutions and individuals linked with the issue of biosafety and biotechnology in Nicaragua, with full names and physical addresses

It is noteworthy that the project mostly achieved the proposed objectives; in addition, during its actions it gained extraordinary experience in negotiating between major players, such as government institutions, civil society, including a sector which represents the private sector, an achievement that led to the consolidation of inter- and intrainstitutional agreements based on the identification of the state of know-how on LMOs, and the need for a specific law on aspects of modern biotechnology, the LMO-risk analyses and the definition of institutional competences to address the issue.

LIST OF ACRONYMS AND ABBREVIATIONS

BCH	Biosafety Clearing House
CONACYT:	Nicaraguan Council on Science and Technology *Consejo Nicaragüense de Ciencia y Tecnología*
CAC:	Central American Agricultural Council *Consejo Agropecuario de Centro América*
CATIE:	Center for Tropical Agricultural Research and Education *Centro Agronómico Tropical de Investigación y Enseñanza*
CCPVV:	Qualifying Committee for the Protection of Plant Varieties *Comité Calificador para la Protección de Variedades Vegetales*
CENIDH:	Nicaraguan Human Rights Center *Centro Nicaragüense de Derechos Humanos*
CGIA:	Consultative Group on International Agricultural Research *Grupo Consultivo para la Investigación Agrícola Internacional*
CIAT:	International Center for Tropical Agriculture *Centro Internacional de Agricultura Tropical*
CIMMYT:	International Center for the Improvement of Corn and Wheat *Centro Internacional para el Mejoramiento del Maíz y el Trigo*
CISAS:	Center for Health Information and Counselling Services *Centro de Información y Servicios de Asesoría en Salud*
CODEX:	Codex Alimentarius
CONARGEM:	National Commission on Risk Assessment of Genetically Modified Organisms *Comisión Nacional de Análisis de Riesgos de Organismos Genéticamente Modificados*
CONASEM:	National Seed Council *Consejo Nacional de Semillas*
CONICODEX:	Nicaraguan Codex Committee *Comité Nicaragüense del Codex*
COP:	Conference of the Parties to the CBD
ECLAC:	Economic Commission for Latin America of the United Nations *Comisión Económica para América Latina de las Naciones Unidas* (CEPAL)
FAO:	United Nations Organization for Food and Agriculture
FENACOOP:	National Federation of Agricultural and Agroindustrial Cooperatives *Federación Nacional de Cooperativas Agropecuarias y Agroindustriales*
FUNICA:	Foundation for the Technological Development of Agriculture and Forestry of Nicaragua *Fundación para el Desarrollo Tecnológico Agropecuario y Forestal de Nicaragua*
GDP:	Gross Domestic Product.
GEF:	Global Environmental Facility
GMO:	Genetically Modified Organisms
IICA:	Inter-American Institute for Cooperation on Agriculture *Instituto Interamericano para la Cooperación en la Agricultura*
INTA:	National Institute of Agricultural Technology *Instituto Nacional de Tecnología Agropecuaria*
ISPM:	International Standard for Phytosanitary Measures No.11
LIDECONIC:	Liga de Defensa del Consumidor de Nicaragua
LMOs	Living Modified Organisms
MAGFOR:	Ministry of Agriculture and Forestry *Ministerio Agropecuario y Forestal*
MARENA:	Ministry of Environment and Natural Resources *Ministerio de Recursos Naturales y Ambiente*

MIFIC:	Ministry of Development, Industry and Natural Resources *Ministerio de Fomento, Industria y Comercio*
OIRSA:	Regional International Organization for Health in Agriculture *Organización Internacional Regional de Sanidad Agropecuaria*
PAIT:	Project for the Support of Technological Innovation in Nicaragua *Proyecto de Apoyo a la Innovación Tecnológica de Nicaragua*
PCAC -UNAG:	Peasant-to-Peasant Project of the UNAG *Programa Campesino a Campesino de la UNAG*
PHBB:	Hemispheric Program on Biotechnology and Biosafety *Programa Hemisférico en Biotecnología y Bioseguridad.*
PND-O/PRORURAL:	National Rural Development Production Plan *Plan Nacional de Desarrollo Rural Productivo*
PNS:	National Seed Plan *Plan Nacional de Semillas*
R & D:	Research and Development
REDBIO / FAO:	Technical Cooperation Network on Plant Biotechnology for Latin America and the Caribbean *Red de Cooperación Técnica en Biotecnología Vegetal para América Latina y el Caribe*
RICYT:	Inter-American Science and Technology Network *Red Interamericana de Ciencia y Tecnología.*
RPI:	Intellectual Property Registry *Registro de la Propiedad Intelectual*
SIMAS:	Mesoamerican Information Service on Sustainable Agriculture *Servicio de Información Mesoamericano sobre Agricultura Sostenible*
SINACYT:	National Science, Technology and Innovation System *Sistema Nacional de Ciencia, Tecnología e Innovación*
SMEs:	Small and Medium Enterprises.
TRIPS:	Trade Related Aspects of Intellectual Property Rights
UCA:	Central American University *Universidad Centroamericana*
UCC:	University of Business Science *Universidad de Ciencias Comerciales*
UITA:	Internacional Union of Food Workers *Unión Internacional de Trabajadores de la Alimentación*
UNA:	National Agrarian University *Universidad Nacional Agraria*
UNAG:	National Union of Farmers and Ranchers *Unión Nacional de Agricultores y Ganaderos*
UNAN:	National Autonomous University of Nicaragua *Universidad Nacional Autónoma de Nicaragua*
UNAPA:	National Agricultural Union of Associated Producers *Unión Nacional Agropecuaria de Productores Asociados*
UNEP:	United Nations Program for Environment
UPANIC:	Nicaraguan Union of Agricultural Producers *Unión de Productores Agropecuarios Nicaragüenses*
UPOLI:	Polytechnic University of Nicaragua *Universidad Politécnica de Nicaragua*
UPOV:	International Union for the Protection of New Varieties of Plants
URACCAN:	University of the Autonomous Regions of the Caribbean Coast of Nicaragua *Universidad de las Regiones Autónomas de la Costa Caribe de Nicaragua*
WTO:	World Trade Organization.

1. INTRODUCTION

Before starting this introduction, it is important to point out that in order to implement an action like the one we are concerned with here, it was necessary to learn of the experiences of other countries and their processes to establish a legal biosafety framework for the treatment of Genetically Modified Organisms (GMOs), in order to attain inputs to support Nicaragua in the formulation of Project No. GFL/2716-01-4319 (PMS: GF/6010-01-01) Subproject No. GFL/2716 - 02-4554 (PMS: GF/6010-01-88), expecting to reach the goal of drafting a National Regulatory Framework in line with following relevant provisions, the objectives and elements of the Cartagena Protocol on Biosafety:

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of the Protocol is to help ensure an adequate level of protection in the transfer, handling and use of living modified organisms generated by modern biotechnology which may have adverse effects on the conservation and sustainable use of the biological diversity, taking into account the risks to human health, and specifically focusing on trans-border movements. Thus, the interrelation between the following main elements must be found, in order to ensure an adequate level of protection:

- In the transfer, handling and use of living modified organisms resulting from modern biotechnology;
- Adverse effects on the conservation and sustainable use of biological diversity
- Consider the risks to human health
- Concrete actions referring to trans-boundary movements

2. GENERAL STATE OF BIOTECHNOLOGY AND BIOSAFETY IN NICARAGUA.

2.1. State of Biotechnology

The agricultural biotechnology sector in Nicaragua is, in the best of cases, in its early stages of development. In this sense, it shares a general feature of the entire sector of research and development in support of the rural sector of the country. Despite this situation, it is also true that a series of skills and advances have been made in various areas that would permit a clear proposal for its development and application in order to make significant contributions in this field. The proposal is to work on these components in order to create adequate conditions for better exploitation of new technologies, which can bring development to the rural areas of the country.

A recent study on the nature of interactions between science and technology capabilities and the productive sectors and the adoption of technological innovations in the different levels of agro-food chains in the country (Hartwich, et al, 2006) concludes, among other points, that except for sectors such as the coffee-planters, producers of peanuts, shrimps and dairy products, the levels of interaction and innovation - both in the primary sector and in the processing phases - are very low to low, and average in the best cases (vegetables), and that there is no direct relationship between the type of production (traditional, intermediate or nontraditional) and the innovation level of the subsector (see table 1).

Table 1. General characterization of the level of interaction and innovation in production among the main agricultural sectors of Nicaragua. [1]

Traditional Sub Sectors	***Intermediate Sub sectors***	***Non-traditional sectors***
Beef	**Cocoa**	**Melon**
Intermediate interaction	Low interaction	Average interaction
Low innovation in primary production	Low innovation in primary production	Low innovation in primary production
Average innovation in processing	Very low innovation in processing	Very low innovation in processing
Red Bean	**Banana**	**Vegetables**
Very low interaction	High Interaction	Average interaction
Very low innovation in primary production	Low innovation in primary production	Average innovation in primary production
Low innovation in processing	Low innovation in processing	Average innovation in processing
Dairy	**Forestry and furniture**	**Tobacco**
Average interaction	Low interaction	Very low interaction
Average innovation in primary production	Low innovation in primary production	Very low innovation in primary production
High innovation in processing	Low innovation in processing	Very low innovation in processing
Coffee	**Peanut**	**Shrimps**
High interaction	High interaction	Very high interaction
Average innovation in primary production	High innovation in primary production	Very high innovation in primary production
Average innovation in processing	High innovation in processing	High innovation in processing

Source: Hartwich, *et al*; 2006:63.

2.2. State of Biosafety in the political-institutional framework

The development plans of the Government of Reconciliation and National Unity express the political will to progress toward an equitable system of production, where citizen participation becomes the motor, in conjunction with the government, which drives the axis of development. In this context, policies, strategies, investments and actions are being designed to combat poverty; for example, the Zero Hunger Program, aimed at more than 70 thousand families

[1] Among the leading public and private institutions developing R & D activities in the agricultural sector in Nicaragua are:

- The Nicaraguan Institute of Agricultural Technology, INTA
- The Foundation for the Technological Development of Agriculture and Forestry of Nicaragua, FUNICA
- The National Union of Farmers and Cattle Ranchers UNAG and the Nicaraguan Union of Agricultural and Livestock Producers, UPANIC
- The National Agrarian University, UNA
- The Central American University, UCA
- The National Autonomous University of Nicaragua, UNAN
- The University of Commercial Sciences, UCC
- The University of Nicaragua, UPOLI

engaged in agricultural production, the plans to establish a development bank to guarantee financing for small and medium-sized producers and the formulation of a law for the food and nutrition sovereignty.

From the legal point of view, the government works in a consistent manner, making use of the law on the organization and competences of the executive power and with a vision of harmonization, alignment and adaptation of actions and trust systems, thus creating an adequate environment to work on relevant issues such as biosafety, which is so closely linked to food security.

2.2.1 Regulations and competent authorities

The institutional framework issues related to agricultural biotechnology in general and biosafety in particular is a vast and complex system. It is primarily based on the competences of the various Ministries to address the different aspects involved; however, the Ministry of Agriculture and Forestry, MAGFOR, is the agency appointed to formulate and implement specific policies, standards and the overall development of the agricultural sector; it operates as the competent authority for the authorization of LMOs for contained use, testing and trials in the field or in a sheltered environment, evaluation of crops, seed multiplication, production or first time imports for direct consumption or processing, and other applications.

The Ministry of Environment and Natural Resources serves as focal point of the Convention on Biological Diversity (signed in June 1992 and ratified in November 1995) and the Cartagena Protocol on Biosafety (ratified in 2003) and acts as a competent agency for the authorization of Biotechnology Studies.

The Ministry of Development, Industry and Trade is the regulatory agency for Consumer Rights and Food Security, in coordination with the Ministry of Public Health. It administrates the Registry for Intellectual Property Rights, Patents, trademarks, new varieties of plants, etc. Finally, the Ministry of Public Health acts as the agency that norms and regulates aspects of human health related to biotechnological products.

The four aforementioned ministries are members of the National Commission for the Analysis of Genetically Modified Risks and of the National Coordination Committee of the Biosafety Project GEF/UNEP/Nicaragua, both presided by MAGFOR.

2.2.2 Capacities, Scientific Development and Experiences

The institutional system for Research and Development (R & D) in general, and for agricultural biotechnology in particular, is structured around two main components. On the one hand, there is a set of public institutions and universities which are the real promoters of the activities developed. On the other hand, from the point of view of the definition and implementation of national policies for the sector, the National System of Science, Technology and Innovation, SINACYT – created through a gradual structuring process - has the function of strengthening and enhancing the scientific and technological development of the country. The executive body of this system is the Nicaraguan Council on Science and Technology CONICYT, established in 2001 as part of a Loan Agreement with IDB (IDB Loan Contract No.1079/SF-NI, Support Project for Technological Innovation of Nicaragua, PAIT), which provided the resources required to implement a series of research lines considered as priorities for the country, and to lay the foundations for a dynamic national innovation system, promoting technological innovation by

small and medium-sized enterprises (SMEs). Due to limited budgets, the CONICYT has not been able to achieve the expected results; but now there is the interest, on the part of institutions and organizations linked to scientific and technological development as well as of the current authorities of CONICYT, to advance towards the consolidation of the SINACYT, as a path towards a better utilization of the scarce resources available to the country in this field, and to establish a more fluid communication with the productive sectors in terms of which activities to develop.

Within this institutional framework, the National Institute for Agricultural Technology (INTA) is the most important scientific institution in terms of development, transfer and promotion of innovations in the local agricultural sector. It plays a significant role within the framework of the plans and programs for Rural Development encouraged by the Government of Reconciliation and National Unity, in which technological innovation is a key component for a sustainable increase of the rural productivity and for the protection of natural resources. More specifically, INTA works both in strategic research (germplasm, enhancement) and in applied research (adaptation and transfer of technologies) and also engages in activities of cooperation with key national actors and a wide range of research institutions at the international level.

As to human resources, a conservative estimate assumes that there are 250 researchers related to agro-development, although an important part of these have no relationship with the National Science & Technological system. Hudson (2006) indicates that most of these researchers have only reached a bachelors degree (BS), or its equivalent; and even in the case of Master's Degrees or Doctorate levels, students have studied little or made few postgraduate studies.[2] This aspect has often been raised as a subject of concern by the associations of producers and other technology users, and is one of the main constraints to ensure a greater level of technological development and transfer.

This situation is also reflected by the state of research capacities in agricultural biotechnology (see table 2). At the country level, there are only slightly more than 30 researchers scattered in 11 institutions, who report activities in the field of agricultural biotechnology; 5 of which have a PhD, 8 are M.Sc. and the rest are assistant staff, who work basically in the areas of lesser scientific complexity - different micro-propagation techniques and diagnostic systems- - depending, in almost all cases, on international cooperation for their funding (Hudson 2006). Of particular relevance in this scenario is the strong influence of the universities in this sector in comparison to public institutions specialized on agriculture, such as the INTA. While most institutions report products and services at a commercial level, there is a widespread view that the relationship between universities and the productive sectors is not effective, and that its R & D efforts very rarely respond to the problems of the productive sectors, and that even when they do, the impact is reduced due to the lack of adequate transfer mechanisms.[3]

2.2.3. Living Modified Organisms present in the country.

The presence of LMOs in the country is limited only to licensed events to be used as commodities; until now, 19 events have been authorized by using the regulatory framework already indicated in this document.

[2] As to the dissemination of research results, between 1995-2004 Nicaraguan researchers published only 12 articles in publications on the Science Citations Index (SCI). In Nicaragua, there are aproximately 47 universities (Hartwich et al., 2006), with little research activities and very low levels of internationally renowned, peer-reviewed scientific production.

3. DEVELOPMENT OF A BIOSAFETY FRAMEWORK

As explained above, the motivations for the establishment of a National Biosafety Framework, root in the Cartagena Protocol and the proliferation of LMOs in countries with an extraordinary potential for the production and dissemination of state-of-the-art technology, using international free trade as a vehicle. Parallel to this phenomenon, there is an on-going controversy on the consumption and circulation of these organisms, which is why it is necessary to establish the limits and clearly define the rules of biosafety. And so this situation can be seen at two levels: the first level is an international context in which countries with high technological capabilities have strong programs based on genetic engineering; the second level has to do with the demands or concerns that arise in relation to living modified organisms produced through modern biotechnology. This situation aroused the interest in addressing the issue of biosafety under legal norms.

Once the decision is taken to build a regulatory framework, in which the country had no prior experience, the next step is to review the relevent instruments as a starting point for a safe course in terms of coordinating efforts and avoiding the overlapping of legal actions regarding the legally guarded asset or assets. The following tools serve as reference points:

- The UNEP International Technical Guidelines on Biosafety;
- The OIRSA Regional Technical Guideline on Modern Biosafety;
- International Standard for Phytosanitary Measures No.11 ISPM Pest Risk Analysis for living organisms;
- Central American Regulatory Framework on Living Modified Organisms;
- Cartagena Protocol on Biosafety to the Convention on Biological Diversity;
- Decisions of the Conference of the Parties acting as the meeting of the Parties for the COP-MOP1Protocol;
- Law No. 291, Basic Law on Animal and Plant Health and its Regulations
- Health Provisions Decree No. 394;
- Law No. 423, General Law on Health and its Regulations;
- Decree No. 99-2002, Creation of the Nicaraguan Codex Committee, CONICODEX;
- Law No. 217 General Law on the Environment and Natural Resources and its Regulations;
- Decree No. 45-94 Regulations on Permits and Environmental Impact Assessment;
- Convention on Biological Diversity;
- International Convention on Phytosanitary Protection;
- Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization, WTO.

Once this important analysis is done, a bill of law emerges, which aims at consolidating positions and institutional arrangements in order to finetune the skills and responsibilities in the different levels. The following describes in detail the most relevant guidelines addressed by the project, a copy of which is in the Annex.

The purpose of the bill is to establish the regulations on the activities with living modified organisms resulting from the use of molecular biotechnology (genetic engineering) in order to prevent, avoid and reduce potential risks for the environment, agriculture, forestry and aquaculture, taking into account particularly the risks to human health.

As to its scope, the proposal covers the work in laboratories (confined use), contained use, such as the release with security barriers, the research activities with genetic engineering

applications, the release into the environment - that is the authorization for sowing, multiplication, reproduction - the evaluation of crop fields, commercialization, transportation, import, export, first time production or import bound for direct use as food or feed or for the processing and transit of living modified organisms - any use in agriculture, forestry and aquaculture, bioremediation, conservation, preservation and other uses related to biodiversity. Excluded from the scope of the Law are products derived from living modified organisms that do not show detectable traces of transgenic or transgenics, the living modified organisms resulting from the different techniques described above, such as the conventional breeding methods, creation of genetic variaties by mutagenesis, polyploidy, among others, when recombinant DNA is not used; as well as the use of living modified organisms for industrial applications, pharmaceutical products for humans, the raw materials obtained from industrial processing used in the production of balanced feed and their byproducts for animal consumption.

The project establishes two competent authorities, depending on the issues dealt with. The Ministry of Agriculture and Forestry is responsible for the use of living modified organisms in agriculture, forestry and aquaculture, while the Ministry of Environment and Natural Resources will be responsible for matters relating to the use of bioremediation, preservation and other uses related to biodiversity. The Ministry of Health, through the existing regulatory framework in the field of medicine and food, already has the legal authority and sufficient legal ability to authorize or deny authorization for the use or consumption of products generated through molecular biotechnology.

In terms of operations, a consultative committee was established, the Commission on Risk Assessment of Living Modified Organisms - CONARGEN, which will not only have functions related to the analysis and risk management of LMOs, but also advise the authorities on technical and scientific issues related to molecular biotechnology, support in the formulation of policies and strategies on molecular biosafety and in the development and implementation of a national strategy on biosafety.

The CONARGEN will be composed of:

- A representative of the Ministry of Health
- A representative of the Laboratory of Tissue Cultivation of the National Autonomous University of Nicaragua-León
- A representative of the biotechnology laboratory of the National University of Engineering Sciences
- A representative of the laboratory of molecular biology of the Central American University
- A representative of the laboratory of molecular biology of the National Agrarian University
- A representative of the National Institute of Agricultural Technology
- A representative of MAGFOR
- A representative of MARENA
- A representative of the civil society organizations
- A representative of the private farming and livestock breeding sector

When faced with specific requests, the Commission must issue a non-binding scientific-technical verdict, and subsequently the corresponding authority, MAGFOR or MARENA, will issue a properly reasoned resolution authorizing or denying an application on the basis of a risk analysis. It is also established that the permits to release living modified organisms into the environment must be based on a step by step procedure and include information concerning at least the following aspects:

- Results of the step by step procedure, confined use and contained use, with reference to the permits issued for such purposes
- Specific recommendations on management in the field, transportation and storage
- Accreditation of the living organism to be freed, according to the type of use in the country of origin or in the country in which it was developed, on conformity with the legislation of that country

In general, the project currently under consideration (Annex) is part of the general trend in this field, and even though it is multi-institutional and crosses diferent ministries, it clearly delimits areas of responsibility as to who should decide on each case; therefore, it can be predicted that, unlike what has happened in other countries, there should be no major conflicts in this regard in Nicaragua. The main flaw of the proposed structure lies in the weakness of the institutional procedures it is built on, and the lack of adequately trained staff in the different areas involved with capacities to give judgments on the issues that are brought to their consideration.

Regulations in the area of intellectual property

The protection of intellectual property in Nicaragua is regulated by a complex system of rules for issues of patenting and plant breeders' rights, and others such as trademarks, industrial design issues, etc. The system of protection is based on the following norms with national application:

- Paris Convention for the Protection of Industrial Property
- Trade Related Aspects of Intellectual Property Rights (TRIPS) of the WTO
- The UPOV Convention 1978 Act
- Patent Cooperation Treaty (PCT)
- Agreement with U.S. on Intellectual Property
- Free Trade Agreement between Central America, Dominican Republic and United States
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedures
- Law No.354 on Patents on Inventions, Utility Models, Industrial Designs
- Law No. 579 on Amendments and additions to Law 354 on Patents on Inventions, Utility Models, Industrial Designs
- of invention patents, Utility Models and Industrial Designs
- Law No. 380 on Trademarks and other Distinctive Signs
- Law No. 580 on Amendments and additions to Law 380 on Trademarks and other Distinctive Signs
- Law No. 318 on the Protection of Plant Varieties
- Decree N^0 37-2000 Regulating Law N^0 218 on the Protection of Plant Varieties

The competent authority with regards to the administration of intellectual property in Nicaragua is the Intellectual Property Registry, a unit of the Ministry of Promotion, Industry and Trade. According to current regulations, it is the Registry`s responsibility to process and, if applicable, to grant:

- Patents on/for Inventions
- Registration of utility models
- Registration of Industrial designs
- Registration of Trademarks and other distinctive signs
- Plant breeder´s certificate
- Intellectual property title

- Filing or registration of copyright and related rights,
- And others, according to the laws on intellectual property.

This set of instruments provides a broad framework of protection for biotechnological innovations, both in terms of the patenting of materials, processing and genes, as in regards to manipulations of new plant varieties which then serve as a basis for biotechnological innovations.

With regards to the manipulation of biological materials and to the procedure to obtain biological material, the patent law states that the protection provided will be extended to all biological material generated by multiplication or propagation of the material directly obtained from the procedure, as long as it has the same characteristics. If such protection is based on a specific gene sequence or biological material containing such a sequence, the protection will be extended to all products incorporating such sequence or material and possessing the corresponding genetic information. As for individual genes, the Nicaraguan law does not pose constraints on patenting an gene isolated from its natural environment, purified and properly characterized, if it fulfills the conditions for patentability, i.e. novelty, inventive height and sensitive to an explicit industrial application. In practical terms, such patent has not yet been granted in this field.

As for the Rights for Plant Breeders, the titles are issued on all varieties of plants of all genera and species which meet the requirement of being new, distinct, sufficiently uniform, stable and branded with a unique name; they are granted for a limited period of 20 years and they are valid throughout the nation. The protected varieties can be used to obtain new varieties without the authorization of the title-holder, except in certain situations, generally applicable to the ornamental varieties.

While the Competent Authority responsible for the administration and implementation of this issue is, as noted above, the Ministry of Development, Industry and Trade, through the Intellectual Property Registry - RPI, where the right of the breeder will be established and the respective property titles issued. The technical aspects and the in-depth examination in the case of plant breeder’s rights is the responsibility of the Department of Seed and the Qualifying Committee for the Protection of Plant Varieties (CCPVV), created by legislation.

Until today, there have been no problems with the implementation of the framework; as no patent has been issued, there have been no points of conflict between the various components of the legislation - which could have arisen as a result of the fact that Nicaragua is a member of the UPOV (International Union for the Protection of New Varieties of Plants) Convention according to the 1978 Act, which states that the right of the breeder can be recognized by granting a certificate of protection or a patent, but that only apply one of these can be applied to the same genus and species.

Due to this, and the fact that the Breeders' Rights apply to all plant genes and species, in principle it would be impossible to patent plant varieties in Nicaragua. But since the Patent Law allows the protection of procedures to obtain biological material or a specific genetic sequence, or biological material containing such a sequence; and since in such cases the protection would be extended to all products or materials incorporating this sequence and possessing the respective genetic information, it is unclear how the UPOV Act 78 would be applied to a species breeders rights have been granted for, if a procedure is applied to it to incorporate such a gene, and then the breeder wants to patent this variety as well.

As indicated above, this type of conflict has not occurred in practice, but it should be anticipated and the legislation on plant breeders' rights should be improved, striving to make it more efficient and effective and to take advantage of the opportunity of these legal changes to meet the commitment assumed in the Free Trade Agreement between Central America and Dominican Republic and the U.S. (CAFTA) to adhere to the UPOV 1991 Act by the year 2011.

The legal update should:

- extend breeder's rights to the reproduction or multiplication of the material, the possession for any of the above mentioned purposes, to the product of the harvest, including whole plants and parts of plants obtained by unauthorized use of reproducted or multiplied material of the protected variety, unless the breeder has reasonably exercised his right in relation to the material for reproduction or multiplication; and
- incorporate temporary protection to safeguard the interests of the breeder during the period between the filing of the application for the title or its publication and the granting of the title.

In addition to the above-mentioned aspects, this legal updating should include the issue of access to phytogenetic resources, which is a particularly important issue given the biodiversity resources of the country. In this regard, a consensus proposal on this issue is currently being discussed as part of a Bill of Law on Conservation and Sustainable Use of Biological Diversity, submitted to Parliament by an Inter-Agency Working Committee, integrated by: MARENA MAGFOR, INTA, IICA,UNA,URACCAN and the Alliance for the Protection of Biodiversity of Nicaragua (formed by civil society organizations, including: CENIDH, CISAS, CENTRO HUMBOLDT, FENACOOP, LIDECONIC, UNAPA, UITA, SIMAS and PCAC-UNAG).

This proposal presents a complete system of access to biological resources, and is applicable to in-situ and ex situ conservation, protected natural areas, centers of genetic diversity, and the access to these resources, ensuring the fair and equitable sharing of benefits arising from the exploitation of biological diversity, the promotion of research on biodiversity, the respect for and preservation of know-how, innovations and the practices of indigenous and local communities with traditional lifestyles based on conservation and sustainable use of biodiversity. However, the current text does not explicitly take into consideration the multilateral system of access to phytogenetic resources and the distribution of benefits included in the FAO's International Treaty for Phytogenetic Resources for Food and Agriculture, to which Nicaragua is a Party, and therefore it should be amended to ensure the existence of necessary and appropriate legal measures for the implementation of the multilateral system.

With regards to national capacities, the bill of law establishes an institution in charge of managing the access to phytogenetic resources, with enough trained personnel and adequate regulations for the performance of this important task. The proposal also recognizes biotechnology as a tool for the production of know-how, whose application has to produce goods and services; it should be used to contribute to the identification of and knowledge on agricultural biodiversity in Nicaragua, thereby enhancing its genetic resources.

Taking advantage of the change of policy mentioned in the current legislation regarding rights of the breeders and the proposal on access to phytogenetic resources, certain implementation mechanisms of the application of the Farmer's Privilege should be adjusted. To this aim, certain factors should be examined when considering the regulation, within reasonable limits, of certain species, the objective of the cultivating the crop, the size of the exploited area / area of

cultivation, in order to only authorize small producers, limiting the crop to a maximum area and the volume of the harvested crop by setting a maximum % of the area of cultivation.

The framework described - including both the existing aspects as the ones proposed for the new law - appears to be, in general, well-suited to the needs of the immediate present and future; however, the situation is quite different in terms of the capacity to implement the framework, since neither MIFIC nor MAGFOR possess the administrative capacity and the human resources for an effective implementation of the existing regulations. This is a deficiency that no matter what policies are adopted, should be considered a priority to be solved; it should, however, be worked out taking into account that the domestic demand, both from the research sector as from part of the private sector, is very reduced or non-existent.

At the research level, there are no incentives at INTA or the universities to use the intellectual property instruments for the products they develop, since the academic “products" - publications etc. – are more important than the ones linked to the market. On the other hand, in the business sector the release, registration and protection of both domestic and foreign new plant varieties are quite limited (on the Nicaraguan market, INIA is the institution with the majority of releases, and so far it does not protect the rights of its materials); as a result, there is no organization of plant breeders in Nicaragua to protect their interests and structure the management of the production, trade and licensing of protected materials. Improving this situation should be a priority, regardless of the relevance these issues may have in the development of a biotechnology policy, as without a functioning seed system, not only the benefits of such technologies are lost but also the ones that could be obtained from conventional technologies.

3.1 Scope of the present report

The scope of this report is based on the completion of the Project and its achievements, and so it gathers the important activities developed through the planning process. Moreover, considering that its main components are organized according to the provisions and guidelines serving as a reference for the building of a legal framework for biosafety, and which have significant implications, a legal biosafety framework should be designed under a strategic concept. This cannot be achieved through a project alone, as the country will have to continue working towards completing its jurisprudence on the implementation of standards and gaining a thorough understanding of scientific and technical knowledge in this field.

3.2 Major issues addressed and the emphasis of the project.

The emphasis of the project cannot be seen one-dimensionally, because it needed to take advantage of its strength to achieve the generation of essential instruments, such as the Bill of Law on Biosafety (Annex), which is currently being examined by the National Congress. In addition to this effort, other major issues addressed and generated as products can be mentioned:

- Significant assessments on the legal status and the way the country was dealing with the issue;
- A structure of scientific character, composed of state institutions and the scientific branch of the relevant universities in the country, National Agrarian University,
  National Autonomous University of Nicaragua and the University of Engineering Sciences;
- Strengthening of the Commission on Risk analysis of genetically modified organisms;
- An inter-agency committee, with the participation of representatives from civil society where diverse issues relating to Genetically Modified Organisms are being discussed;

- Support to the formulation of a project for the management of information on LMOs, called BCH, which has already been approved by UNEP and the Nicaraguan authorities;
- Trainings on GMO-related knowledge for the staff of state institutions, universities and civil society;
- The attenuation of a strong controversy in the country on how to address the issue of biosafety;
- Before the project, there was not enough clarity among the relevant institutions and civil society on genetically modified organisms;
- The issues of biosafety served as an axis for multidisciplinary committees and to address the issue objectively;
- As a strength of the working committees, a channel for the exchange of knowledge on the issue of biosafety with the Members of Parliament on the Health Committee of the National Assembly was established;

4. THE CARTAGENA PROTOCOL ON BIOSAFETY

More than 130 countries adopted the Protocol on Biosafety in Montreal, Canada, on January 29, 2000. It is called the Cartagena Protocol on Biosafety in tribute to Colombia, which hosted the Extraordinary Conference of the Parties to the Convention on Biological Diversity (CBD) in Cartagena in 1999. The objective of this first Protocol to the CBD is to contribute to a safe transfer, handling and use of living modified organisms (LMOs), such as genetically modified plants, animals and microbes, which cross international borders. The protocol is designed to prevent adverse effects on conservation, sustainable use of biodiversity and human health. Based on this background, Nicaragua as a signatory country has maintained its active participation and follow up of the established guidelines.

4.1 Country participation in the COP/MOPs and in the previous stages

Nicaragua has participated in three COP / MOPs; this participation has been vital because those elected have been able to get trained on the handling of the negotiations regarding the resolutions, which represent the decisions and guidelines to follow as to LMO-related issues; Nicaragua participated with three representatives in the COP/MOP 1 and COP/MOP 2 and with two representatives in COPMOP 3.

4.2 Ratification Process

It is important to mention that despite being a very important event, the process for ratification of the Protocol by Nicaragua met with no major obstacles because the country was aware of the importance of having such a tool for following up on the issue of LMOs; therefore, in conformity with the national legislation, the state of Nicaragua approved and ratified the Cartagena Protocol through Legislative Decree No.3248 of the National Assembly and through the Executive Decree issued by the President of the Republic, for the deposit of its instrument of ratification, dated March 21,2002 and June 28, 2002, published in the Official Gazettes No. 56 and 121 respectively.

5. BIOSAFETY POLICY

With respect to a biosafety policy, an attempt was made to formulate a policy through a preliminary document, relegated due to the fact that more emphasis was given to a Biosafety Law. The National Assembly received two bills of law on biosafety: one bill submitted by the executive branch and the other by civil society - a situation which originated in the creation of a large commission to address the issue. After countless workshops, a single bill was agreed upon, based on the two mentioned bills. The new bill was rooted in a broad consensus of all the actors, a fact which diminished the scope of the biosafety policy which had been presented as an draft.

However, there is another initiative to formulate a biotechnology policy, based on the premise that in the last twenty years, biotechnology has gradually established itself as the basis for technological development in agriculture and food production, and at the same time, as the basis of a fairly intense debate about the risks and opportunities its use entails. That this has happened should not be surprising, partly because it is clear that new technologies require much more complex systems of knowledge and social management than those once installed to manage the technologies that today we refer to as "conventional". Issues such as the regulation and management of intellectual property, protection of the environment and consumer health, public–private relationships, are turning into a central and inescapable axes of the debate, both nationally and internationally, for which clear and specific definitions are beginning to be demanded from governments and diverse social actors. Because of these changes and the controversy which has accompanied them, the discussion needs to be deepened, in order for smart decisions to be made as to how to respond to these new scenarios and maximize the opportunities offered by such new knowledge.

All this has been demonstrated by a diagnosis of the status of biotechnology and biosafety in Nicaragua, which has served as a bases for the Government of Reconciliation and National Unity to formulate a biotechnology policy, which is obviously closely linked with the issue of biosafety. However, the need for a biosafety policy in the future is being assessed, for which a basic outline has already been developed.

With regards to the biosafety policy, which is now in the process of being approved by the competent authority, seven strategic guidelines are defined which reflect the needs and priorities of development of the country:

1) Strengthening, promotion and coordination of the legal framework

- Promotion of at least the following legal instruments:
    - o General Law on Prevention of GMO risks, from which the corresponding regulations will be derived;
    - o Law on liability and reparation of damages resulting from GMO-related activities;
- Promotion of the legal instruments necessary to establish an intellectual property regime for the protection of processes and techniques associated with biotechnology.
- Legislative framework related to the recognition of collective intellectual property rights, knowledge, traditional practices and innovations of indigenous peoples, ethnic and local communities associated with the use of agricultural and forest genetic resources, with the objective of facilitating the transfer and distribution of benefits derived from biotechnology

2) Institutionalization of biotechnology

- Creation of the department of biotechnology in the Ministry of Agriculture and Forestry, with the aim of strengthening the implementation and monitoring of policies and programs and and risk assessment and management;
- Establishment of mechanisms for the compliance of international commitments on the matter of biosafety, by promoting its incorporation into national legislation, policies, plans, sectorial strategies and national programs;
- Execution of a National Biotechnology Program for sustainable development in the agriculture and forestry sector;

3) Development of research and transfer of biotechnological techniques

- Formulation of thematic lines for the development of biotechnology for sustainable development and growth of the agriculture and forestry sector;
- Promotion of the training of human resources in biotechnology for development and growth of the agriculture and forestry sector;
- Promotion and strengthening of research and the implementation of mechanisms that contribute to the conservation, protection and sustainable use of genetic resources in the country;
- Development of a national network for the protection, rescue, conservation, sustainable use and molecular characterization of genetic resources of National species;
- Promotion of research and transfer programs in agricultural and forestry biotechnology to promote knowledge, management and the sustainable use of genetic resources for the agriculture and forestry sector and for environmental protection;

4) Market Access and Development

- Database for the assessment and creation of an inventory of institutional capacities, the identification of and access to goods and services available in the country in the field of agricultural and forestry biotechnology;
- Promotion of the development and commercialization of biological control agents, biopesticides and biofertilizers, and systems for diagnostisis, micropropagation, health, and reproductive management and others of national interest;
- Integration of the issues of biotechnology into international negotiations, with emphasis on the protection and sustainable use of agricultural and forest genetic resources;
- Inclusion of the subcomponent of the agricultural and forest biotechnological services into the information system of agricultural markets and prices;

5) Creation of Financing and Incentives

- Creation of incentives aligned with the national economic policy to promote agricultural and forestry biotechnology;
- Management of resources to finance research and development of biotechnology in the country;
- Encouragement of investment and development in the public and private sectors related to biotechnology in agriculture and forestry through national plans;
- Facilitation and promotion of the development and maintenance of the necessary infrastructure to encourage investment in biotechnology;
- Definition of the funds necessary to comply with the guidelines of this policy;

6) Education and Capacity-Building

- Participatory development and proposal of the thematic lines in biotechnology to be included in the plans and programs of the different levels of formal and informal education
- Strengthening of human resources on biotechnology through training and education;

- Creation of coordinating spaces among researchers, universities, scientific research and competent government entities, aimed at creating mechanisms for technology transfer, education, training, capacity-building and other lines of interest;
- Strengthening of technical skills of small and medium size-producing families in the area of genetic improvement to enhance their development and growth;

7) Information

- Establishment of a national information system of agricultural and forestry biotechnology;
- Facilitation of the access and exchange of information and scientific, technical, environmental and legal experiences related to agricultural and forestry biotechnology;
- Dissemination of laws, regulations, rules and national guidelines in biotechnology;

8) Regulatory System on Biosafety

The legal framework for the management of biotechnology and biosafety in Nicaragua is not one-dimensional: it can be seen as a system, since the Constitution touches on the subject in general when regulating fundamental rights on aspects such as healthy environment, free enterprise and private property, among others. The General Law on Environment and Natural Resources (Law 217), the Basic Law on Animal Health and Plant Health (Law 291) and the Law of Seed Production and Trade (Law 280) also intervene on biotechnological issues.

From the operational point of view, matters relating to the handling and use of genetically modified organisms (GMOs) are regulated by Law 290 on the Organization, Jurisdiction and Procedures of the Executive Branch. Within this framework, Decree 59-2003 provides that the Ministerial Minister of Agriculture and Forestry, after the technical opinion of the National Commission on the Risk Assessment of Genetically Modified Organisms, CONARGEM - constituted by representatives of all ministries mentioned previously and by representatives of the National Institute of Agricultural Technology, the Center for Molecular Biology of the Central American University, the Molecular Biology Laboratory of the National Agrarian University and the Tissue Cultivation Laboratory of the National Autonomous University of Nicaragua, León - and the communication to the members of the Cabinet of Competitiveness and Production may make resolutions for the approval of GMOs. It also establishes that a technical standard should be developed with at least the technical specifications for the confined use, handling, transport and labeling of seeds from genetically modified plants.

Upon termination of the report, a technical and legal proposal was made on these aspects, summarized in a Bill of Law on the Prevention of Risks From Living Modified Organisms through Molecular Biotechnology, submitted to the Legislative Branch for its approval. This bill addresses the issues comprehensively and includes the general and specific objectives of the policy on biosafety, the institutional implementation strategy and the management of GMO information, among other issues. Beyond these actions, CONARGEN has not had any major activity and has only issued one resolution approving the import of 15 events of GM corn.

9) Decision-Making System on Biosafety

The decision-making system on biosafety is of a collective character. It has been created based on the mandate of Law 291, Basic Law on Animal and Plant Health, which according to Article 108 creates the National Commission on Risk Analysis of Genetically Modified Organisms (CONARGEM) under the Ministry of Agriculture and Forestry (MAG-FOR), through the General Direction for Protection and Animal Health (DGPSA). Article 109 stipulates the creation of CONARGEM, composed of delegates and their deputies, with:

1. One representative of the Ministry of Development, Industry and Trade.
2. Two representatives of the Ministry of Agriculture and Forestry.
3. One representative of the Ministry of Health.
4. One representative of the Ministry of Environment and Natural Resources.
5. One representative of the National Institute of Agricultural Technology.
6. One representative of the Center for Molecular Biology of the Central Americna University.
7. One representative of the Laboratory of Molecular Biology of the National Agrarian University.
8. One representative of the Tissue Cultivation Laboratory of the National Autonomous University of Nicaragua - León.

The members of the Commission shall be appointed by the President of the Republic, following a proposal by these institutions, which shall select technical staff with experience in risk analysis and biosafety or relevant related topics.

A representative of MAG-FOR selected by the President will chair the Commission. It will be subordinated to MAG-FOR's General Direction for Protection and Animal Health (DGPSA), which will provide administrative support for its operations.

5.1 Current administrative processes (how an application is processed)

As to the processing an import permit of agricultural LMO-products, the application should be addressed to Dr. Guillermo Ibarra, General Director of DGPSA / MAGFOR, who in turn calls upon CONARGEN to make a risk analysis, and based on the results the Minister of MAGFOR will make his/her decision on the import of the requested events. To date, 19 events of yellow corn have been approved for their introduction into the country as commodities.

5.2 Participation Mechanisms and Public Information on Biosafety

It is important to clarify in this chapter that citizen participation and public information is stipulated by two legal instruments, Law No. 475 on Citizen Participation and Law No. 621 on Access to Public Information".

The law on citizen participation has the objective to establish rules for public participation in setting out the regulatory provisions for the establishment of structures for public participation at the national level, without detriment to the previously established laws and decrees.

It further establishes that it corresponds to the President of the Republic to provide, through an Executive Decree, for the creation of National Sectoral Counsels for the formulation of public sectoral policies in support of the Executive Branch, as well as the creation, if necessary, of new sectorial consultative bodies to complement the already existing ones. Also, the organization and functioning of the existing sectorial bodies can be best adjusted by incorporating delegates or representatives of organizations or institutions whose activity is related to the respective public sector.

Law No.621 on Access to Public Information aims at "regulating, guaranteeing and promoting the right of access to public information existing in documents, files and databases of organizations or public institutions, mixed companies and the ones subsidized by the state as well as private entities that administrate, manage or receive public funds, tax benefits or other benefits, concessions or privileges." It also states that everyone has the "Right to Access Public Information" held by the institutions subject to this law.

To put the access to information into practice, the Attorney General of the Republic created the Public Information Office and instructed public servants in charge of this office to deliver or enable citizens to locate and access the requested information.

5.3 Knowledge among the general population on biosafety

As the issue of biosafety is a very specialized and recent topic in Nicaragua, knowledge is mainly restricted to the university level, government ministries related to the subject and the level of non-governmental environmental agencies.

6. RECOMMENDATIONS AND NEXT STEPS (FUTURE CHALLENGES, PRIORITIES, CONTINUITY)

One of the main priorities for the Ministry is the creation of a team to start formulating the regulations of the Biosafety Law, issued by the National Parliament's health committee, so that once the law is approved, the relevant legal instances can begin to operate.

As to potential recommendations, the international agencies related to biosafety consider that it is is not yet a settled issue, and that not all of the necessary links and platforms for the management of a subject as complicated as living modified organisms can be created through a bill of law. Therefore, these agencies should remain on the lookout for biotechnological advances which could provide feedback to countries in their quest to resolve issues linked to their external and internal commitments.

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8. ANNEX

A copy of the proposed "Law on the Prevention of Risks stemming from Living Organisms Modified by Means of Molecular Biotechnology," developed through this Project is attached (in a separate document).