

**State Secretariat of the Environment  
And Natural Resources**

***“UNEP/GEF Project for the  
Development of the National  
Biosafety Framework  
in the Dominican Republic”***

**Final Report**

**2007**

**National Biosafety Committee**

National Project	UNEP/GEF Project for the Development of the National Biosafety Framework Sub-project No.CF/2716-03-4661
Name of the Country	Dominican Republic
Start/Ending Dates	June 30, 2003 September 2007
National Executing Agency	Department of Genetic Resources, Division of Biodiversity and Wildlife
National link of the Project	<b>Marina Hernández</b> , in charge of the Department of Genetic Resources, Division of Biodiversity and Wild Life. e-mail: <a href="mailto:recursos.geneticos@medioambiente.gov.do"><u>recursos.geneticos@medioambiente.gov.do</u></a>
National Project Coordinator	<b>Omar Ramírez</b> , National NBF Project Coordinator. September 2005 - January 2006 <b>David Hernández M.</b> , National Project Coordinator September 2003- June 2005.
National Project Committee	<b>Omar Ramírez</b> , National Project Coordinator, President of the National Project Committee <b>Angel Daneris Santana</b> , Sub Secretary of Protected Areas and Biodiversity <b>Amarilis Polonia</b> , Division of Biodiversity and Wild Life <b>Marina Hernández</b> , Department of Genetic Resources. <b>Yocasta Valenzuela</b> , SEMARN Division of International Treaties <b>Salvador Hiciano</b> , State Secretary of Public Health <b>José Nova</b> , National Council for Agricultural and Forestry Research (CONIAF) <b>Marisol de Castro</b> , Institute of Industry and Biotechnology Innovation (IIBI) <b>Freddy Cruz</b> , State Secretariat of Industry and Commerce(SEIC) <b>José Rafael Almonte</b> , Legal Advisor of the State Secretariat of the Environment and Natural Resources <b>Bienvenida Hernández</b> , Legal Sub-division, Subsecretariat of Protected Areas and Biodiversity <b>Ana Loida Herrera</b> , Legal Sub-division <b>Brigido Hierro</b> , Deputy Director of the Department of Genetic Resources

## EXECUTIVE SUMMARY

This is the final report for the project “**Development of National Biosafety Framework for the Dominican Republic UNEP/GEF**”, Subproject No. CF/2716-03-4661 executed by the Secretariat of the Environment and Natural Resources through its Department of Genetic Resources of the Directorate of Biodiversity and Wildlife of the Under-Secretariat of Protected Areas and Biodiversity, and co-financed by the Global Environment Facility (GEF) and United Nations Environment Programme (UNEP) as Executive Agency.

The first part of the report emphasizes the antecedents of the project and provides a brief description of the project. It provides information about the organizational structure of the project as well as activities and results.

In the first phase of information gathering we should highlight four national consultancies. These consultancies allowed drawing a comprehensive diagnosis legal and institutional context concerning biotechnology and biosafety at the national and international level. The results provided the basis for the elaboration of the first draft of the National Biosafety Framework. The consultants were hired on the basis of a national bid published in a newspaper of nationwide circulation.

The second part of the inform refers to the analysis carried out for the preparation of the National Biosafety Framework and describes the consultation workshop by which the key stakeholders where asked to determine the aspects that should be included within the National Biosafety Framework. During this phase there was a public information campaign in which citizen participation was an integral part of the process.

The third part of the report describes the elaboration process of the National Biosafety Framework as well as the process by which to elaborate a consensus draft for a biosafety bill. As a last step of this phase the bill proposal was reviewed by national and international experts about the legal aspects of the document.

The annexes includes the consultancies performed, the Biosafety bill proposal, the proposal of the resolution to form the Technical Biosafety Committee, public information material used during the project as well as photographs of the workshops and meetings.

<b>TABLE OF CONTENTS</b>
--------------------------

	Page
<b>Executive Summary</b> .....	3
<b>1. Introduction</b> .....	7
<b>2. Background Information of the Project “Development of the National Biosafety Framework in the Dominican Republic” (NBF)</b> .....	7
<b>3. Description of the NBF Project</b> .....	8
3.1 General Objectives.....	8
3.2 Relevance of a National Biosafety Framework in the Dominican Republic.....	8
<b>4. Organizational Structure of the Project</b> .....	8
4.1 National Executing Agency .....	8
4.2 National Coordinating Committee of the project .....	8
4.3 National Project Coordinator.....	8
<b>5. Results obtained during the development of the NBF project</b> .....	9
5.1 Phase 0: Establishment of the Institutional Structure.....	9
5.2 Phase One: Information Gathering.....	9
5.2.1 –Analysis of the Degree of Development of and the Training Programs on Biotechnology and Biosafety in the Dominican Republic.....	9
5.2.2 –Analysis of the National State Policy, the Legal Status and the Regulations on Biotechnology and Biosafety in the country.....	9
5.2.3 –Analysis of International Policies influencing the Development of Biotechnology and Biosafety in the Dominican Republic.....	10
5.2.4 –Preparation of a database and research on the establishment of the BCH Mechanism.....	10
5.3 Phase Two: Analysis for the identification and preparation of the National Biosafety Framework.....	11
5.3.1 Consultative Workshop for the Development of a National Biosafety Framework....	11
5.3.2 Campaign for the disclosure of information and participation in events.....	12
5.4 Phase Three: Preparation of the Draft for the National Biosafety Framework.....	14
5.4.1 National Workshop for the review of the Bill of Law on Biosafety.....	15
5.4.2 Draft Resolution for the Creation of the Biosafety Technical Committee.....	15
<b>6. Ratification and Promulgation of the Cartagena Protocol on Biosafety (CPB)</b> .....	16
<b>7. Review of the Bill of Law on Biosafety by International and National Experts</b> .....	16
<b>8. Main elements of the Bill of Law on Biosafety</b> .....	17
<b>9. Regulatory developments related to Biosafety in the Dominican Republic</b> .....	18
9.1 The General Law on the Protection of Consumers or Users (Law 358-05).....	18
9.2 Bill of Sectorial Law on Biodiversity and Regulations for Access to Genetic Resources.....	18
<b>10. Project for “Capacity Building for the Biosafety Clearing House (BCH)”</b> .....	18

**11. Conclusions and Pending issues in order to complete the NBF in the Dominican Republic.....18**

**12. Recommendations.....19**

**13. Annexes.....19**

**Annex 1.** Analysis of the Degree of Development of and Training Programs on Biotechnology and Biosafety in the Dominican Republic.

**Annex 2.** Analysis of the National State Policy, the Legal Status and Regulations on Biotechnology and Biosafety in the Dominican Republic

**Annex 3.** Analysis of the International Policies influencing the development of Biotechnology and Biosafety in the Dominican Republic.

**Annex 4.** Development of a database and research on the establishment of the Biosafety Clearing House BCH.

**Annex 5.** Bill of Law on Biosafety

**Annex 6.** Information materials

**Annex 7.** Draft Resolution for the Creation of the Biosafety Technical Committee

**Annex 8.** Pictures of workshops and meetings held during the development of the project

## Acronyms and Abbreviations

NCA	National Competent Authority
BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
NCC	National Coordinating Committee
NPC	National Project Coordinator
CONIAF	National Council for Agricultural and Forestry Research <i>Consejo Nacional de Investigaciones Agropecuarias y Forestales</i>
GEF	Global Environment Facility
IIBI	Institute for Industrial and Biotechnological Innovation <i>Instituto de Innovación en Industria e Biotechnológica</i>
GMOs	Genetically Modified Organisms
LMOs	Living Modified Organisms
CPB	Cartagena Protocol on Biosafety
SEIC	State Secretariat of Industry and Commerce <i>Secretaría de Estado de Industria y Comercio</i>
SEMARN	State Secretariat of the Environment and Natural Resources <i>Secretaría de Estado de Industria y Comercio</i>
UNEP	United Nations Environment Programme

## **1. Introduction**

The project for the Development of National Biosafety Frameworks was executed by the State Secretariat of the Environment and Natural Resources, through its Sub-Secretariat of Biodiversity and Protected Areas, with the financial support of the Global Environment Facility-GEF and technical assistance by the United Nations Environment Program-UNEP.

The fundamental objective of the project was to prepare the country for the implementation of the Cartagena Protocol on Biosafety and to endow the Dominican Republic with an organized legal framework to regulate the production, entry in or transit through the national territory of living modified organisms, and to be able to make decisions on the conservation of biodiversity, the protection of human health and the natural environment in face of the domestic use of these products.

This project would establish a government policy on biosafety, including laws, regulations and guidelines to regulate the activities of modern biotechnology, and an administrative system to manage applications, permits, assessments and risk management in the use of biotechnology.

As a reference, the project used the Cartagena Protocol on Biosafety (PCB) of the United Nations Convention on Biological Diversity (CDB).

## **2. Background Information**

In January 2000, the Cartagena Protocol on Biosafety (CPB) was internationally adopted as a supplementary agreement to the Biodiversity Convention, which aims to "to contribute to ensuring an adequate level of protection" in the safe transfer, handling and use of living modified organisms (LMOs)<sup>33</sup>resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biodiversity, "taking also into account risks to human health, and specifically focusing on transboundary movements."

In November of the same year, the Council of the Global Environment Facility (GEF) adopted the "Initial Strategy for assisting countries to prepare for the entry into force of the PCB" in its 16th session. At the same meeting, the Council also approved the Global Project of the United Nations Environment Programme (UNEP)/ GEF called "Development of national frameworks on biosafety", whose initial target was to help up to 100 eligible countries to prepare their national biosafety frameworks and foster collaboration and exchange of experiences on issues of interest to the national biosafety frameworks at regional and sub-regional levels. It was hoped that the countries benefiting from this project would become part of the PCB before the end of its national project, a goal that was successfully achieved by the Dominican Republic.

In 2002, the State Secretary of the Environment and Natural Resources began the negotiations with the United Nations Environment Programme (UNEP) to launch the UNEP / GEF project for the "Development of the National Biosafety Framework" in the Dominican Republic.

The project formally began in September 2003.

### **3. Description of the National Biosafety Framework Project**

#### **3.1 General Objectives**

To prepare a national biosafety framework in accordance with the Cartagena Protocol on Biosafety to establish a government policy that includes:

- Laws, regulations and guidelines to regulate the activities of modern biotechnology
- An administrative system to manage applications, permits, assessments and risk management
- Mechanisms to ensure the sensitization and participation of the public.

#### **3.2 Relevance of a National Biosafety Framework**

Once all of the elements of the national biosafety framework have been established, the country will have an organized system to proceed with regards to the deliberate or accidental introduction of LMOs, as well as their production or transit through the territory; to make the right decisions in relation to the protection of our biodiversity, the health of our citizens and the environment. The country will be better able to participate in the Biosafety Clearing House that the PCB establishes in Article 20 so that the Parties to the protocol can exchange information. All this will contribute to maintaining international relationships with other countries that developed their framework in accordance with the PCB.

### **4. Organizational Structure of the Project**

#### **4.1 National Executing Agency (NEA):**

Department of Genetic Resources of the Division of Biodiversity and Wildlife, the Sub-Secretariat of Protected Areas and Biodiversity, State Secretariat of the Environment and Natural Resources. This department was the entity responsible for the technical execution of the project, designated by the National Government after consultation with the United Nations Environment Programme (UNEP) and those who would become members of the National Committee of the Biosafety Project. It worked as the entity organizing the implementation of the technical activities of the project, alongside the National Coordinator of the project.

#### **4.2 National Committee of the Biosafety Project:**

Includes representatives from government agencies, the private sector, including academic institutions and non-governmental organizations (NGOs). It was a multidisciplinary and multisectorial team. Established by the NEA in order to provide guidance and advice in the preparation of the National Biosafety Framework. Upon completion of this project and after having gone through several changes in its structure, there will be an enhanced and strengthened National Committee on Biosafety.

#### **4.3 National Project Coordinator (NPC):**

The NBF project was led by two National Coordinators during implementation: in the first phase by Dr. David Hernandez Martich (September 2003 - June 2005) and in its second phase by BS Omar Ramirez Tejada (September 2005 - January 2006), both appointed by the Sub-Secretariat for Protected Areas and Biodiversity, in consultation with UNEP. The

coordinators were responsible for the general supervision, coordination and management of all the technical aspects of the project.

## **5. Results obtained during the development of the NBF**

The results obtained during the development of the project are presented according to the phases of its development. Among the achievements that were obtained by the project and through the effort of developing a "National Framework" are a significant number of legal and technical products, as well as the success of participatory processes and the involvement of sectors. These achievements are summarized below, while **Annex 8** presents photographic record of the events held by the project.

### **5.1 Phase 0: Establishment of the institutional structure**

This phase consists of the establishment of the institutional structure and management. The National Implementation Body was established, the National Project Coordinator (NPC) was hired and the National Committee for the Biosafety Project was created, and a bank account was opened specifically for the project. These key features are presented in a table at the beginning of this report.

### **5.2 Phase One: Information Gathering**

Inventories and diagnostic studies on:

1. The use of biotechnology
2. National legislation related to biotechnology and biosafety
3. National projects under implementation or planned to build capacities in the safe use of biotechnology.
4. Lists of national experts, including their experience and knowledge to assess needs in this regard.
5. Analysis of international policies, international aspects (Conventions, treaties, agreements)

These results were obtained by carrying out the following consultancies (**Annexes 1-4**):

#### **5.2.1 Analysis of the Degree of Development of and the Training Programs on Biotechnology and Biosafety in the Dominican Republic**

This consultancy was carried out in accordance with the terms of reference provided by the aforementioned institution. The central objective was to describe the state of biotechnology and biosafety of the Dominican Republic at that time, including infrastructure and training programs related to their development, as well as an assessment of the existing experience in the country in these two areas.

The report consists of two parts; one describing the state of biotechnology and biosafety in the country in general terms, and the other providing an inventory of experts and projects for biotechnology and biosafety in the country.

#### **5.2.2 Analysis of the National State Policy, the Legal Status and the Regulations on Biotechnology and Biosafety in the country**

This study pursued an analysis of the National State Policy, the legal status and the Biotechnology and Biosafety Regulations in the Dominican Republic.

The whole national legislation on development, creation, construction, manipulation or the reproduction of animals and plants for commercial or experimental use was reviewed, determining the role played by various state and private institutions in the management of living modified organisms and biosafety.

This consultancy was limited to the collection, description and analysis of national policies on Biotechnology and Biosafety, as well as commitments made in the framework of international agreements relating to the management and the development of Biotechnology and Biosafety in the country.

### **5.2.3 Analysis of International Policies influencing the development of Biotechnology and Biosafety in the Dominican Republic**

This study's aim was to:

- analyze the development of the international policy of the Dominican Republic in the field of Biotechnology and Biosafety;
- study the various international legal instruments related to biotechnology already in force or planned;
- study the Cartagena Protocol on Biosafety and mention its most relevant parts and implications;
- make an assessment of the national and international institutions related to this topic.

An assessment of the actual state of the national and international policy with respect to biotechnology and biosafety was carried out.

Among the most important achievements was the compilation of information on biotechnology and biosafety in the country, the countries of the region and the major players on the world market with respect to LMOs and in terms of impact on the environment, as well as on related topics.

Among the most notorious limitations are the lack of available documentation, the lack of state policy, and budgetary constraints, which various agencies and producers in the country are undergoing.

### **5.2.4 Preparation of a database and research on the establishment of the BCH Mechanism**

This report intended to establish clear objectives for the analysis, development and implementation of a National Database on Biosafety.

This database has the characteristic that all users authorized for the collection of information may be connected to it from any part of the country or the planet through the Internet. It creates an administration for users under which they can act independently and an administration for everything relating to: National Contacts, Laws and Regulations, Capacity Building, Decisions and Statements, List of Experts, and other resources.

**a) Analysis and definition of Requirements:** The services, restrictions and goals of the system on the basis of consultations with users. This serves as a punctual specification of what the system is and what its use will be.

**b) System and program design:** It is the process by which the systems are divided into requirements for hardware or software systems. Here we establish a complete architecture of the system. The software design identifies and describes the fundamental abstractions of the system and their relations.

**c) Implementation and tests of units:** The programs or the individual units of programs are integrated and tested as a complete system to ensure they meet the program requirements. After testing the software, the system or systems are delivered to the user.

**d) Operation and maintenance:** For this particular project, this phase will not be presented to date, unless the user or users require it.

### **5.3 Phase Two: Analysis to identify and prepare the main elements of the Biosafety Framework**

In this phase of the project, an analysis was made for the preparation of a national biosafety framework. A national Workshop for consultation with the involved sectors was conducted, to identify the elements that would form part of the National Biosafety Framework in the Dominican Republic.

Additionally, consultations were carried out via the email-address of the Biosafety Project, using a questionnaire with questions related to the issue of biosafety in the country.

In this phase, a campaign to spread information was started with public participation and public information.

Among the aspects analyzed in order to identify the main elements of the National Biosafety Framework are:

1. Access for stakeholders to information of interest
2. Program for the development of databases on biosafety and links to the Biosafety Clearing House established by the CPB
3. Identification of the components of the National Biosafety Framework in consultation with the interested and involved sectors.

In this second phase, the following activities will be developed to meet the objectives:

#### **5.3.1 Consultative Workshop for the Development of a National Biosafety Framework**

This workshop aimed at generating the key elements and components of the national biosafety framework on the basis of the contributions of the experts from the public sector, civil society and the private sector on the different aspects of biosafety in the Dominican Republic.

#### **Specific Objectives:**

- To gather all inter-institutional and inter-sectorial actors who are relevant for the biosafety issue in a discussion forum on the elements, components and requirements of the biosafety framework for the country.
- To identify the elements and components of the national biosafety framework and their articulation in the institutional context of the country.
- To assess the existing risks, threats, constraints and opportunities for generating a national biosafety framework.
- To identify mechanisms of collaboration and exchange of information on biotechnology and biosafety.

This consultation workshop consisted of two parts: a first part with presentations on the project and the current level of performance; inputs were provided for group discussions, and it was held in the form of a panel. The second part was the workshop itself, in which contributions were generated from the participants on the different topics addressed.

Within each working group, an analysis of two phases was conducted: (i) a SWOT analysis (strengths, weaknesses, opportunities, threats) on the biosafety framework in the current institutional context of the country, (ii) Identification and articulation of the elements and components of the national biosafety framework. The first phase of the analysis showed the risks and appropriateness of the framework and the second revealed its composition.

The working groups were organized in a sectorial manner, so that there were groups representative of: (i) the academic community: universities and public and private institutes for research on biotechnology, (ii) the private sector: companies directly related to biotechnology (iii) the public sector: representatives of state institutions concerned specifically with the regulation and/or management of biotechnology, (iv) civil society: organizations of the third sector promoting consumer rights, management of and access to genetic resources, among others.

The results of the workshop were systematized in order to become a key input from which to derive the national biosafety framework for biosafety.

### **5.3.2 Campaign for the disclosure of information and participation in events**

In this second phase informative materials were prepared, to be used especially in meetings and workshops, and to be distributed to the general public (**Annex 6**). In addition, with the support of the NEA, those who led the project participated in various events, activities and instances of political and academic nature, whereby the objective of the project as well as the issue of biosafety were highlighted as subjects of national and international contingency:

1. Development of informational brochures containing the elements of the National Biosafety Framework Project (2004).
2. Reproduction of the Cartagena Protocol on Biosafety to be used in workshops and meetings of the NBF, (2004).
3. Presentation of the project "Development of the National Biosafety Framework UNEP/GEF" in the Caribbean Congress on Biodiversity by the Regional Coordinator of UNEP project, Giovanni Ferraiolo. Santo Domingo (January, 2004).
4. Presentation of the Project "Development of the National Biosafety Framework UNEP / GEF" by Marina Hernandez at the First International Conference on Genetically Modified Organisms (transgenes), held in Santo Domingo, on the 2<sup>nd</sup> and 3<sup>rd</sup> of June 2005 and the subsequent publication of the presentations of the Conference, Santo Domingo (January 2006).
5. "National Forum on Transgenic Organisms." Solution or threat to food and biodiversity? The State Secretariat of the Environment and Natural Resources participated in the Forum with the aim of learning about the progress in the development of the project. (2005).
6. Production of posters, CDs and stickers referring to Biosafety (2004 and 2005).

7. Permanent Lectures on Biodiversity and Biosafety in the Masters' Modules of the Institute of Higher Education of the Armed Forces (Air Force, Navy and Army); this is a permanent activity of SEMARN.

8. Conference on Biosafety and the Cartagena Protocol on Biosafety in the Week of the Environment in June, 2005, celebrated by the Iberoamerican University (UNIBE).

9. **DR-CAFTA AND THE REGULATORY FRAMEWORK ON ENVIRONMENTAL ISSUES AND BIOSAFETY.** With this title, the coordinating committee made a presentation at the Academy of Sciences of the Dominican Republic at the invitation of the Dominican GMO-Network on November 7, 2005. The aim of this conference was to outline the current state of the regulatory framework for environmental issues and biosafety in view to the entry into force of the Free Trade Agreement DR-CAFTA with the United States and the Central American countries, and to see the potential impacts of free trade on biodiversity and the environment and enhance the efforts and participation in the implementation of a regulatory framework on biosafety (2005).

10. There were three meetings with Members of the Committee on the Environment and Natural Resources of the National Congress, where the importance and relevance of the entry of the Free Trade Agreement DR-CAFTA with the United States and Central American countries was explained to them. To reach the goal, the coordinating committee produced two documents titled "**The Dominican State's commitments and benefits from the Cartagena Protocol (Biosafety)**", to provide a report to the Committee's work and speed up the process for approval (2006).

11. Participation (panel) in the **International Day of Biotechnology in the Dominican Republic.** (February 9, 2006).

12. Conference on Biodiversity and Biosafety, School of Higher Education of the Armed Forces, as part of the Environmental Module of SEMARN. (March 7, 2006).

13. Participation in the workshop "**Towards the Strategic Planning of Biotechnology in the Dominican Republic**" (IIBI, FAO, CEDAF)(March 8,9,10, 2006).

14. Various publications of articles on GMOs in the national newspapers.

15. A televised program communicating the objectives of the Bill of Law on Biosafety (February 2, 2007).

16. Presentation of the topics of Biotechnology and Biosafety at the Institute of Higher Education of the Armed Forces. (March 14 2007).

17. Presentation to National Congress of the **Final Bill of Law on Biosafety** by the State Secretary of the Environment and Natural Resources, Dr. Max Puig and a Committee of the Secretariat.(May 16, 2007).

18. Inclusion of the subject of biosafety as an "Environmental issue" on the website of the State Secretariat of the Environment and Natural Resources, [www.ceiba.gov.do](http://www.ceiba.gov.do)

#### **5.4 Phase Three: Preparation of the Draft for the National Biosafety Framework.**

In this phase of the project the consolidation of the Final Draft of the Proposed Law on Biosafety began, with several meetings of the National Committee of the National Biosafety Framework project and successive discussion sessions.

The National Committee of the Biosafety Project held a series of meetings with the aim of obtaining a consensus document from the then two Bills of Law existing on Biosafety. One proposal drafted by the State Secretariat of the Environment and Natural Resources through the project, and a second draft prepared by the National Council for Agricultural and Forestry Research (CONIAF). More sectors involved in the issues of biotechnology and biosafety participated during this phase of the project.

To reach this phase of the project, the National Coordinator and the National Executing Agency (NEA) established a strategy to bring together the Government Institutions and NGOs with influence in the issue of biotechnology and biosafety in the Dominican Republic.

A first task was to establish working meetings with the institutions whose missions are linked to the objectives and activities of the project. Visits were made to these institutions with the aim of motivating a reorientation of the project and encourage their integration and participation of the pending activities.

The following governmental institutions and non-governmental organizations were visited:

**Institute for Industrial and Biotechnological Innovation (IIBI).** The participation of the IIBI was agreed upon in the National Committee of the Project as a way of incorporating new key players for the development of the participatory process and correct decision making. The IIBI was one of the institutions which were integrated into the Committee for the drafting of the national regulatory framework for its character as a research institute in the area of Biotechnology. The IIBI was created in January 2005 and thus became the last institution to be part of the of the Biosafety Project Committee.

**National Council for Agricultural and Forestry Research (CONIAF).** Since the beginning of the project, the CONIAF was part of the Biosafety Project Committee participating very actively throughout the development of the project. It was the Institution that had prepared a second draft Law on Biosafety, for which an international consultant has been hired. In 2005, a meeting was held in which the roles of the State Secretariat of Environment and Natural Resources regarding the implementation of biosafety were established.

After clarifying some situations and misunderstandings, work was resumed. It was agreed to merge SEMARN and CONIAF's proposals and to submit this document to a consensus-building workshop.

Similarly, meetings were held with the **Inter-American Institute for Cooperation in Agriculture (IICA)**, an International Cooperation Agency, which then accompanied the State Secretariat of Agriculture in reforming the policy framework for the agricultural and rural sectors. In meetings, it was agreed not to duplicate efforts in regulating biotechnology, since the State Secretariat of Environment and Natural Resources has the legal mandate and institutional competence in the matter, but had not participated regularly in the meetings and workshops within the framework of the elaboration of policies affecting the national biosafety framework.

In a brief analysis, it was determined that in the proposals for Sector Policies as well as for Plant Health Protection and the National Law on Seeds, issues that impact on Biosafety are dealt with, and therefore must be looked over by both working teams.

It was agreed to work together on both proposals and initiatives to avoid a confusion of roles and institutional competences as well as a duplication of efforts on Biosafety.

Along with these activities in coordination with other institutions involved in biotechnology and biosafety, meetings were held with the Environmental Committees of the Senate and the Chamber of Congressmen with the aim of obtaining the ratification of the Cartagena Protocol on Biosafety by National Congress. At the meeting of the Senate on October 18, 2005, the Cartagena Protocol on Biosafety was approved.

After holding meetings with the other institutions, the two proposals, which had worked on national regulatory framework or Law on Biosafety separately, with some points of coincidence but also some different perspectives, were consolidated into one single document, after a consensus on the matter was finally reached.

To achieve consensus for a single draft document, a Petit Committee was formed from the National Committee on Biosafety. It assisted in the development of a proposal, which was then discussed at the National workshop for the review of the **Bill of Law on Biosafety**.

#### **5.4.1 National Workshop for the review of the Bill of Law on Biosafety.**

This national workshop was held in the city of Santo Domingo, with the presence of the national authorities of the Environmental Sector and the Agricultural Sector. These sectors were summoned from the different regions of the country.

The goal of the workshop was to receive inputs and first comments on the proposed Law on Biosafety, since the different organizations had received the proposal in advance via email.

The methodology implemented was the creation of three work groups, one based on institutional and administrative aspects, a second on assessment and management of environmental risks and impacts, and a third on violations, sanctions and prohibitions. One hundred and nineteen (119) comments on the document were received through the three work groups formed to discuss the document and receive the opinions and inputs.

#### **5.4.2 Draft Resolution for the Creation of the Biosafety Technical Committee**

During this phase of the project, the draft resolution for the creation of the **Biosafety Technical Committee** was drawn up (**Annex 7**). The preparation of this draft resolution served to define the necessary elements for the creation and development of the National Biosafety Council by the Law on Biosafety. It is important to point out that this Committee was supposed to be transitional until the adoption of the Law on Biosafety. Even though at the end it was not formed, it represented an important action in the development of the institutional components that would later make up the National Biosafety Council. This resolution had the following articles:

**Article 1:** *A transitional Biosafety Technical Committee is created as a multisectorial and multidisciplinary agency in charge of regulating the activities related to the safety of modern biotechnology and decision-making on this matter.*

**Article 2:** *The fundamental objective is to implement the terms of the Cartagena Protocol on Biosafety of the Convention on Biological Diversity.*

**Article 3:** *The mission of the Biosafety Technical Committee is to help ensure an adequate level of protection in the field of safe transfer, handling and use of living modified organisms and/or genetically modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biodiversity.*

**Article 4.** *The Biosafety Technical Committee shall be composed of:*

- a) *The Secretary of State for the Environment and Natural Resources, who will chair it;*
- b) *Sub-Secretary of State of Protected Areas and Biodiversity;*
- c) *The Director of the Division of Biodiversity of the State Sub Secretariat of Protected Areas and Biodiversity*
- d) *The person in charge of the Department of Genetic Resources of the State Sub Secretariat of Protected Areas and Biodiversity;*
- e) *A representative of the Sub Secretariats of Environmental Management, Forestry, Marine and Coastal Resources, Soils and Water Bodies, Environmental Information and Education and the Office for Sectorial Planning and Programming;*

Section: The Biosafety Technical Committee will work in coordination with:

1. Secretariat of the Environment and Natural Resources (SEMARN) as chair;
2. State Secretariat of Agriculture (SEA);
3. Secretariat of Higher Education, Science and Technology (SEESCYT);
4. State Secretariat for Industry and Commerce (SEIC);
5. Institute for Biotechnological and Industrial Innovation in (IIBI);
6. State Secretariat of Foreign Affairs (SEREX);
7. State Secretariat of Public Health and Social Welfare (SESPAS);
8. State Secretariat of Education;
9. Dominican Institute of Agricultural and Forestry Research (IDIAF);
10. General Customs Directorate (DGA);
11. State Secretariat of Armed Forces;
12. National Council for Agricultural and Forestry Research (CONIAF);
13. Representatives of the Consumer Sector;
14. Autonomous University of Santo Domingo (UASD);
15. Representatives from the Business Sector

## **6. Ratification and Promulgation of the Cartagena Protocol on Biosafety (CPB)**

The Cartagena Protocol on Biosafety was ratified by National Congress (December 27, 2005) and promulgated by the President of the Dominican Republic (February 2006) and entered into effect in September 2006.

With the ratification of the Cartagena Protocol, a central goal result of the Development of the National Biosafety Framework is achieved.

## **7. Review of the Bill of Law on Biosafety by International and National Experts**

The Bill of Law on Biosafety was reviewed by one international legal expert and national legal experts. Therefore, several meetings were held to discuss the proposal of the Law

on Biosafety. The international expert was **Dr. Orlando Rey** from the Ministry of Environment, Science and Technology of the Republic of Cuba, whose support was requested from UNEP's Regional Office for Latin America and the Caribbean and financed through this Office's Program for Environmental Law. National experts in environmental matters were **Dr. Yocasta Valenzuela and Mr. José Rafael Almonte**.

## 8. Main elements of the Bill of Law on Biosafety

The final version of the revised proposal can be found in **Annex 5**. Chapter I, “On the Basic Principles”, sets out the basic principles for the formulation and conduction of the Biosafety Policy.

The Objectives are contained in Chapter II: to guarantee, through Biosafety, the safe use of modern biotechnology by helping to achieve an adequate level of protection for the use of living modified organisms and its derivatives; to prevent adverse effects on the conservation and sustainable use of biodiversity, human health and the environment in general resulting from the use of living modified organisms and their derivatives; and to establish the general precepts that regulate research, testing, development, handling, transportation, transit, commercialization, import, export and use.

In terms of application, the Bill of Law covers activities carried out with any kind of living modified organisms in the Dominican Republic and pharmaceutical products containing LMOs, provided they are not subject to supervision by other laws.

In Section II the Institutional Framework establishes that the Implementing Authority is the State Secretariat of the Environment and Natural Resources, responsible for organizing, directing and controlling the activity of biosafety in the country. In Chapter II of the same Section, the National Biosafety Council is created as a decentralized, Inter-institutional and multi-sectorial and multi-disciplinary agency in charge of advising the Implementing Authority in the development of the activities related to biosafety.

Title III includes the Risk Assessment Study, Environmental Impact Study, Risk Management and the guidelines for risk assessment.

It is established that all activities with living modified organisms taking place in the Dominican Republic require an administrative authorization through a permit or license issued by the State Secretariat of the Environment and Natural Resources. In addition, the procedure of the Advanced Informed Agreement will be applied by the Authority, before the first transboundary movement of a LMO destined for introduction into the environment.

Chapter III deals with LMOs destined for direct use as food or feed or for processing.

Other chapters deal with “Other Authorizations”, “Exports”, “Review of Decisions”, “Bilateral Arrangements”, “Information to the General Public”, “Confidential Treatment”, and other provisions such as on handling, transport, packaging and identification.

The proposed Law establishes a System of Responsibility, including Offenses and penalties.

Currently, the SEMARN's Department of Communication is preparing a printed copy of the Bill of Law on Biosafety.

## **9. Regulatory developments related to Biosafety in the Dominican Republic**

### **9.1 The General Law on the Protection of Consumers or Users (Law 358-05)**

This law was enacted one year after the consultancy on the review of the National State Policy, the legal status and the regulations on Biotechnology and Biosafety in the country, which is why there is no mention of it in the consultancy. In Article 74 it refers to the entry of unauthorized **GMO** food and substances that have not complied with the risk analysis and the use of which could affect human health and the environment.

### **9.2 Bill of Sectorial Law on Biodiversity and Regulations for Access to Genetic Resources**

The State Secretariat of the Environment and Natural Resources, through the Department of Biodiversity and Wildlife, prepared the **Bill of Sectorial Law on Biodiversity and Regulations for Access to Genetic Resources and Shared Benefits**. These two legal instruments are complementary to the Law on Biosafety. The Bill of Sectorial Law on Biodiversity, and will be sent shortly to the Executive Branch as the Bill of Law on Biosafety.

## **10. Project for “Capacity Building for the Biosafety Clearing House (BCH)”**

After the finalization of the activities of this project, in July (2007) the State Secretariat of the Environment and Natural Resources, through the Department of Genetic Resources of the Sub-Secretariat for Protected Areas and Biodiversity, began the project for "Capacity Building for the Mechanism of Information Exchange on Biosafety (BCH)", which aims at creating the necessary capacities to implement the Biosafety Clearing House (BCH), pursuant to Article 20 of the Cartagena Protocol on Biosafety.

For the development of this project, a working group was established, which consists of Institutions representing the Competent National Authorities (for Public Health, Industry and Commerce, Foreign Affairs, Agriculture) and other Institutions in the Biotechnology and the Agricultural Sector, as well as from the Academic Sector. Some of these Institutions formed part of the Biosafety Project Committee, which demonstrates the continuity of the work in biosafety and its strength.

## **11. Conclusions and Pending issues in order to complete the NBF in the Dominican Republic**

In the final phase of the project, issues that should be developed by the State Secretariat of the Environment and Natural Resources were identified, including:

1. Development of a National Policy on Biosafety.
2. Promulgation of the Biosafety Law by National Congress.
3. Capacity-building in risk assessment and analysis through the recruitment of a regional expert from the area.
4. Capacity-building for the implementation of the PCB and the National Biosafety Framework.

These tasks were determined based on the following conclusions resulting from the project:

The need for a biosafety policy was expressed by participants in the consultation workshops and meetings of the Biosafety Project Committee.

It is very important to study the environmental impact, including an assessment of the risks of introducing LMOs.

During the development of the project, it became evident that it is important to create capacities in the area of biotechnology and biosafety.

During the project, it could be observed that the Dominican population is not adequately informed on the issues of modern biotechnology and genetically modified organisms, products of genetic engineering.

## 12. Recommendations

- A biosafety policy should be developed
- The Bill of Law on Biosafety should be passed by National Congress
- The Cartagena Protocol on Biosafety should be made effective by implementing the Law on Biosafety.
- Administrative procedures for a better implementation of the Cartagena Protocol on Biosafety and the Biosafety Law need to be adopted after their approval.
- The National Biosafety Council should be established as a decentralized, inter-institutional, multi-sectorial and multi-disciplinary organization in charge of advising the Implementing Authority on biosafety, in fulfillment of the requirements established in the Biosafety Law.
- Increased training in biosafety-related issues should be given to decision makers.
- A research program in biotechnology and biosafety should be established.
- The current situation of living modified organisms in the country should be diagnosed by creating a national database of biotechnology and biosafety.
- The campaign for information, awareness-raising and dissemination should be continued in order to generate increased participation on the subject by civil society.
- It is essential to create the necessary capacities for the implementation phase of the NBF.
- International funding for the implementation of NBF should be identified.

## 13. Annexes

**In an independent file: (see refer to Spanish version)**

### **ANNEX 1: p1**

Analysis of the Degree of Development of and Training Programs on Biotechnology and Biosafety in the Dominican Republic.

### **ANNEX 2: p24**

Analysis of the National State Policy, the Legal Status and Regulations on Biotechnology

and Biosafety in the Dominican Republic

**ANNEX 3: p136**

Analysis of the International Policies influencing the development of Biotechnology and Biosafety in the Dominican Republic.

**ANNEX 4: p197**

Development of a database and research on the establishment of the Biosafety Clearing House BCH.

**ANNEX 5: P208**

Bill of Law on Biosafety

**ANNEX 6: p233**

Information materials

**ANNEX 7: p238**

Draft Resolution for the Creation of the Biosafety Technical Committee

**ANNEX 8: p249**

Pictures of workshops and meetings held during the development of the project