"STUDY ON THE IMPLEMENTATION OF THE STRATEGIC PLAN 2011-2020

OF THE CARTAGENA PROTOCOL ON BIOTECHNOLOGY SAFETY (CPBS) IN ECUADOR;

NATIONAL PLAN FOR LIVING WELL (NPLW) 2013-2017;

NATIONAL BIODIVERSITY STRATEGY AND ACTION PLAN (NBS-AP);

AND, NAGOYA KUALA LUMPUR PROTOCOL (NKLP) ON LIABILITY AND COMPENSATION SUPPLEMENTARY TO CPBS"[1].

FINAL REPORT

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ABBREVIATIONS

AGROCALIDAD	Agency for Agro Quality Assurance
ARCSA	National Agency for Regulation, Control and Health Surveillance
CDB	Convention on Biological Diversity
CIBE	Biotechnology Research Center of Ecuador
CONABIO	National Biosafety Commission
ENB-PA	National Biodiversity Strategy and Action Plan
ESIGEF	Financial Management System
FMAM	Funding for Global Environment
IICA	Inter-American Institute for Cooperation on Agriculture
INSPI	National Research Institute of Public Health
INTA	National Agricultural Technology Institute
MAE	Ministry of Environment
MAGAP	Ministry of Agriculture, Livestock and Fisheries
MSP	Ministry of Public Health
OGM	Genetically Modified Organism
PCSB	Cartagena Protocol on Biotechnology Safety
PNBV	National Plan for Living Well
PNUMA	United Nations Environment Programme
PNKL	Nagoya Kuala Lumpur Protocol
PNUMA	United Nations Environment Programme
SAE	Ecuadorian Accreditation Service
SCDB	Secretariat of the Convention on Biological Diversity
SENESCYT	National Secretariat of Higher Education, Science, Technology and Innovation
USFQ	Universidad San Francisco of Quito

1. INTRODUCTION

The Convention on Biological Diversity is the first global agreement addressing aspects of biodiversity, at all levels. It is an international legal instrument aimed at creating practices for the conservation of biological diversity, the sustainable use of its components and, the fair and equitable participation of benefits arising from the utilization of genetic resources. At the same time, it establishes the basis for biotechnology safety[2], through the Cartagena Protocol on Biosafety, which is an international agreement that seeks to contribute to ensure an adequate level of protection in the field of safe transfer, handling of certain genetically modified organisms resulting from the application of modern biotechnology that may have adverse effects on the conservation and sustainable use of biodiversity as well as the controlling of transboundary movements of such organisms. In addition, it establishes a procedure for a preliminary well-versed agreement to ensure that each country has the necessary information for decision-making on imports of genetically modified organisms into their territory.

The governing body of the Convention on Biological Diversity is the Conference of Parties (COP), which meets every two years with participants from all countries (Parties) that have ratified their adhesion, with the purpose to discuss, among other topics, the progress of the program, to set priorities and supervise the process of implementation and future development of the Agreement. In the same way, it acts as the meeting organizer of the Parties (COP-MOP) for the implementation of the Cartagena Protocol on Biosafety and the Conference of Parties. To date, seven meetings have been held and, in December of this year, the eighth meeting (COP-MOP 8) will take place in Cancun, Mexico. At the Fifth Meeting of the Conference of Parties acting as the meeting organizer of the Parties (COP-MOP 5), the Strategic Plan for the Cartagena Protocol on Biosafety was approved for the period 2011-2020, among other things.

Under the Convention on Biological Diversity, the Ecuadorian State in 2003, subscribed the Cartagena Protocol on Biosafety (CPB), and, through the Ministry of Environment, as one of the relevant entities in the regulation of biosafety in the country, together with other public/private/academic sector's entities is carrying out activities to fulfill its obligations as member country of said Protocol.

In this context, in October 2015, Ecuador developed a proposal, which was selected by the Secretariat of the Convention on Biological Diversity among top ten, worldwide, for the implementation of a Global Project: *"Creation of capabilities to promote full implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity, at national level."*

The project, within each country, among other things, seeks to facilitate the integration of biosafety into national biodiversity strategies (NBS), action plans (AP), programs and other sectoral and cross-sectoral policies as well as to reinforce national inter-sectoral coordination mechanisms. Activities that will enable the Secretariat of the Convention on Biological Diversity (SCBD), to systematize relevant experiences, good practices and lessons learned from pilot countries, to assess capacity needs and national gaps, to develop training materials to orientate people on biosafety and their integration to ENB-PA and to national development plans, as well as the coordination of a national workshop for focal points of CBD and PCSB to meet and share their knowledge and experience in the integration of biosafety in ENB-PA and full implementation of the Convention and the Protocol.

In order to implement the above mentioned Project, the Ministry of Environment and the Secretariat of the Convention on Biological Diversity (SCBD) subscribed a Cooperation Agreement on April 14th. of this year. Similarly, at national level, the Ministry of Environment subscribed a Technical Cooperation Agreement with the Inter-American Institute for Cooperation on Agriculture (IICA) to perform a theoretical study with the objective to get an overview of current status of biosafety in Ecuador, as well as to identify gaps or blanks in the implementation of the Plan, training needs, best practices and lessons learned in the country, proposed activities for inclusion or development of biosafety in the National Plan for Living Well (PNBV) 2013-2017; National Biodiversity Strategy and Action Plan (ENB-PA); other strategies and/or sectoral action plans plus a feasibility analysis for the subscribing and implementing of the Nagoya Kuala Lumpur Protocol (PNKL) on liability and compensation supplementary to PCSB.

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[2] Article 8: *In situ conservation*, literal g: *"It will establish or maintain means to regulate, manage or control the risks arising from the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect conservation and sustainable use of biological diversity, taking also into account risks to human health "..*

2. OVERVIEW ON CURRENT SITUATION OF BIOSAFETY IN ECUADOR

Ecuador, as a signatory member to the Cartagena Protocol on Biosafety and an active participant in meetings of the Parties (COP - MOP), has encouraged important processes for the management of biosafety in the country, based, among other aspects, on the objectives of the Strategic Plan 2011-2020 of the Protocol, counting with the support of organizations such as the United Nations Environment Programme (UNEP) and Funding for Global Environment (GEF), among others.

A general view of current situation of biosafety in Ecuador can be summarized in five areas: Political, Legal, Institutional, Social and Financial.

On the subject of Political issue, the country counts on Policy 7.5: "*Ensuring biosafety thereby safeguarding the health of people, of other living beings and nature"*, which has five strategic guidelines. This policy is included in the National Plan for Living Well 2013-2017.

With regards to legal framework, it could be mention that since the Constitution of the Republic of Ecuador became effective in 2008, work has been done on a proposal for a Biosafety Law and Regulation; the Unified Text of Secondary Environmental Legislation of the Ministry of Environment has been updated; Ministerial Agreement 013, whereby nature and functions of the National Commission on Biosafety were updated. Currently, the Environmental Organic Code and other laws related to biosafety management are being revised by the National Assembly.

Referring to the institutional framework, it could be also mentioned that the issue of biosafety is steered by four competent institutions: Ministry of Agriculture, Livestock, Aquaculture and Fisheries, Ministry of Public Health, Ministry of Environment and, the Ministry of Higher Education, Science, Technology and Innovation. There are other institutions that are also related to the subject, some of which are attached to the aforementioned entities. In relation to private sector, it does not have a significant involvement, and, in the case of academic sector, it could be said that at present certain universities include, within their program of study, some courses in biotechnology related to biosafety issues.

Regarding social participation, no formal mechanisms for public participation have been established so there is no intervention of citizens in biosafety issues.

With regards to funding issues, Biosafety activities in Ecuador have been carried out with financial support from organizations such as GEF through UNEP, SCBD, and, the Ecuadorian State, through public institutions and with the support of other allied countries, through practices under bilateral agreements, especially in events for creation of capabilities.

Of the five above mentioned areas, it can be highlighted that:

On the regulatory issue, even though some legal documents have been generated which demand the regulation of the subject and to establish some measures for its treatment, a clear political decision by the State is still needed, as well as the generation of specific, consolidated and consensus regulations from a complementary, interdisciplinary and inter-institutional coordination perspective. The establishment of new strategies and sectoral plans is also required, in order to encourage and reinforce sustainable agricultural models adjusted to national reality, to overcome inconveniences among various actors and to promote the sustainable use of agricultural biodiversity and existing technological advances.

To address the lack of legal support for a comprehensive management of biosafety of GMOs in the country, a proposal for a Law and Regulation on Biosafety has been submitted, with a multisectoral and multidisciplinary approach that would allow an effective regulation and will impulse the research on modern biosafety and biotechnology, protecting the Ecuadorian State of risks that GMOs may have on the environment, biodiversity and human and animal health. The proposals were developed based on existing legislation and through a participatory work with different actors in public, industrial and academic sectors. However, these legal bodies are still under review and analysis in the Legal Secretariat of the Presidency of the Republic.

Under the provisions of current legislation[3], the country counts on a National Biosafety Commission, which is responsible for coordinating, formulate and implement National Policies on Biosafety, in coordination with Authorities from entities of Environmental, Agriculture, National Health and National Authority on Higher Education, Science, Technology and

[3] Unified Text of Secondary Legislation of the Ministry of Environment, published by Executive Decree No. 3516, Official Gazette E.E. 2 of March 31, 2003. Ministerial Agreement No. 013 signed on January 22, 2015 and published in the Official Gazette No. 245 dated January 27, 2015.

Innovation sectors. However, this Commission is not yet fully established and functioning, therefore, it is necessary to reactivate their actions seeking autonomy and sustainability, so as to achieve viable legal and technical processes that would enable a better treatment of GMOs.

With regard to issues of creation of capabilities, awareness, access to information and public participation, there are important contributions. Plans and Strategies for training and communication are available as well as two laboratories for GMO detection, situational studies of laboratories, manuals and protocols for monitoring, detection, identification and quantification of GMOs, technical guidelines for assessment, administration of risk's communications, socioeconomic aspects and inter-institutional cooperation agreements for training processes. It is worth mentioning that 39 training events have been carried out, that is, workshops, courses, breakfast meetings, forums and national seminars, with approximately 469 employees being trained (technicians and authorities) from National Secretariats, Coordinator Ministers, Sectoral Ministries, Agencies of Control and Public Research Institutes, in topics related to research, use, production, risk analysis[4] and regulation of GMOs.

However, GMOs and their products are still sensitive issues in Ecuador, so it is necessary to continue with training processes, awareness, access to information and public participation, involving all related sectors, including non-governmental and academic organizations, community leaders, consumers, producers and farmers, taking into account activities carried out, legislation in force, geographical situation, production systems, and especially, the needs and the national reality.

3. BIOSAFETY INTEGRATION INTO NATIONAL AND INTERNATIONAL LEGISLATION

According to the objectives of the Strategic Plan for the Cartagena Protocol on Biosafety, one of the areas of priority attention for the implementation of the Protocol is *to facilitate the establishment and further development of systems on biotechnology safety*, through the creation of national frameworks on biosafety with standards, administrative procedures and implementation guidelines. In this context, the adopted legal instruments as well as the achievements on legislation in the country are hereby documented, as follows:

3.1 International Level

At present, there is a wide range of international legal documents related to biosafety, among which, it is important to mention the following:

3.1.1 Convention on Biological Diversity

The Convention on Biological Diversity was adopted at the forum of the United Nations Conference on Environment and Development, "Earth Summit" in 1992, in Rio de Janeiro, and entered into force on December 29, 1993. At present, 196 countries have ratified their subscription, and it is considered as the main international treaty covering all issues related to biodiversity, promoting measures leading to a sustainable future and it is based on three main objectives: conservation of biological diversity, sustainable use of its components and fair and equitable sharing of benefits arising from the utilization of genetic resources.

One of the topics covered by the Convention on Biological Diversity (CBD) within its scope is to establish the basis for biosafety, based on concepts related to the need to protect human health and the environment against possible adverse effects that products of modern biotechnology may represent. In this regard, Article 8, literal *g* of CBD states that countries being Parties shall establish means to regulate, manage or control the risks arising from the use or release of genetically modified organisms (GMOs); also, Article 19 paragraph 3 calls Parties to consider the need and modalities of a legally binding international instrument that would establish the appropriate basis for transfer, handling and use of GMOs as a result of modern biotechnology. Pursuant to this mandate, a Special Working Group on Biosafety drafted and adopted the Cartagena Protocol on Biosafety (Convention on Biological Diversity, 2007).

3.1.2 Cartagena Protocol on Biotechnology Safety

Under the Convention on Biological Diversity, on January 29, 2000, the Cartagena Protocol on Biosafety was adopted as a supplementary agreement to the Convention on Biological Diversity, and entered into force on September 11, 2003. Ecuador

[4] Risk analysis is a logical sequence of steps, where risk assessment is the first step to identify, assess and prevent possible adverse effects on human health, biodiversity and the environment arising from the products of modern biotechnology . Thus, the measures or strategies to be implemented are determined in order to manage these risks obtaining an acceptable level of safety (Convention on Biological Diversity, 2007).

ratified its membership on November 7, 2002. Currently, 170 countries have ratified it. It is an international agreement that seeks to protect biological diversity from potential risks that may occur in genetically modified organisms (GMOs) resulting from modern biotechnology as well as from transboundary movements of these organisms. In the same way, it establishes a preliminary agreement procedure that ensures that each country has the necessary information in order to make GMO's import decisions. It also establishes a Biosafety Information Exchange Center to enable the exchange of information on GMOs and other important aspects for the implementation of the Protocol (Secretariat of Convention on Biological Diversity, 2000).

The Cartagena Protocol in its regulations (40 articles) describes some of the items to be considered by the Parties when framing their national regulations and other provisions concerning the handling, transport, packaging and identification of GMOs, involuntary transboundary movements and emergency measures. Article 4, for example, refers to the scope of application of this international instrument, with scope to *"transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable utilization of biological diversity, taking also into account risks to human health ".*

Without prejudice to Article 4 and to the sovereignty that each country has to consider submitting GMOs to a risk assessment, all pharmaceutical products for human use are excluded from this agreement, which also have been addressed by other agreements or relevant international organizations, as well as derived products such as food, canned food, or other products made from GMOs, and the regulation of the transport of GMOs through their territory (Secretariat of Convention on Biological Diversity, 2000).

Country Parties, in order to analyze the level of implementation of the Protocol, hold meetings every two years. At its 5th. Meeting[5], held in October 2010, they adopted important decisions, pointing to new strategic directions for the implementation of the Protocol in the next ten years, within which, the Strategic Plan for the Cartagena Protocol on Biosafety 2011-2020 is highlighted.

3.1.2.1 Strategic Plan for the Cartagena Protocol on Biosafety 2011-2020

The Strategic Plan for the PCSB and the corresponding multi-year work program, took effect in October 2010 and it is proposed as an instrument for guidance to facilitate the implementation of the Protocol; it consists of a vision, mission and five strategic objectives, and it has been prepared based on the submissions of the Parties, the analysis of the first national reports, decisions taken by the Conference of the Parties acting as the meeting of the Parties in the Protocol, general discussions, comments submitted by the Parties, other governments and interested stakeholders, and the experience gained through the development, implementation and revision of the Strategic Plan of the Convention (Secretariat of the Convention on Biological Diversity. 2011).

The five basic objectives of the Strategic Plan describe the focal areas that must be addressed to fulfill the vision and mission of the Plan during its ten years of existence. Reference is made to these areas:

• To facilitate the establishment and further development of safety systems on biotechnology for an effective implementation of the Protocol.

• Creation of capabilities: *"To further develop and reinforce the capability of Parties to implement the Protocol"*

• Compliance and review: *"Achieving compliance with the Protocol and its effectiveness"*

• Information exchange: *"Improve availability and exchange of relevant information"*

• Divulgation and cooperation: *"Expanding the scope of the Protocol and promoting cooperation"*

[5] The fifth Meeting of the Parties for the Cartagena Protocol on Biosafety was a historic event and a major turning point for the Protocol, it also marked the end of the first work program, in the medium term, of the governing body of the Protocol and the beginning of a new stage

3.1.3 *Nagoya-Kuala Lumpur Protocol on liability and compensation supplementary to the Cartagena Protocol on Biosafety*

The global community, at the fifth meeting of the Conference of Parties, acting as the meeting of the Parties to the Cartagena Protocol, held in Nagoya, Japan on October 15, 2010, adopted a new international treaty, the Nagoya - Kuala Lumpur Protocol on liability and compensation supplementary to the Cartagena Protocol on Biosafety. This Protocol, in accordance with Article 27 of the Cartagena Protocol, was developed to provide international regulations and procedures on liability and compensation, in those cases where there is damage or potential damage to biodiversity resulting from transboundary movements of GMOs (Convention on Biological Diversity, 2007).

The Nagoya - Kuala Lumpur Protocol on liability and compensation was open for its signature at the United Nations headquarters in New York, between March 7, 2011 and March 6, 2012. It will enter into force 90 days after being ratified by at least 40 Parties of the Cartagena Protocol. Ecuador has participated in the negotiation process, however, has not yet subscribe it. (Convention on Biological Diversity, 2007).

Article 3 of the Protocol establishes its application scope, referring to "*damage resulting from genetically modified organisms whose origin was a transboundary movement"* for GMOs intended for direct use such as food, feed or for processing, to those destined for contained use and intentional introduction into the environment. Also, intentional transboundary movements, that is, damage resulting from any authorized use of GMOs (Convention on Biological Diversity, 2007).

In relation to response measures (Article 5), the operator or operators responsible for the damage, shall immediately inform the competent authority, to assess the damage and take appropriate response measures. The competent authority, with regards to the requirements of national legislation, shall identify the operator causing the damage, assess the damage and shall determine which response measures should be taken by the operator. Besides, this Supplementary Protocol *"shall not limit or restrict any right of recourse or indemnity that an operator may have against any other person."* Thus, the Protocol becomes an important international reference when outlining and implementing national regulatory frameworks (Convention on Biological Diversity, 2007).

3.1.4 *Andean Strategy on Biodiversity for Tropical Andean Countries*

The Member Countries of the Andean Community: Bolivia, Colombia, Ecuador, Peru and Venezuela, by Decision 523, approved in 2002 the Regional Strategy on Biodiversity for Tropical Andean Countries, in order to identify and agree on joint actions for conservation and sustainable use of biological diversity.

The Andean Strategy in its Action Line 7 states: *"To establish policies and joint actions on biosafety";* it also mentions that *"It is important to establish a policy that defines the consensus Andean position and takes into account the latest developments in international agreements on biosafety, such as the Cartagena Protocol on Biosafety. Andean Tropical countries will undertake joint actions to mutually strengthen the management of Living Modified Organisms (LMOs)".* And, in the results of this line of action, the following results are outlined:

Result 7.1: *Adopted mechanisms and joint procedures for the control of trade and cross-border movement of GMOs, their products and derivatives. New national and sub-regional regulations and mechanisms will be developed to assess the risks posed by GMOs, as well as to control their marketing and transportation between TAC countries and others in the region and in the world. Specifically, scientific basis for risk assessment shall be established; labeling guidelines shall be adopted and principles shall be established to determine liability and compensation for damage caused by GMOs.*

Result 7.2*: Experiences on use and handling of GMOs, systematized and disseminated. Countries of the sub-region and of the world have and will have different experiences in testing GMOs, which must be systematized and shared in the sub-region, preferably through electronic media, for consultation in databases, via Internet.*

Result 7.3*: In order to reinforce the capabilities of countries to implement the Cartagena Protocol on Biosafety in the sub-region, some research works should be carry out to identify the risks that could cause the GMOs to the environment and to human health; thus, establishing scientific bases and defining the introduction or not of any particular GMO.*

3.1.5 *Andean Environmental Agenda, 2012 – 2016*

At the 5th. Meeting of the Andean Council of Ministers of Environment and Sustainable Development held on April 10th. 2012, the Andean Environmental Agenda 2012-2016 was approved, which is a planning tool that guides and supports the sustainable

development in the region through the coordination of policies and community strategies, in order to improve the environmental management and sustainable development within the Andean Community. This Agenda has been prepared and is developed through the joint work of organizations and government agencies in each member country: Bolivia, Colombia, Ecuador and Peru (General Secretariat of the Andean Community, 2012).

The Andean Environmental Agenda is mainly based on three core topics (biodiversity, climate change and water resources) with their respective objectives and lines of action. In topic 1, biodiversity, the action line 1.3 mentions: *"To promote joint initiatives in biosafety issues"* meaning that each member country has to take actions for the generation of policies and cooperation tools as well as the strengthening of institutional and sub-regional frames for environmental management associated with the management of GMOs, their products and derivatives (General Secretariat of the Andean Community, 2012).

3.1.6 Other documents of relevance

In previous sections, the most important legal documents that address the safety of modern biotechnology are described; however, it is relevant to mention that there are other important international instruments that should be considered when developing a national legislation, these are: Principles developed by the *Alimentarius* Codex Commission, which is a joint program of the World Health Organization (WHO) and the United Nations Organization for Food and Agriculture (FAO), which deals with food safety program, in order to provide a framework for conducting risk analysis related to nutrition and safety of foods derived by using modern biotechnology techniques and, the agreements of the World Trade Organization (WTO) which contains provisions relevant to the safety of biotechnology in terms of commercialization and distribution of genetically modified products (FAO, 2004).

3.2 National Level

Processes including related to biosafety articles for genetically modified organisms (GMOs) within different legal bodies basically respond to structural changes which the country has gone in the last decade: the first one, prior to the 2008 Constitution of Ecuador, and the second, corresponds to the new constitutional framework adopted after of 2008, whereby some several legal bodies were generated or reformed.

Additionally, some other known elements have encouraged this inclusion, as the pressure for handling of the issue made by sectors such as industrial, academic, and civil society groups as well as the compliance with the Environmental Management Act of 1999 and international instruments such as the Cartagena Protocol on Biosafety which was adopted by the Ecuadorian State in 2003; and, the implementation of the Project "Development of the National Biosafety Framework" 2003-2006 and, the Project "Implementation of National Biosafety Framework" 2010-2015.

With regards to Resources used for the generation of legal bodies in question, mainly come from tax funds of the annual allocation made by the Government for different public entities and each institution distributes the funds received for the activities established in their annual planning.

A decisive factor for incorporation processes of biosafety of GMOs in the country has been the compliance with current legislation: Constitution of the Republic of Ecuador, 2008 and Policy 7.5 of the National Plan for Living Well, 2013-2017 as well as training processes performed with professionals with technical level and authorities of the member institutions of CONABIO and other entities related to the issue.

In the same way, several administrative actions have been taken in three institutions related to the subject: at public institutions level, the Ministry of Environment with the creation of the Biosafety Unit, as part of the capacity building processes of the laboratory of molecular biology of the Ecuadorian Agency for Agro Quality Assurance (AGROCALIDAD), entity under the Ministry of Agriculture, Livestock, Aquaculture and Fisheries which offers, within its service portfolio, the detection of GMOs in raw material (corn and soybean) and, at academic level, service offering detection of GMOs in processed food at the laboratory of the Polytechnic School of the Littoral (ESPOL). The National Biosafety Committee can be counted on, which is composed of representatives of four competent institutions: Ministries of Agriculture, Environment, Health and the Secretariat of Higher Education[6]:

[6] The hierarchy of the norm has been made based on the provisions of Article 425 of the Constitution of the Republic of Ecuador: "*The hierarchical order of application of the norms is as follows: the Constitution; international treaties and conventions; organic laws; ordinary laws; regional standards and district ordinances; decrees and regulations; ordinances; agreements and resolutions; and other acts and decisions of public authorities.*

3.2.1 The Constitution of the Republic of Ecuador

The Constitution of Ecuador, 2008, in its Article 15, Title II, Chapter Two, "Rights for good living; Healthy environment" states: "*It is prohibited the development, production, possession, commercialization, import, transport, storage and use of chemical, biological and nuclear weapons, highly toxic persistent organic pollutants, agrochemicals internationally prohibited, and technologies and experimental harmful biological agents and* ***genetically modified organisms harmful to human health or undermining food sovereignty or ecosystems*** *as well as the introduction of nuclear and toxic waste into the national territory*".

In Title VI, Chapter Three, on Food Sovereignty, Article 281, paragraphs 8 and 9, establishes the responsibilities of the State *"To ensure the development of scientific research and appropriate measures for technological innovation to ensure food sovereignty"; and, "To regulate, under biosafety standards, the use and development of modern biotechnology and its experimentation, use and commercialization."*

In addition, in Title VII, second chapter on Diversity and Natural Resources, second section, Biodiversity, Article 401, states: "*It is hereby declared that Ecuador is free of transgenic crops and seeds. Exceptionally, and only in case of national interest duly substantiated by the Presidency of the Republic and approved by the National Assembly, genetically modified seeds and crops may be introduced. The State shall regulate under strict biosafety standards, the use and development of modern biotechnology and its products as well as their experimentation, use and commercialization. The application of risky or experimental biotechnologies is prohibited ".*

3.2.2 Organic Law on Food Sovereignty

The Organic Law on Food Sovereignty was published in Official Gazette No. 349 of December 27, 2010. In Chapter IV on Health and Food Safety, it establishes in its Article 26 the Regulation of biotechnology and its products: *"It is hereby declared that Ecuador is free of transgenic crops and seeds. Exceptionally and only in case of national interest duly substantiated by the Presidency of the Republic and approved by the National Assembly, genetically modified seeds and crops may be introduced. The State shall regulate under strict biosafety standards, the use and development of modern biotechnology and its products as well as their experimentation, use and commercialization. The application of risky or experimental biotechnologies is prohibited ".*

"Raw materials containing transgenic inputs may only be imported and processed, provided that they meet the requirements of health and safety, and their ability to reproduce is disabled, respecting the precautionary principle, so that they do not represent any harm to human health, food sovereignty and to ecosystems. Processed products based on GMOs will be labeled according to the law regulating consumer protection.

"The laws regulating agricultural biodiversity, biotechnology and the use and commercialization of its products, as well as animal and plant health, will establish mechanisms for food safety and adequate instruments to ensure respect for the rights of nature and the production of safe food by establishing a differential treatment in favor of micro-entrepreneurs, micro-enterprises or micro, small and medium producers. "

3.2.3 Organic Law for Consumer Protection

The Organic Law of Consumer Protection, published in the Official Gazette S. 116 of July 10, 2000, Article 13 states: *"Production and Transgenic. - If products of human or livestock consumption to be marketed have been obtained or improved by transplantation of genes or, in general, genetic manipulation, that fact should be warned on the label of the product, with duly highlighted letters. "*

Article 14. states: *"For the minimum labeling of food, without prejudice to technical standards on this respect, suppliers of food products for human consumption shall obligatorily display on the labeling of products the following information: (literal l) indicating whether it is artificial food, irradiated or genetically modified. "*

3.2.4 Organic Health Law

The Organic Health Law was published in Official Gazette Supplement 423 of December 22, 2006. This Law has 4 articles relating to regulations on products resulting from modern biotechnology.

Literal d) of Article 146 states: *"As regards food, it is prohibited (... ..)*

*"The use of raw materials and products treated with ionizing radiation or that have been **genetically modified** in the preparation of infant formula and baby food; (... ..) ".*

Article 149 states that*: "The development, treatment, processing, production, application, handling, use, storage, transport, distribution, importation, marketing and sale of food for human consumption consisting of or containing genetically modified products, shall be made whenever their food safety and security for consumers and for the environment had been demonstrated to the competent authority, through technical and scientifically advanced studies.*

To fulfill this purpose, the national health authority shall coordinate with corresponding technical public and private agencies."

Article 150 states*: "The donation of foods containing genetically modified products as well as their utilization, use and handling in plans and programs and food aid programs, will be accepted if their safety and security is demonstrated to the national health authority through technical and scientifically advanced procedures.*

To fulfill this purpose, the national health authority shall act in accordance with universal principles of public health and the provisions stipulated in the second paragraph of the preceding article".

Article 151 also states: *"The packaging of products containing genetically modified foods, domestic or imported, must necessarily include on their labels, in a visible and comprehensive manner, the indication of this condition, in addition to other requirements established by the national health authority, in accordance with the law and regulations to be issued for this purpose."*

3.2.5 Coding of Environmental Management Law

The coding of the Environmental Management Law published in the Official Gazette Supplement 418 of September 10, 2004, in its Article 8 states: *"The national environmental authority shall be exercised by the relevant ministry, acting as the governing, coordinating and regulatory body of the Decentralized National Environmental Management System, without prejudice to the competencies within the scope of its powers and in accordance with the laws that regulate them, other State institutions exercise.*

The relevant Ministry will count with technical and administrative agencies for the support, consulting and execution necessary for the implementation of environmental policies, issued by the President of the Republic."

In addition, paragraph l of Article 9 adds: *"It is incumbent on the relevant Ministry (... ..)*

"To regulate, through biosafety standards, the propagation, experimentation, use, commercialization and importation of genetically modified organisms (... ..)"

3.2.6 Unified Text of the Secondary Legislation of the Ministry of Environment

The Unified Text of the Secondary Legislation of the Ministry of Environment was published by Executive Decree No. 3516, Official Register S.E. 2 of March 31, 2003. It is a legal instrument that unifies environmental secondary legislation for a better access to required standards.

3.2.6.1 Creation of the National Biosafety Commission, Executive Decree 3516, 2003

The unified Text consists of nine books and some of them have their corresponding annexes. In Title VII: Biodiversity, Book IV, Article 179 it is stated that *"The National Biosafety Commission is created under the Ministry of Environment of Ecuador, responsible for the proposal of the Biosafety Policy of the country and for giving advice in the establishment of regulations to control activities with Genetically Modified Organisms -GMOs-, their derivatives and products containing them, as well as for their development, introduction, handling, production, distribution, release, propagation, confined use, transportation, storage, culture, export and import"* . And, in Articles 180, 181 and 182, it stipulates the establishment, powers and functions of the National Commission on Biosafety.

3.2.6.2 Ministerial Agreement 013: Establishment of the National Biosafety Commission, functions of the Commission and Technical Secretariat.

Issued in Official Gazette 3rd. S. 425. Published: January 27, 2015, Title VII of Book IV of the Unified Secondary Legislation of the Ministry of Environment Text is reformed and Articles 180, 181 and 182 are replaced, as follows:

Article 1. *To replace the content of Article 180 of Book IV of the Unified Text of Secondary Environmental Legislation of the Ministry of Environment, by the following: National Biosafety Commission, which will be composed of:*

a. The National Environmental Authority, or his delegate, who will preside and have deciding vote;

b. The National Agricultural Authority or his delegate;

c. The National Health Authority or his delegate, and;

d. The National Authority for Higher Education, Science, Technology and Innovation or his delegate.

Article 2. *To replace the content of Article 181 of Book IV of the above referred Text, by the following:*

The Technical Secretariat of the Committee will be in charge of the National Environmental Authority. Each member of the Commission shall designate a member for permanent liaison with the National Environmental Authority.

The National Environmental Authority, in its capacity and as technical body and Secretary of the Commission, shall be responsible for the following functions:

a. Tracking and monitoring of the articulated execution of entities involved in the field of biosafety;

b. To submit, to the National Biosafety Commission, a report from the ad hoc group of experts and a copy of file for their pronouncing.

c. To receive and coordinate plans, programs, projects and other activities necessary for the proper management in the field of biosafety, and put them for consideration by the Commission;

d. To inform the Commission of the development of coordinating, monitoring and technical support activities in the field of biosafety for genetically modified organisms;

e. To establish and maintain permanent records of information for the normal and efficient functioning of the National Commission on Biosafety;

f. To prepare internal regulations of the Commission; and,

Any other incumbent actions on the matter and those that may be assigned by the Commission.

Article 3. - *To replace the content of Article 182 of Book IV of the above referred Text, by the following:*

Main functions and faculties of the National Biosafety Commission are as follows:

a. To propose a National Policy on Biosafety;

b. To propose a national biosafety agenda for genetically modified organisms;

c. To propose plans, projects and other activities necessary for the proper management in the field of Biosafety;

d. To propose and negotiate with competent organizations the approval of regulations related to GMOs, their derivatives and products containing them;

e. To approve internal regulations of the National Commission on Biosafety;

f. To propose, to the national environmental authority, the granting or rejection of authorizations, according to the case, for activities with GMOs, their derivatives and products containing them, as well as for the development, introduction, handling, production, distribution, release, propagation, contained use, transportation, storage, culture, export or import, based on the technical report from the National Commission;

g. To supervise all assessment procedures, risk management and control mechanisms, monitoring of activities with GMOs, their derivatives and products containing them, which are carried out as provided in the regulations or permits issued;

h. To report, to the National Environmental Authority, all cases showing an express breach of biosafety regulations for GMOs, their derivatives and products containing them, that have been verified, and may constitute a threat to human health, to the environment and biological diversity and negotiate their recall with corresponding authority;

i. To convene professionals from public institutions, researchers and academic officers to form an ad hoc group of experts for the treatment of specific issues in the Biosafety area;

j. To create and maintain updated records of: biosafety experts, natural or legal persons, public or private national or foreign country engaged in activities with GMOs, their derivatives and products containing them; whether they are produced or brought into the country;

k. Request support, at national or international level, whenever it is required, to perform specific technical activities related to the detection, control and management of GMOs, their derivatives and products;

l. To promote the development of capabilities, especially related to GMOs, their derivatives and products containing them: training, research, technology and infrastructure at national level in coordination with competent entities;

m. Any other incumbent actions on the matter and those that may be assigned by the Commission.

3.2.7 National Environmental Policy

The National Environmental Policy is legal instrument of cross application that is strictly related with the provisions of the Constitution of the Republic of Ecuador, and provides guidelines for specific actions on the issue led by the Environmental Authority. However, many legal frameworks still need to be strengthened to improve their applicability and impact.

Specifically it has Policy VI, Strategy 1: To update and implement effectively the Environmental Legislation, it stipulates that: *"To assess the enactment of different instruments, such as: Coastal and Oceans Law, regulation and enforcement of CITES, procedures application under national regulations framework on biosafety, regulations for the sustainable management of wetlands and moors, regulations for the sustainable forest use of forest ecosystems, regulation for wildlife management and regulations for a cleaner and sustainable production."*

3.2.8 Ecuadorian Technical Regulation RTE INEN 022

By means of Agreement No. 14511, the Ecuadorian Technical Regulation RTE INEN 022 (2r) Labeling of Processed Food Products, Canned and Packaged, was approved and made official with mandatory character, in Official Gazette S. 402 published on December 22, 2014.

Item 5.2 of section 5: Requirements, states*: "For processed foods containing transgenic ingredients in the product, the label should declare in the main panel, in letters properly highlighted and in accordance with the provisions in Annex B of standard NTE INEN 1334-1, "IT CONTAINS TRANSGENIC", as long as the content of GM material exceeds 0.9% in product."* In item 5.3 of same paragraph, it says: *"Whenever genetically modified ingredients are used, the ingredient name must be declared in the ingredient list, followed by the word" TRANSGENIC" as long as the content of GM material exceeds 0.9 % in product."*

And, item 5.4 of paragraph 5, states: *"For purposes of traceability the manufacturer must request the provider to declare whether the ingredient is transgenic or not."*

3.2.9 Substitute Health Regulation for Labelling of Processed Foods for Human Consumption

Substitute Health Regulation for Labelling of Processed Foods for Human Consumption, was published in the Official Gazette 2nd. S 318 published on 25 August 2014. It establishes, in Chapter V, Transgenic, Article 22: *"As described in the Ecuadorian Technical Regulation RTE INEN 022, in force, on Labeling of Processed Foods, Canned and Packed foodstuffs, all processed foods for human consumption that present transgenic in their composition, should include in their labelling the following phrase: "TRANSGENIC CONTAINED".*

3.2.10 Bylaw of the Regulation for agricultural organic production in Ecuador

The Bylaw of the Regulation for Agricultural Organic Production in Ecuador was published under Agreement No. 302, Official Gazette 384, on October 25, 2006. In paragraph 5 of Article 13 it is stated: Use of seeds, seedlings and propagating material. Chapter IV: Agricultural Organic Production, establishes that *"Seeds, seedlings or propagating material produced from genetically modified crops (GMOs) are not permitted."*

Article 64, Chapter V: Processing, states*: "All finished product marketed as organic, must contain all the ingredients of agricultural origin, produced, imported or obtained in accordance with current regulation. Notwithstanding, they can be used within the maximum limit of 5 % by weight of ingredients, products of agricultural origin that do not meet the requirements of*

this regulation, provided that their use is essential and that they are non-genetically modified organisms (GMOs) or derivatives, and that the same are not produced by organic systems."

3.2.11 Instructional for General Regulations to Promote and Regulate Organic - Ecological – Biological Production in Ecuador

The General Regulations to promote and regulate the Organic-Ecological-Biological Production in Ecuador, issued through Ministerial Agreement No. 299 was published in Official Gazette No. 34 of July 11, 2013; it regulates and controls actors involved in the organic production chain in Ecuador.

Article 7 states: Of the prohibition of genetically modified organisms (GMOs), Chapter III: Organic Production, General Regulations for Production, establishing that:

a) *In organic production, GMOs cannot be used nor products produced from or by GMOs such as food, feed, processing aids, plant protection products, fertilizers, soil conditioners, seeds, seedlings, vegetative propagating material, microorganisms or animals except for those used as veterinary drugs.*

b) *For the purposes of the prohibition of GMOs and products produced from GMOs for food and feed as established in Paragraph a, operators may not rely on the labels accompanying a product or any other accompanying document, as long as they require the vendor to confirm that products supplied have not been produced from or by GMOs in accordance to the model declaration indicated in Annex 10, ensuring the traceability of them.*

c) *For the purposes of the prohibition of GMOs and products produced from or by GMOs for products other than food and feed as established in Paragraph a, operators using non-organic products from these categories and purchasing them from third parties shall require the vendor a confirmation that products supplied have not been produced from or by GMOs in accordance to the model declaration indicated in Annex 10, ensuring the traceability of them.*

Article 88 states: Related to calculation of organic ingredients, Chapter IV: Processing, Transportation, Storage, Commercialization of Organic Products Processing, stipulates that: *"All finished product that is marketed as organic, must contain all the ingredients of agricultural origin, produced, imported or obtained, in accordance with present Instructive. Notwithstanding, they can be used within the maximum limit of 5% by weight of ingredients (weight at processing), products of agricultural origin that do not meet the requirements of present Instructive, unless that its use is necessary and they are not genetically modified organisms (GMOs) or their derivatives, and same are not produced by organic systems."*

In compliance with the Instructive, the Ecuadorian Agency for Agro Quality Assurance (AGROCALIDAD) carries out controls on the content of GMOs in national organic production, by declaring GM-free products for certification and registration of exports.

3.2.12 Other documents of national relevance

3.2.12.1 National Plan for Living Well, 2013-2017

The National Plan for Living Well 2013-2017 was approved at the meeting held on June 24, 2013, by Resolution No. CNP-002-2013. It was prepared by the National Planning and Development Secretariat (SENPLADES) in its capacity of Technical Secretariat of the National Decentralized Participatory Planning System.

The National Plan for Living Well is a practical instrument of the National Government with clear guidelines to create public policies under the administration and public investment during the four years proposed in the Plan. It is the third Plan developed at national level and, it is nourished by the experiences of previous two plans: National Development Plan 2007-2010 and National Plan for Living Well 2009-2013. Plan's structure contains 12 objectives, 83 goals, 111 policies and 1.089 strategic guidelines.

Objective 7. *"To guarantee the rights of nature and to promote regional and global environmental sustainability"*; Policy 7.5: *"To ensure biosafety thereby safeguarding the health of people, of other living beings and of nature"* proposing the following actions:

a. *"To generate biosafety regulations based on a precautionary principle, to address and reduce the risks associated with the presence and use of living modified organisms".*

b. *"To develop and implement a comprehensive national biosafety system for the control of potential hazards and risks in the transfer, handling, release and use of the results of biotechnology".*

c. *"To implement protocols to prevent and manage adverse effects that modern biotechnology may arise in human health, food sovereignty and the conservation and use of biodiversity".*

d. *"To promote research, education, training, coaching and communication on biosafety, biotechnology and genetically modified organisms."*

e. *"To implement measures and safeguards in order to promote the involvement and participation of communities, people and nationalities in the processes that affect their cultures and natural environments as a result of biotechnological manipulation practices."*

3.2.12.2 Intersectoral Plans

With regards to intersectoral Plans, in our country, no intersectoral coordinating plans have been generated for the implementation and execution of a public policy on biosafety, although the Institutional Strategic Plan of the National Secretariat of Planning and Development SENPLADES, 2014-2017 is available, but the management of modern biotechnology and its products has not been included in their strategic and political objectives.

4. INSTITUTIONAL FRAMEWORK

Taking into consideration the provisions related to biosafety in mandatory regulations for the Ecuadorian State, mainly the Constitution of Ecuador, international treaties such as the Convention on Biological Diversity and the Cartagena Protocol on Biosafety. Regulations such as the Organic Health Law, the Organic Law on Consumer Protection, the Organic Law on Food Sovereignty, the Coding of Environmental Management Law, the National Plan for Living Well 2013 - 2017, among others, it is established the competent national authority on biosafety so that the country can count with an institutional framework for biosafety, in order to lead processes of detection, control, monitoring and risk analysis of GMOs. The designation of the member institutions of the National Biosafety Commission (CONABIO) has been established under the current legislation and specifically according to the provisions of the Unified Text of Secondary Environmental Legislation, published by Executive Decree No. 3516, Official Gazette 2 dated March 31, 2003, and through, Ministerial Decree No. 013 signed on January 22, 2015 and published in the Official Gazette No. 245 dated January 27, 2015, whereby creation and functions of this Commission were updated; and, the competence according to institutional mandates of each entity is as follows:

- *Ministry of Environment*: The national environmental authority shall be exercised by the relevant ministry, acting as the governing body, coordinating and regulating the National Decentralized System of Environmental Management, without prejudice to the powers within the scope of its competences and in accordance with regulating laws, exercising other State institutions.

- *Ministry of Agriculture, Livestock, Aquaculture and Fisheries*: It is the governing body of multisector to regulate, norm, facilitate, monitor, and evaluate the management of agricultural, livestock, aquaculture and fisheries production in the country; promoting actions to foster rural development and sustainable growth of production and productivity of sectors, improving the development of producers, particularly represented by family farming, keeping the incentive to productive activities in general.

- *Ministry of Public Health*: To exercise guidance, regulation, planning, coordination, control and management of the Ecuadorian Public Health through governance and surveillance and sanitary control and to guarantee the right to health through the provision of individual care services, disease prevention, health promotion and equality, health governance, research and development of science and technology; articulation of the actors in the system, in order to guarantee the right to health.

- *Secretariat of Higher Education, Science, Technology and Innovation*: To exercise governance of public policy for higher education, science, technology and ancestral knowledge and to manage their implementation, focusing on the strategic development of the country. To coordinate actions between the executive and higher education institutions in the interests of academic, productive and social empowerment.

Under the provisions of previous legislation, the National Biosafety Commission (CONABIO) is responsible for the coordination, formulation and implementation of the National Biosafety Policy in the country. The Commission is composed of four National Competent Authorities (CNAs): the National Environmental Authority, or his delegate, who will preside; the

National Agricultural Authority or his delegate; the National Health Authority or his delegate; and, the National Authority for Higher Education, Science, Technology and Innovation or his delegate, and their assigned agencies.

In the nature of full establishment of the Commission, two operating levels are established: one of political nature, composed of the highest authority or the delegate of the competent institutions[7] and other of technical operational dimension, called the Technical Secretariat, composed of technical delegates from the institutions conforming the Commission. In addition, CONABIO will be supported by a group of advisors *Ad hoc*, who will be local and international technicians and professionals from public, private and academic sectors with expertise in the areas for which support is requested.

A chart describing the institutional framework of the National Biosafety Commission is as follows:

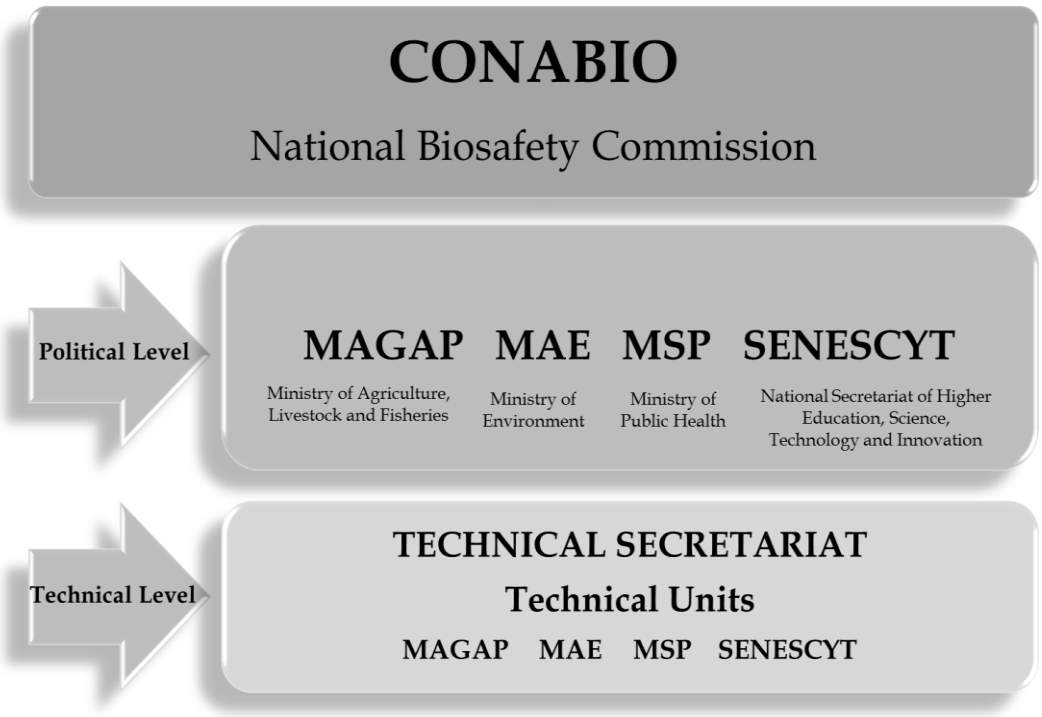

Chart 1. Institutional framework of the National Biosafety Commission.

Once the conformation of CONABIO was completed, its first meeting was convened on May 6, 2015, attended by authorities and decision makers of the four main competent institutions. The meeting was prompted in order to officially establish the formation and actions of the Commission, for this reason, in this first approach it was agreed to develop a regulation for internal functioning of the CONABIO and to proceed with regulatory work required by the country on the subject. Subsequently, and in accordance with what was agreed at the first meeting, the Technical Secretariat in coordination with technical delegates of the competent institutions held six work meetings for the presentation and discussion of the draft document on internal regulations of the Commission. It should be mentioned that the aforementioned document is under approval process.

Communication and coordination between institutions is done through CONABIO and inside of it through working meetings with delegates of each institution. CONABIO decisions are implemented through each of the member institutions.

With regards to institutional arrangements made within functional organic entities related to biosafety, it can be highlighted that MAE currently has a Biosafety Unit with trained personnel on the topic and activities aimed at the implementation of the

[7] Ministry of Environment, Ministry of Agriculture, Livestock and Fisheries, Ministry of Public Health and National Secretariat of Higher Education, Science, Technology and Innovation.

Cartagena Protocol in the country. In Chart 2, a synthesized organizational chart is presented for a better appreciation of the position and link of this Unit within the Ministry. In relation to other competent entities, no organizational structure for GMO biosafety has been reported, except in the case of the establishment of a laboratory for detection of GMOs in AGROCALIDAD, entity under the Ministry of Agriculture.

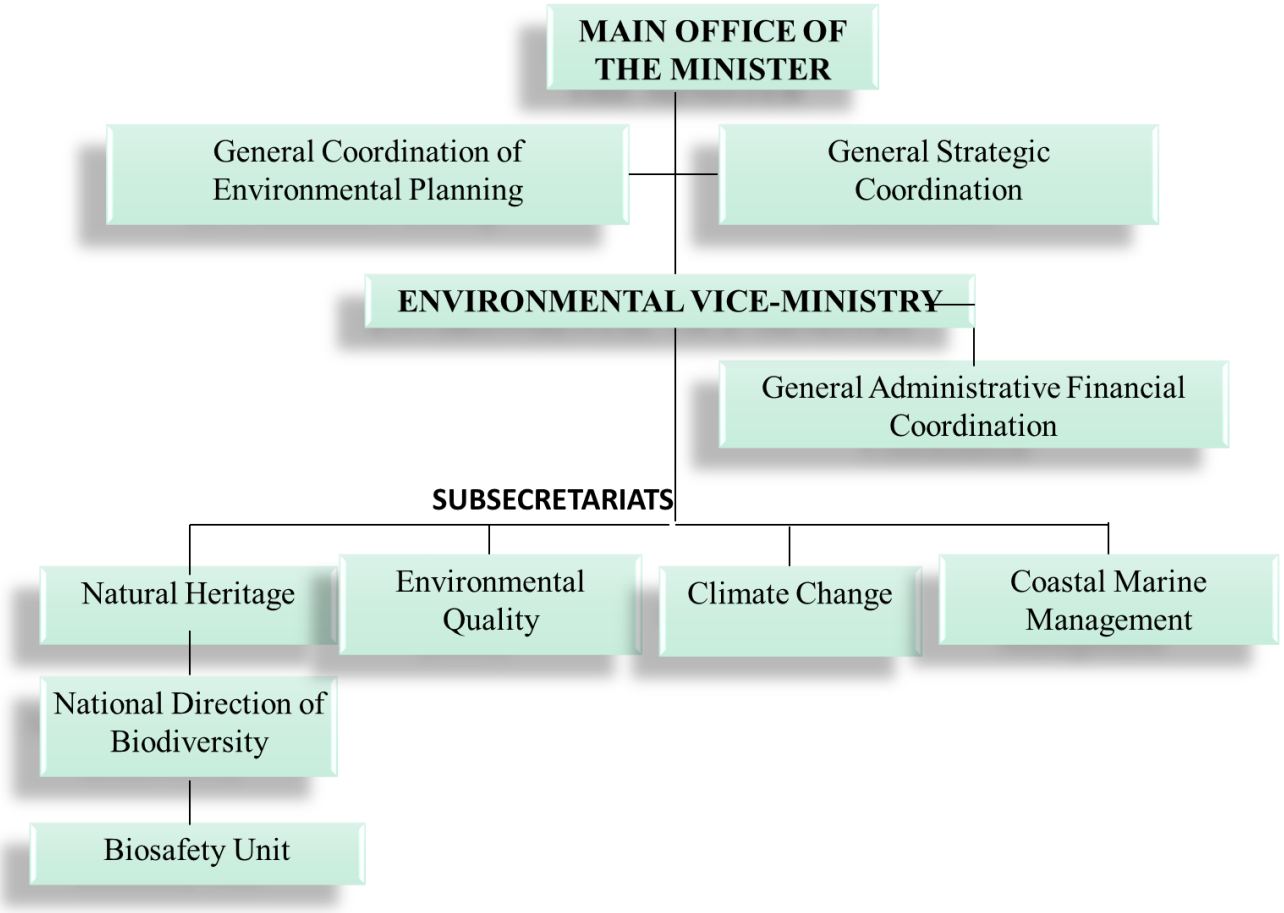

Chart 2. Synthesized Organizational Chart of the Minister of Environment.

With regards to the actions that each member institution of CONABIO has done to contribute to the integration of biosafety in the country, it is through the creation of Policy 7.5 of the National Plan for Living Well, 2013-2017, that was developed with the participation of representatives of the Ministries of Environment, Agriculture, Health, the National Secretariat of Higher Education, Science, Technology and Innovation, and other entities who were part of the Monitoring Committee of the Project "Implementation of National Biosafety Framework".

In relation to intersectoral organizations, the Foreign Trade Committee -COMEX, a collegiate body of intersectoral public nature can be counted on; it is composed of holders or delegates from various institutions, and it is the agency responsible for the regulation of all processes and issues related to foreign trade. However, the issue of biosafety has not yet been considered within this Committee.

5. PROCESSES AND MEASURES IMPLEMENTED FOR THE INCLUSION OF BIOSAFETY IN THE COUNTRY BASED ON THE STRATEGIC PLAN OF PCSB

In accordance with international responsibilities assumed by Ecuador by being a member of the PCSB, several activities have been developed, through the Ministry of Environment as one of the responsible entities for the regulation of biotechnology, in order to support incorporation processes of biosafety in the country, such as: preparation of a regulatory framework on

biosafety, initiatives for decision-making, management measures, creation and reinforcement of capabilities, awareness and access to official information, in coordination with related institutions and under the guidelines established in the Strategic Plan 2011 - 2020 of the Protocol. For the review, assessment and validation of these activities, information from official documents and information generated by the Ministry of Environment was collected; also, three roundtable meetings were scheduled and held in the three major cities (Guayaquil, Loja and Quito) and a national seminar for authorities in the city of Quito.

Roundtable meetings were held with the participation of 69 professionals from different public agencies and representatives of institutions related to the subject of genetically modified organisms (Annex 1). Prior to the execution of events, an assessment matrix was prepared taking as a reference the elements (5 strategic objectives and 78 indicators) established in the Strategic Plan. 80 questions were prepared for the assessment, which were divided according to the subject into three sections: 43 questions were related to *legal and institutional framework*, 15 on *creation of capabilities* and 22 on *awareness and access to official information*, addressing in this way all the issues reflected in the strategic objectives and Plan indicators. In the first instance, matrices were agreed upon and validated through meetings with technical delegates of MAE and IICA, and also with professionals from the National Bureau of Biodiversity of MAE who have experience in the field and, later on, with professionals participating in roundtable meetings (Annex 2).

The national seminar was attended by 43 representatives (authorities and decision makers) of 21 public and private entities, summarized in: The Vice President of the Republic of Ecuador, National Assembly, National Secretaries, Coordinator Ministries, Sectoral Ministries, Agencies of Control, Public Research Institutes, Academy, Autonomous Provincial Governments and representatives of civil society (Annex 3).

For the purpose of this event, a matrix document was prepared, where actions carried out in the country were pointed out as well as future proposals for activities to continue with the implementation processes of the Cartagena Protocol and its Strategic Plan. Actions and proposals were generated and presented according to the five strategic guidelines of Policy 7.5 of the National Plan for Living Well 2011 - 2020. These proposals were agreed and validated with the technical delegates of MAE and IICA, together with professionals from the National Biodiversity Direction of MAE and with the attendees to the national seminar (Annex 4).

Information obtained from the review of documents and the development of participatory events is described in the following sections and, in Annex 5, a photographic record of the execution of those events is presented.

The information obtained from the document review and development of the events of participation are described in the following sections and in Annex 5 a photographic record of the execution of those events occurs.

5.1 Regulatory framework on Biosafety

Section 3: Integration of biosafety into the national legislation; this document describes legal instruments adopted by the country and the progress made in regulations on biosafety, however, in the following points some other issues of equal importance are discussed, which are currently under development or have not yet been officially deliberated.

Legal instruments have been worked and socialized according to the procedures established in the Organic Law of the Legislative Function and with the participation of all institutions and sectors of society that are directly related to each of them. For example, in the specific case of the elaboration process of the Proposal for Organic Law of Agrobiodiversity and Seed, it was led by the Plurinational Conference and Intercultural Food Sovereignty (COPISA), with the participation of 2066 representatives of 553 organizations, highlighting the participation of the Ministry of Agriculture, Livestock, Aquaculture and Fisheries; Coordination of Production; Employment and Competitiveness; Industries and Production. The National Planning Secretariat of State Universities and Polytechnic Schools, Autonomous Governments of Cantons and Provinces, Chambers of Production, Industry and Small Industry, Federation of Livestock of Ecuador, Cattlemen's Association of Guayas and Galapagos, Cattlemen's Association of Highland and Amazon Regions, and the main social, indigenous and countrymen organizations. Each representative basically contributed in the elaboration and revision of articles of the Law according to their fields of competence.

5.1.1 Organic Enviromental Code Project

The Organic Environmental Code Project (COA) was originated with the purpose to create and restructure existing environmental standards, by generating a codified legal document, under cross-criteria systematization, updating, hierarchization and efficient standards.

The Organic Environmental Code Project seeks to systematize and avoid contradictions between the various legal bodies related to environmental issues. As an instrument of the Organic Code, it provides higher hierarchy to the legal issue for its applicability.

COA consists of 280 articles, six general provisions, eight transitional provisions, five reformatory provisions, eight derogations, one final disposition and a glossary of terms. Paragraph 9, Article 5 states: "*The right to live in a healthy environment"* Title II: ON THE RIGHTS, DUTIES, WARRANTIES, LIABILITIES AND PRINCIPLES: *"The use and development of biotechnology and its products as well as their experimentation, use and commercialization under strict biosafety standards, without prejudice to the prohibitions contained in the Constitution and other regulations in force".*

Paragraph 11 of Article 21: Objectives, Title I: Biodiversity, BOOK TWO, NATURAL HERITAGE, states: *"To establish and implement biosecurity measures for the conservation, sustainable use and management of biodiversity and its components."*

And, Paragraph 6, Article 56: Access to Genetic Resources, Chapter VII: GENETIC RESOURCES, states: *"Regulations on biosafety and biotechnology."*

At present, the Organic Environmental Code Project has been submitted to the National Assembly for its First Debate.

5.1.2 Project of Organic Code for the Social Economy of Knowledge, Creativity and Innovation

The Project of Organic Code for the Social Economy of Knowledge, Creativity and Innovation is a regulatory tool that intends to radically modify existing paradigms in the generation, use, development and distribution of knowledge of public interest, through the implementation of legal regulations that would make fair relations viable among various social actors, as well as the conditions for a well-balanced access to benefits in order to achieve the highest possible level of satisfaction of needs and full exercise of the rights of people and nature.

The objective of this Code is as follows: *To regulate the National System of Science, Technology, Innovation and ancestral knowledge, and its articulation mainly to the National System of Education, the Higher Education System and the National System of Culture, in order to create a legal framework in which the social economy of knowledge, creativity and innovation is structured.* This Code consists of 567 articles, 24 general provisions, 20 transitional provisions, 10 reformatory provisions, 4 derogations and 3 final provisions. Article 44 reads: Safety of Scientific Research, Title II: OF THE EXERCISE OF RESPONSIBLE RESEARCH, stating that: *"The Secretariat of Higher Education, Science, Technology and Innovation will be responsible for establishing, through corresponding legal and technical instruments, the principles and regulations aimed at ensuring safety in the processes of scientific research, in order to protect human life and nature."*

At present, the Project of the Organic Code for the Social Economy of Knowledge, Creativity and Innovation has been submitted to the National Assembly for its First Debate.

5.1.3 Proposed Organic Law for Agrobiodiversity and Seed

This proposal for a Law is an essential instrument for national strategic development, at economic, political, social, cultural and environmental levels. Its objective aims *"to regulate the use and conservation of agricultural biodiversity in relation to plant genetic resources for food and agriculture; it also regulates the use, conservation, qualification and free exchange of native seeds; and, the production, certification, commercialization and access to quality seed, through research and development; respecting sumak kawsay."*

The proposal consists of 46 articles, 5 general provisions, 4 transitional provisions and two derogations. In literal b) Very serious infringements, Article 41: Infringements, Chapter II: OF INFRINGEMENTS, it states what a serious infringement will be: *"Commercializing, planting, storing or releasing transgenic seed for food and agriculture without meeting legal requirements ".*

Article 46: Cancellation of the registration, it points out the cause for cancellation of the registration: *"In the event of the introduction into the national territory of transgenic seeds for food and agriculture without complying with legal procedures, they will be forfeited and incinerated, in addition to the cancellation of the registration of importer or responsible for their introduction and this shall be penalized as a very serious infringement".* And, *"public action is granted to denounce the introduction of GM seeds for food and agriculture, according to the law."*

At present, Proposal for the Organic Law is in pre-legislative consultation status.

5.1.4 National Biodiversity strategy 2015 - 2030

The National Biodiversity Strategy and Action Plan for the period 2015-2030 was developed under the framework of the project *"National Biodiversity Planning to support the implementation of the Strategic Plan 2011-2020 of CDB in Ecuador"*. The Strategy is a specific component developed for biodiversity management planning in the period 2015 - 2030, and to contribute to the fulfillment of the obligations that Ecuador has as a signatory country to the Convention on Biological Diversity.

The National Strategy was developed based on several additional planning tools that are mandatory for the country, among which, stands out the Politics and National Biodiversity Strategy 2001-2010, the National Plan for Living Well 2013-2017, the Strategic Plan for Biodiversity 2011-2020 and the Aichi Objectives. And, in order that the country could have a set of measures to guarantee the right to live in a healthy, sustainable, pollution-free environment, and that the rights of nature are duly protected.

The Strategy consists of seven sections or chapters with points of normative reference, strategic framework, policies and goals, national results, monitoring and impact assessment and the Action Plan for the implementation of the National Strategy for the period 2015-2021. With regards to biosafety related to GMOs, Policy 7.5 of the Strategy states: *"To ensure biosafety thereby safeguarding the health of people, of other living beings and of nature"*, from Objective 7 of the National Plan for Living Well 2013- 2017 in Goal 9.5: *"By year 2021, there will be a political, regulatory and technical framework for Biosafety, which promotes sustainable management of systems of agricultural, forestry and forestry production, while reducing any adverse effects for the conservation and sustainable use of biological diversity."* Result 9: *"Ecuador ensures sustainable management of systems of agricultural, agro-forestry and forestry production through the use of technologies and clean energies, ensuring conservation of biodiversity" from* Objective 2: *"To reduce pressure and misuse of biodiversity at levels that ensure their conservation."*

5.1.5 Proposal for Law and Biosafety Regulation

As part of the compliance with Presidential Commitment, titled: "Research on Transgenic - Code 19357" as requested by the Legal Secretariat of the Presidency to the Ministry of Environment, a draft was prepared for a Law and a Regulation on Biosafety for Genetically Modified Organisms. The Proposals for Law and Regulation provide legal support to the integral managing of GMOs biosafety in the country, with guidelines for analysis under a multisectoral and multidisciplinary approach that would allow an effective regulation encouraging research in biosafety and modern biotechnology, contributing to the change of the productive matrix as a development tool, protecting the Ecuadorian State from the risks that GMOs could represent to the environment, biodiversity and human and animal health.

The proposals were developed based on existing legislation and through a participatory work with different actors of public sector, industry and academic circles, linked to the issue. The law applies to all activities related to GMOs within the entire national territory, in order to: *"Regulate under strict biosafety standards the development, research, testing, introduction, handling, production, distribution, release, dissemination, contained use, internal and cross-border transport, storage, culture, marketing, import, export, utilization of genetically modified organisms GMOs, their products and derivatives, as well as the labeling of food containing GMOs in order to contribute to good living standards or sumak kawsay, protecting human health, animal and plant health, environment wild biodiversity, domesticated and/or cultivated, and promoting the development of research, science and technology, applying the principles established in the Constitution and, in national and international regulations. "*

The proposal of law consists of 34 articles, 2 transitional provisions and 1 final provision, and the Regulation has 63 articles, 3 transitory provisions, 6 final provisions and 9 annexes. These proposals have not yet been formalized, at the moment they are at the Legal Secretariat of the Presidency for their respective process and analysis.

The Proposal for Biosecurity Law and its Regulations encourages the operation of CONABIO in the first instance and subsequently it proposes the establishment of a framework for the operation and implementation of an interinstitutional mechanism for permanent coordination between National Authorities responsible for activities related to GMOs. Moreover, within its articles, the performance of a risk analysis has been considered, which is a technical instrument requiring multisectoral and multidisciplinary participation in decision-making in the field of GMOs.

The proposals were developed based on existing legislation and through a participatory work, through meetings and socialization workshops with technical and legal representatives of institutions such as the Coordinator Ministry of Strategic Sectors (MICSE), the Coordinator Ministry of Knowledge and Human Talent (MCCTH), the Coordinator Ministry of Social

Development (MCDS), the Coordinator Ministry of Production, Employment and Competitiveness (MCPEC), the National Secretariat of Planning and Development (SENPLADES), the National Secretariat of Higher Education, Science , Technology and Innovation (SENESCYT), the National Secretariat of Policies Management (SNGP), the Ministry of Industry and Productivity (MIPRO), the Ministry of Public Health (MOH), the Ministry of Foreign Affairs and Human Mobility (MREMH), the Ministry of Agriculture, Livestock, Aquaculture and Fisheries (MAGAP), the Ministry of Environment (MAE), the National Agency for Regulation and Health Surveillance (ARCSA), the Ecuadorian Agency for Agro Quality Assurance (AGROCALIDAD), the National Institute of Public Health Research (INSPI), the National Institute of Agricultural Research (INIAP), the Ecuadorian Accreditation Service (SAE), the Inter-American Institute for Cooperation on Agriculture (IICA), the University of San Francisco of Quito (USFQ), the University of the Armed Forces (ESPE), the University of the Americas (UDLA) and the German Technical Cooperation (GIZ - GESOREN).

5.1.6 Policies and Decennial Action Plan on Biosafety

In 2011, as part of the execution of the project Implementation of National Biosafety Framework led by the Ministry of Environment, the following consultancy was carried out: "Development of Policies and Ten-Year Plan on Biosafety", being its main objective to count on a proposed policy on biosafety for the management of GMOs with an action plan for a period of 10 years; both consultancies were developed based on the principles of the Ecuadorian Constitution and the Cartagena Protocol on biosafety.

The Decennial Plan consisted of eight objectives, each of them with specific goals and activities, aimed at guiding the implementation of the national biosafety framework in the country, respecting the environment, biodiversity, food sovereignty, human and animal health, and the welfare of Ecuadorian people. It must be mentioned that this information served as the basis for the elaboration of the policy contained in the National Plan for Living Well and currently The Plan is the guide for internal work of the Biosafety Unit of the Ministry of Environment also contributing to support the implementation of the Strategic Plan of the Cartagena Protocol in coordination with all institutions related to the topic. However, for the elapsed time and changing scenarios, review and update is required.

5.2 Initiatives for decision-making and biosafety measures

With the purpose to support processes for the establishment of administrative, legal and other national frameworks and other activities related to biotechnology safety, some basic technical information has been generated, aimed at decision makers of relevant bodies on biosafety, including officials that work or are linked to public health, food safety, human and animal consumption, agriculture and environment. Also, guidelines on the use of GMOs, for discussion and also as options available to those responsible, at national level, handling this issue in various contexts. Documents generated on this line were developed as part of the fulfillment of activities of Project for Implementation of the National Framework on Biosafety carried out by the Ministry of Environment.

5.2.1. Manuals of Procedure, methodologies and protocols for detection of genetically modified organisms in crops, food, feed and other living beings

These information was generated in 2012, as part of a consulting work, with the purpose of preparing manuals of procedures, methodologies and protocols, necessary for the detection of GMOs in crops, food and products in bulk for food industry as well as to determine whether a living organism (animals, microorganisms) is GMO or not, both at the laboratory and at the field. The idea was to make basic information available for the implementation of a methodology duly validated by designated referential national laboratories and to comply with the provisions of the Constitution, being the State the regulator entity that regulate, under strict biosafety standards, the use and development of modern biotechnology and its products as well as their experimentation, use and commercialization.

5.2.2 Proposed guidelines for decision-makers regarding risk analysis for the use of genetically modified organisms

Proposed guidelines for decision-makers regarding the analysis of risks in the use of GMOs was developed based on secondary information obtained in international legal instruments and also technical documents of research with biotechnology, GMOs and biosafety, as part of the activities undertaken within Component 2 of Project on Implementation of the National Framework on Biosafety: Implementation of a complete functional system for decision-making and control of GMOs.

This technical document has been elaborated to support decision making, control of GMOs and to promote process of discussion and analysis on the issue and to make it available to the scientific community and relevant entities in biosafety, basic documents

that will facilitate a better understanding and comprehension of the subject and sustain the guidelines that the Ecuadorian State should consider in the assessment and risk management of GMOs. It is important to mention that proposal has been reviewed and approved by international experts and relevant authorities of the Ministry of Environment.

5.2.3 Study of key socio-economic considerations for assessing and managing risks prior to the use of genetically modified organisms

The study of socio-economic considerations was carried out under a consultancy executed in the period October 2013-January 2014. The overall objective of this study was to determine those factors that could become key elements to analyze the potential advantages and disadvantages in social, cultural and economic levels that the probable use of GMOs may have in small, medium and large producers in the country, compared to other technology alternatives and their implications for national food sovereignty, taking as a reference an assessment carried out in 4 representative crops.

The work basically consisted of a socio-economic study of production chains of 4 representative crops (banana, corn, potato and soybean) and the analysis of potential risks that these crops would have in the likely event of use of GMOs in our country. In addition, to mark the beginning of a series of dialogues among relevant institutions on Biosafety in relation to the various socio-economic considerations to be taken into account before a possible release of GMOs in the country.

5.3 Strategic actions to create capabilities

In Article 22 of the Cartagena Protocol, the topic of creation of capabilities is contemplated and valued since the issue of GMOs is of important complexity, technically and scientifically, and requires Parties to cooperate in the development and/or strengthening of human resources and institutional capabilities in the biosafety field, towards an effective implementation of the Protocol and, taking into account the needs of Parties. For the fulfillment of this provision, at the first meeting of the Parties in 2004, an Action Plan for Creation of Capabilities was adopted for the implementation of the Protocol, also the preparation of a new document to replace the current Plan was recommended, which should contain two components[8]: one to be used as a reference tool and guidance, and another consisting of prioritized actions, expected results of goals/objectives and a limited set of indicators aligned with the Strategic Plan for the Protocol, for the period 2011-2020.

Under this context, several initiatives have been developed in the country on the subject, taking as reference the Work Programme on Awareness, Education and Public Participation on Safe Transfer, Handling and Use of Living Modified Organisms 2011-2015 and the Strategic Plan of the Protocol. Accordingly, an important database is currently available of professionals that have been trained in events carried out for the creation and reinforcement of capabilities within political, technical and legal ambits, as part of the compliance of activities executed by the Ministry of Environment through the Project "Implementation of National Biosafety Framework".

The most relevant result of training processes executed in the country is the strengthening of the Biosafety Unit of the Ministry of Environment, which has trained professionals in the field, service detection of GMOs in AGROCALIDAD laboratories for raw materials (corn and soybean) and in ESPOL for processed products. In the same way, it is considered that the creation and establishment of CONABIO is the result of the training received on the subject.

Country's participation at international summoning for access to resources for biosafety projects is the result of the training conducted, as well as the establishment of strategic alliances with national and international entities.

5.3.1 Quinquennial Plan for training

The five-year training plan is a document generated for education and training in the regulation, management and safe use of GMOs (biosafety) for the period 2012 - 2017. This Plan is designed on the basis of most important elements that can contribute to promote a culture on biosafety in the country and also to meet the needs of knowledge and most relevant skills to achieve functionality in the national biosafety system that is intended to implement.

This document provides the basis and necessary elements for the preparation of annual training plans and their monitoring as well as suggestions for achieving sustainability of training, funding mechanisms, strategic and learning approaches and, specific actions for each year (2013-2017) with an estimate for training of staff and required funding.

[8] The independent assessment of the Action Plan conducted in late 2011 and early 2012, recommended the development of a new document to replace current action plan and to have two components: i) "framework for creation of capabilities", and ii) "an action plan based on the results"

Based on this Plan and although there is no continuous training programs at long term, 39 training sessions have been carried out in the country, that is, workshops, courses, breakfast meetings, forums and national seminars where approximately 469 workers were trained (technicians and authorities) from National Secretariats, Coordinator Ministries, Sectoral Ministries, Control Agencies, Public Research Institutes, among others.

5.3.2 Study on situation of biotechnology laboratories

This study was developed with the purpose to identify possible reference laboratories for the detection, identification and quantification of GMOs in raw and processed agricultural products in Ecuador. Such identification was made possible through the study and evaluation of biotechnology laboratories in the country, determining aspects of infrastructure, equipment and supplies, capabilities in different areas of biotechnology and human resource considerations.

As a result of the study two potential reference laboratories for GMO detection were identified, both related to public sector; the first one, belonging to AGROCALIDAD, entity attached to the Ministry of Agriculture and, the second one corresponds to ARCSA belonging to the Ministry of Public Health. These institutions have, among their competencies, some relevant aspects for food sovereignty and health issues, topics closely related to the diverse uses of GMOs. Currently, AGROCALIDAD Lab has the capacity to detect GMOs, along with ESPOL's laboratory, since both have gone through important processes for reinforcing its infrastructure and human capacity.

In addition to this study, an important database (National Laboratory System) is available in the condition of laboratories that will be able to detect, identify and quantify GMOs, as established by the Ecuadorian Accreditation Service (SAE).

5.3.3 Establishment of laboratories for detection of genetically modified organisms

In order to perform actions related to the detection of GMOs that may be found or introduced in the country, the MAE, through the Project for Implementation of National Framework on Biosafety, subscribed an agreement for inter-institutional cooperation with AGROCALIDAD and ESPOL (Escuela Superior Politecnica del Litoral), with the purpose that these two institutions, in their role of national reference laboratories, would implement within its portfolio the analysis of grains, seeds and processed foods that are suspected to be or are derived from GMOs.

Under these agreements, two projects were implemented: "Detection of Genetically Modified Organisms in corn and soybeans, domestically produced by PCR real time" with AGROCALIDAD and, "Detection of Genetically Modified Organisms in processed foods" with Center for Biotechnological Research of Ecuador, CIBE: -ESPOL. For the execution of the activities involved in these projects, MAE provided technical and financial support to these institutions through the coordination of different training activities and the delivery of supplies and laboratory reagents. Currently, these two laboratories are still operating with future projects of accreditation for GMO detection.

5.3.4 Creation and strengthening of capabilities for detection and monitoring of genetically modified organisms

During September-October 2014, consulting work was carried out in order to create capabilities and develop an appropriate strategy for the detection and identification of GMOs, including the choice of methodologies and aspects for decision-making processes that will lead to its application in the context of national regulatory framework, under the direction of an international expert.

Work was done with professionals from competent institutions in the detection and monitoring of GMOs, mainly technical staff from AGROCALIDAD, ESPOL, ARCSA and INSPI laboratories. During this process, a training plan in detection and monitoring of GMOs was implemented, manuals and technical reports were developed for the process of creation and reinforcement of capabilities, and, documents generated by the Biosafety Project by MFA were technically reviewed (technical guidelines for assessment, management and risk communication).

The consultancy was the first step towards the achievement of the operating capacity of AGROCALIDAD laboratory for the detection of GMOs in Ecuador. In addition, a contribution to publicize the importance of developing analytical capabilities to support the implementation of a regulatory framework concerning GMOs was done.

5.3.5 Interagency cooperation agreements for training processes

In order to make them viable and to consolidate training processes conducted by MAE, several inter-institutional cooperation agreements were subscribed with institutions counting with professionals with an extensive experience and knowledge on issues of GMOs, that is, a cooperation agreement was subscribed with Universidad San Francisco de Quito (USFQ) for the

execution of three theoretical and practical courses and a national workshop to provide relevant insights of biosafety in agriculture, medicine, industry and environmental; also, with IICA, for conducting courses, workshops and a series of forums on biotechnology and biosafety of GMOs, directed to technical professionals, authorities and decision makers. 158 employees from the National Assembly, National Secretariats, Coordinator Ministries, Sectoral Ministries, Control Agencies, and Public Research Institutes were trained, among others. Workshops were conducted by renowned national and international professionals, experts in the field, who contributed to deepen the topic and to learn about the experiences of neighboring countries that are developing many biotechnology processes under their own regulations and laws.

5.3.6 International cooperation for the creation of capabilities

A communication and technical cooperation network has been developed with institutions and professionals, worldwide, for guidance and support in processes for the reinforcing of technical and legal capabilities in the area of GMOs, taking as a reference those allied countries that count with specific regulations and practices on the subject.

A relationship for technical cooperation has been maintained with Argentina, through the National Agricultural Technology Institute (INTA) and the Ministry of Agriculture, who has been nominated by FAO as a reference center for GMO regulation; with the Brazilian Agricultural Research Corporation (EMBRAPA) and with the National Technical Commission on Biosafety (CTNBio) in Brazil; contact is kept with National Institute of Food and Drug Monitoring (INVIMA) in Colombia, and also with the Colombian Agricultural Institute (ICA); in U.S.A., contact with professionals from the University of Connecticut; in Mexico, with the Inter-secretarial Commission on Biosafety of Genetically Modified Organisms (CIBIOGEM); the University of Belgium and, the Central IICA in Costa Rica and IICA in Ecuador.

5.4 Awareness and access to official information

In accordance with Articles 20 and 23 of the Protocol, each Party shall encourage and facilitate public awareness, education and participation concerning the safety of the use of GMOs, ensuring that awareness and education involve access to official information. Under these parameters, Ecuador has developed some activities towards the compliance of these provisions; however, it is considered that the issue of education and public information on the use of GMOs is still ongoing as it has not yet generated mechanisms or modalities for public participation.

With regards to the issue of awareness and public participation in biosafety of GMOs, a Plan and Communication Strategy were developed, taking as a reference data generated in a study of public perception of GMOs, Biotechnology and Biosafety, which was conducted in 2008 by MAE, in 11 cities, with a total of 3,200 people interviewed of over 18 years of age, whereby it was determined that only 21% of the Ecuadorian population knows about biotechnology, meaning that this issue is unknown for 79% of the population; 81% does not know what biosafety is and 76% does not know what GMOs are.

5.4.1 Plan and communication strategy on biotechnology, genetically modified organisms and biosafety 2013 -2014

With the purpose to inform Ecuadorian citizenship on issues related to biotechnology, biosafety and GMOs, a Plan and Communication Strategy were developed for 2013-2014, based on the results and objectives of the Communication Plan 2007-2008. Main objective of the Plan, under the guidelines of the Strategy, was to generate appropriate conditions that would facilitate and stimulate conceptual knowledge in targeted population, on biotechnology, biosafety and GMOs, in order to promote and strengthen a conscious participation of citizens and avoiding unsubstantiated rejection and extremist positions on the issue.

According to the target group identified, several communicational materials were developed, that is, a triptych on biotechnology, biosafety and GMOs; a radio spot on biotechnology, biosafety and GMOs - 3 basic concepts; elaboration of bulletins on events and news to refer to MAE's website; information guides on biotechnology, GMOs and biosafety - 3 volumes; training workshops for members of the press, one in Quito and one in Guayaquil; 3 fascicles of Comic "Dr. Experiment explains..."; an audiovisual informative and 2 introductory workshops on the topic and its content from the Information Exchange Center on Biosafety (BCH).

In reference to CIIBS, it is an internet website for the exchange of information and experiences about GMOs in the country. CIIBS was established by MAE to provide information to the central portal that is managed by the Secretariat of the Protocol. Ecuador has reported all relevant information that has been generated (assignation of focal points, submission of reports, regulation related to GMOs, Training Plan, among others), but further reinforcement is required in the advertisement of the webpage, its applications and use.

5.5 Analysis of the implementation of the Cartagena Protocol and its Strategic Plan 2011-2020

As it was mentioned in previous sections, Ecuador has undertaken several actions to implement the PCSB, based on the objectives of the Strategic Plan 2011-2020. By virtue of it, an analysis on the implementation of the Plan was made, which was implemented based on the compliance of the 5 strategic objectives and 78 indicators, divided, according to the subject, into three sections: legal and institutional framework, creation of capabilities, awareness and access to official information.

5.5.1 Legal and institutional framework

Within legal and institutional issues, reference is made to the fact whether Ecuador has or not an updated legislation on biosafety and documentation requirements for GMOs intended for direct use or for intentional introduction into the environment. On this respect, the country counts with legal frameworks (Constitution, National Plan for Living Well 2013-2017, Organic Laws, Secondary Laws, National Strategy on Biodiversity, Regulations, among others), in which one or more articles on regulation of biotechnology have been included. However, Ecuador does not yet counts with a law and official regulation on Biosafety nor documentation requirements for GMOs destined for contained use and for intentional introduction into the environment.

In the same way, considering the assignation of national focal points and competent national authorities, to which the country has complied with, since official focal points are available for CBD, PCSB and the appointment of national competent authorities (MAGAP, MAE, MSP and SENESCYT). In reference to decisions for notifications and communications for import and export of GMOs, there is no record of actions on this regard, and, in the same way for issues of assessment and risk management, unintentional releases, GMOs in transit, contained use, unauthorized GMOs, handling, transport and packaging of GMOs.

On the subject of socio-economic considerations, in spite of the national study conducted on *"Key socioeconomic considerations for assessing and managing risks prior to the possible use of GMOs"*, it is considered that the issue should be addressed in more depth. In relation to whether Ecuador has subscribed the Nagoya-Kuala Lumpur Protocol on liability and compensation supplementary to the PCSB, the country has not signed it as yet the corresponding internal procedures for feasibility of subscription have not been done; however, appropriate internal procedures are being carried out to analyze the feasibility or not of subscription.

Within institutional framework, it is made reference to the existence of infrastructure, including laboratories, since the country has two laboratories for GMO detection in two different institutions, AGROCALIDAD and ESPOL, however, it is considered that these laboratories still require reinforcement and efforts for their accreditation. Finally, on the issue of access to resources, additional funds for training in the handling of BCH-CIISB have been obtained, GEF6 initiative and creation of capabilities.

5.5.2 Creation of Capabilities

With regards to the creation of capabilities, an assessment of needs and mechanisms should be considered for the creation of capabilities in the country. At present, we can count on studies on public perception, study on the status of laboratories and a five-year training plan. No continuous training programs or at a long term are available; however, some training initiatives on biosafety issues have been developed with several courses, workshops, events related to agreements and consultancies executed in the country under cooperation of MFA and several other institutions, national and international, mainly from public and academic sectors.

In relation to the conduction of training events and records of trained people, we can count with approximately 469 officials from National Secretariats, Coordinator Ministries, Sectoral Ministries, Control Agencies, Public Research Institutes, among others, on issues of biotechnology and GMO biosafety. 39 events were held for training. It is reported that Universities (USFQ, ESPE and ESPOL) include, within their curricula, biotechnology, biosafety and programs of fourth level (master studies); however, customs officers have not been trained lately, and no new materials or online training modules have been developed; training on issues of liability and compensation have not been executed, and, training materials and technical guidance are still considered to be insufficient and non-effective.

5.5.3 Raising awareness and accessing to information

On the subject of awareness and access to information, promotion and establishing of compliance activities is still required, since mechanisms to ensure public participation in decision-making regarding GMOs have not yet been developed and public has not been informed on the modalities for participation and/or society's involvement. Even though we can count on a webpage on biosafety and informative guides, brochures, among others, still is necessary to create websites and files for local

research, national resource centers or specific sections in existing local libraries dedicated to educational materials on biotechnology safety.

With regard to informative reports to CIISB, some relevant information has been reported, that is, studies made for assessment of training needs, assignation of focal points, regulation related to biosafety, submission of reports, etc.; however, a reinforcement on webpage diffusion and its usefulness is needed to comply with reports related to user's traffic, participant's online registration for discussions and conferences, users' registration asking for improvements in CIISBH, among others.

5.6 Future Proposals for the implementation of the Cartagena Protocol and its Strategic Plan 2011-2020

Based on the actions taken in the country for the implementation of the Cartagena Protocol and its Strategic Plan and, in order to continue these processes, this section introduces some proposals, possible responsible entities and future activities based on the five strategic guidelines of Policy 7.5 of PNBV and Goal 9.5, result 9 of policy 5 of the National Biodiversity Strategy.

5.6.1 Strategic Guideline 1: To generate biosafety regulations based on a precautionary principle, to address and reduce risks associated with the presence and use of GMOs.

Within this guideline and as shown in Table 1, the proposal and future activities make reference to the generation of specific regulations for biosafety of GMOs, analyzing aspects of involvement of important sectors of civil society (communities, people and nationalities), national secretaries, academic institutions, producers, customs, importers, among others. At the same time, considering identification principles of potential hazards associated with the use of GMOs and processes for evaluation and risk management made, case by case, since nature and required information may vary from one to another, depending on the type of OGM, intended use and likely potential of receiving environment.

Table 1. Proposal and activities for compliance of Strategic Guideline 1 of Policy 7.5 of PNBV within the framework of the implementation of the Cartagena Protocol and its Strategic Plan 2011-2020.

Guideline 1	Proposal	Activities	Responsible
To generate safety regulations based on a precautionary principle, to address and reduce the risks associated with the presence and use of GMOs.	To generate specific and consolidated biosafety regulations, from a complementary interdisciplinary and interinstitutional coordination perspective.	To promote the management and analysis of the Proposal for Biosafety Law and Regulations	Presidency of the Republic and CONABIO
		To update the Proposal for Biosafety Law and Regulations	CONABIO and related entities
		To develop technical standards for: 1. Monitoring and detection of GMOs in field and laboratory 2. Transboundary movement 3. Notifications and requests to approve or reject GMO imports 4. Process assessment and risk management	CONABIO and related entities

5.6.2 Strategic Guideline 2: To develop and implement a comprehensive national biosafety system for controlling potential risks in the transfer, handling, release and use of biotechnology results.

For the creation and implementation of a National Biosafety System, it is important to count with a specific and workable regulatory framework with defined and coordinated institutional capacity, appropriate actions towards creating and

strengthening capacities at all levels and processes for communication and access to official information. In the country, some legal action and institutional measures have been undertaken in order to meet these requirements; the National Biosafety Commission can be counted on, however, that Commission is still functional, therefore, proposal and future activities are aimed at reviving the CONABIO, analyzing aspects of inclusion or process coordination with other entities that are related to the subject.

Table 2. Proposal and activities for compliance with Strategic Guideline 2 of Policy 7.5 of PNBV within the framework of the implementation of the Cartagena Protocol and its Strategic Plan 2011-2020.

Guideline 2	Proposal	Activities	Responsible
To develop and implement a comprehensive national biosafety system for the control of potential hazards and risks in the transfer, handling, release and use of the results of biotechnology	To reactivate the National Commission on Biosafety	To conduct work meetings, convened by the President every three months (regular or special meetings)	President of CONABIO
		To develop a proposed Annual Operating Plan	CONABIO and related entities
		To request official and permanent representatives from member institutions of CONABIO and related entities	President of CONABIO and related entities

5.6.3 Strategic Guideline 3: To implement protocols to prevent and manage adverse effects that modern biotechnology may generate in human health, food sovereignty and the conservation and use of biodiversity.

In this guideline, the proposal is to continue with process of generation of instruments and capability for the monitoring, management and control of GMOs, based on the already developed activities and in terms of those that have not yet been considered (Table 3).

Table 3. Proposal and activities for compliance with the Strategic Guideline 3 of Policy 7.5 of PNBV within the framework of the implementation of the Cartagena Protocol and its Strategic Plan 2011-2020.

Guideline 3	Proposal	Activities	Responsible
To implement protocols to prevent and manage adverse effects that may generate modern biotechnology in human health, food sovereignty and conservation and use of biodiversity. .	To continue with processes for generation of instruments and capabilities for the monitoring, management and control of GMOs	Accredit/certify AGROCALIDAD and ESPOL Laboratories	AGROCALIDAD, ESPOL and CONABIO
		To create a network of laboratories for detection, identification and quantification of GMOs	CONABIO and related entities
		To generate manuals and/or protocols for: 1. Handling and transportation of GMOs 2. Screening and risk assessment	CONABIO and related entities

		3. GMOs' contained use and releases into the environment, provided that they comply with the relevant legal framework.	

5.6.4 Strategic Guideline 4: To encourage research, education, training, coaching and communication on biosafety, biotechnology and GMOs.

For guideline 4, by virtue of the Five Year Plan for Training 2012 -2017, which has been of great importance to the processes already undertaken on this issue, it is believed important to evaluate, update and implement the mentioned Plan with activities that would allow to identify actors that have not yet been trained in the subject, including issues that have not yet been tried in the country and considering the guidance of the toolbox of communication, education and public awareness (CEPA for short English abbreviation) of CBD (Table 5).

Table 4. Proposal and activities for compliance with Strategic Guideline 4 of Policy 7.5 of PNBV within the framework of the implementation of the Cartagena Protocol and its Strategic Plan 2011-2020.

Guideline 4	Proposal	Activities	Responsible
To promote research, education, training, coaching and communication on biosafety, biotechnology and GMOs.	To evaluate, update and implement the Five-Year Training Plan 2012 - 2017	To assess training needs	CONABIO and related entities
		To develop materials and modules for online training on Biosafety	CONABIO and related entities
		To conduct information events and use of the Information Exchange Center on Biosafety, CIISB – Ecuador	CONABIO and related entities

5.6.5 Strategic Guideline 5: To implement measures and safeguards to promote the involvement and participation of communities, people and nationalities in the processes that affect their cultures and natural environments as a result of biotechnological manipulation practices.

The proposal and future activities to promote involvement and participation of communities, people and nations on the issue of GMOs is essential to start with diffusion and training processes to these sectors. For this reason, Table 5 is focused on activities directed to the promotion of these actions based on the updating and implementation of the Plan and Communication Strategy 2013-2014, which within its content, contemplates criteria for identifying actors, tools for appropriate diffusion of each actor, native languages and relevance of its implementation and diffusion.

Table 5. Proposal and activities for compliance with Strategic Guideline 5 of Policy 7.5 of PNBV within the framework of the implementation of the Cartagena Protocol and its Strategic Plan 2011-2020.

Guideline 5	Proposal	Activities	Responsible
To implement measures and safeguards to promote involvement and participation of communities, people and nationalities in the processes that affect their	To update and implement the Plan and Communication Strategy 2013 - 2014	To raise a baseline for knowledge and communication needs on biotechnology, GMOs and biosafety.	CONABIO and related entities
		To identify key stakeholders and different actions to communicate with each of them.	CONABIO and related entities

cultures and natural environments as a result of biotechnology handling practices.		To analyze, define and implement communications strategies based on the Plan and Communication Strategy 2013 - 2014	CONABIO and related entities

6. INVESTMENT SYSTEMATIZATION AND BUDGET ESTIMATES

Activities carried out in the country for the implementation of the Cartagena Protocol and its Strategic Plan 2011-2020 have been developed with financial support from GEF through entities such as PNUMA and SCBD and, at national level, by the Ecuadorian Sate through public institutions involved with this matter. On this regard, important information for budget implementation is available for the period 2010-2015, which is used as the basis for future budget projections. This way, in this section, a systematization of investment and budget estimate is made for the period 2017-2020, so that the country may have referential budgets for actions to support the implementation process of the mentioned Protocol.

Resources used for data analysis were: the Annual Investment Planning (AIP) for period 2011-2015, the Annual Operating Plan (AOP) for the period 2011 -2015 and budget execution reports of the Financial Management System (FMS) for the same period. The referential budget estimate was based on information obtained from said analysis, and the execution was carried out in 2014 as the best year of compliance, with 97%.

6.1 Budget Execution

Data of budget records presented below were revised in the execution of expenditures according to ESIGEF during the period 2011 to 2015, which show the details according to each of the sources 001 and 701.

As shown in Figure 3, for source 001 (Government of Ecuador) in 2011, encoded budget was $33.053, 61 and the executed budget was $30.399,14 being the contract for procurement of technical equipment the most important item. For 2012, encoded budget was $124,311.75 and $83,731.43 was the executed budget and the most representative items were the acquisition of equipment and supplies and salaries for staff contracts. For 2013, encoded budget was $145,000.00 and $111,960.50 was the executed budget and the most representative items were payments made to the contracted team and outstanding payments from previous years. For 2014, encoded budget was $90.531,50 and the executed budget was $90,202.21, being the most representative item the contract of the technical team. Finally, for 2015, encoded budget was $19.813,83 and executed budget was $10.613,96 where most representative items were the contract for hiring of technical team and the purchase of tickets abroad. For greater detail in Annex 6, a record of allocated budget is presented according to the source 001 and its execution during the period 2011-2015.

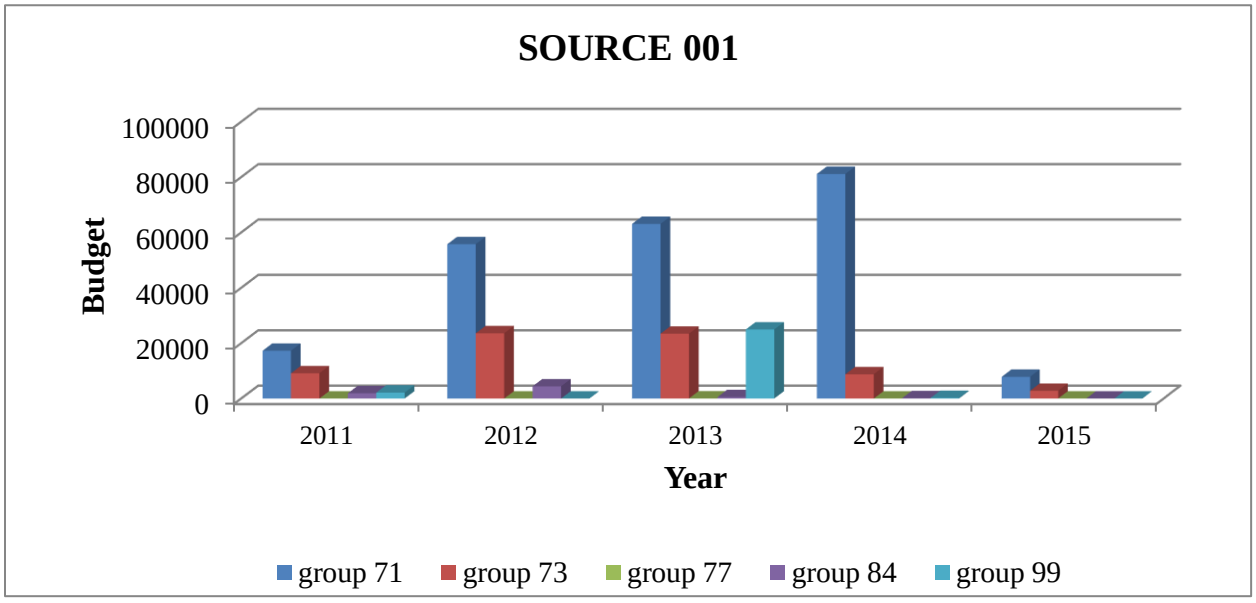

Chart 3: Budget execution, by group of items, carried out in the period 2011-2015 as per source 001**.**

For Source 701 (external donation) during 2011, encoded budget was $ 99.872,00 coded and executed budget was $42,681.67 being the most representative items: consultancy, counseling and specialized research, contracted staff salaries, travel and living expenses abroad; for 2012, encoded budget was $192,826.92 and $ 68,360.26 was the executed budget; for 2013, encoded budget was $386,151.82 and $195,484.46 was the executed budget being the most representative items payment of salaries of staff under contract, advertising services, international tickets and travel allowances; for 2014, encoded budget was $ 175,998.72 and executed budget was $161,922.40, which were distributed mainly in salaries, purchase of laboratory equipment and medical fees. Finally, for 2015 encoded budget was $197,369.21 and executed budget was $74,840.99 aimed at non-financial private sector (Figure 4). Annex 7 also shows records of allocated budget as per source 701 and its execution during the period 2011 to 2015.

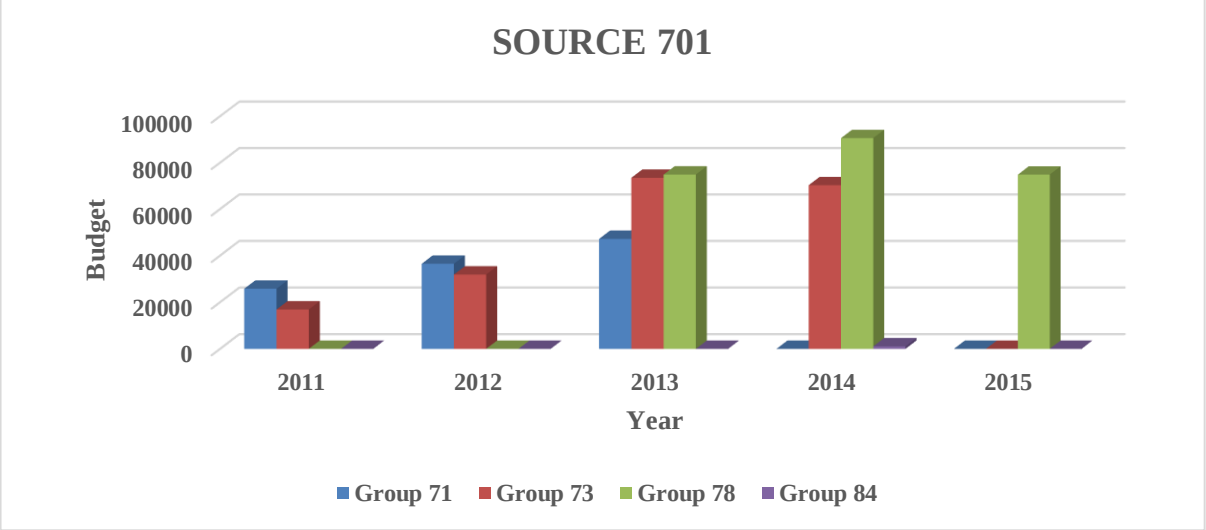

Chart 4. Budget execution, by group of items, carried out in the period 2011 – 2015 as per Source 701.

For a better visual display of the budget execution carried out in the period 2011-2015, according to types of source, Figure 5 is presented as follows:

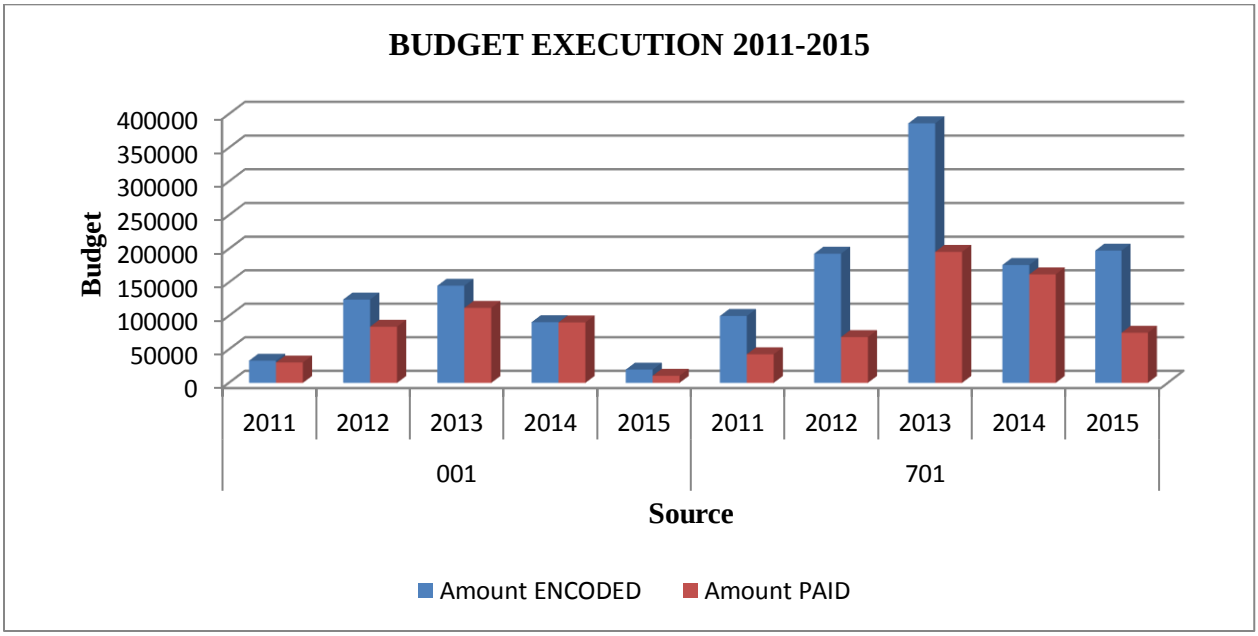

Chart 5. Summary of budget execution for period 2011-2015 as per type of source.

6.2 Projected budget for the period 2017 - 2020

For budget projection of the next four years the execution of budget carried out in the period 2011-2015 was taken as a reference and especially for 2014 as the year of higher compliance (97%); generation processes for regulations, enhancing of human and institutional capabilities, appropriate technical teams for logistics, monitoring and implementation of proposed activities in addition to audits, consultancies and international participation of representatives or their delegates was considered.

Projection was classified by groups of items and amounts were assigned to proposals and future activities that were developed based on the five strategic guidelines of Policy 7.5 of PNBV, which are detailed in Section 5 of this document. It is noteworthy that budget projection presented for the next four years is just an estimate, which must be subsequently revised by CONABIO and all institutions related to the promotion and generation of biosafety policies in the country.

Some budget projections are submitted for the next four years and for each strategic guideline previously established.

6.2.1 Strategic Guideline 1

As for Guideline 1, generating biosafety regulations, Table 6 presents a budget for the next four years amounting $380,400.00, mainly for activities related to consulting services, editing, printing, advertising and publicity, diffusion and training services.

Table 6. Projected budget for the period 2017-2020, based on Strategic Guideline 1 of Policy 7.5 of PNBV

Expense Amount	**Column Title**				
Line Title	**1**	**2**	**3**	**4**	**Total general**
1	**61.500,00**	**87.500,00**	**140.900,00**	**90.500,00**	**380.400,00**
To generate biosafety regulations based on the precautionary principle, to address and reduce risks associated with the presence and use of living modified organisms	**61.500,00**	**87.500,00**	**140.900,00**	**90.500,00**	**380.400,00**

73.02.04 Editing, printing, copying and advertising	25.000,00	40.000,00	55.000,00	55.000,00	175.000,00
73.02.07 Diffusion, information and advertising	5.000,00	16.000,00	4.000,00	4.000,00	29.000,00
73.02.17 Diffusion and information	20.000,00	20.000,00	20.000,00	20.000,00	80.000,00
73.02.18 Advertising and Publicity in Mass Media			50.400,00		50.400,00
73.06.01 Consultancy, counseling and specialized research	9.000,00	9.000,00	9.000,00	9.000,00	36.000,00
73.06.03 Training Services	2.500,00	2.500,00	2.500,00	2.500,00	10.000,00
Total general	**61.500,00**	**87.500,00**	**140.900,00**	**90.500,00**	**380.400,00**

6.2.2 Strategic Guideline 2

For guideline 2, which refers to the development and implementation of a national biosafety system in the country, it is contemplated the same way as for strategic guideline 1 activities related to consulting services, diffusion and information, advertising and training services, with a total amount of $75,000.00 (Table 7).

Table 7. Projected budget for the period 2017-2020, based on the strategic guideline 2 of Policy 7.5 of PNBV

Expense Amount / **Line Title**	**Column Title** 1	2	3	4	**Total general**
2	**16.500,00**	**27.500,00**	**15.500,00**	**15.500,00**	**75.000,00**
To develop and implement a comprehensive national biosafety system for the control of potential hazards and risks in the transfer, handling, release and use of biotechnology results	**16.500,00**	**27.500,00**	**15.500,00**	**15.500,00**	**75.000,00**
73.02.07 Diffusion, information and advertising	5.000,00	16.000,00	4.000,00	4.000,00	29.000,00
73.06.01 Consultancy, counseling and specialized research	9.000,00	9.000,00	9.000,00	9.000,00	36.000,00
73.06.03 Training Services	2.500,00	2.500,00	2.500,00	2.500,00	10.000,00
Total general	**16.500,00**	**27.500,00**	**15.500,00**	**15.500,00**	**75.000,00**

6.2.3 Strategic Guideline 3

For strategic guideline 3, on implementation of protocols to prevent and manage adverse effects that may generate modern Biotechnology on human health, food sovereignty and the conservation and use of biodiversity, for the period 2017-2020, it is contemplated a total amount of $75.000,000, duly distributed in consulting activities, diffusion, information, advertising and training services, as detailed in Table 8.

Table 8. Projected budget for the period 2017-2020, according to strategic guideline 3 of Policy 7.5 of PNBV

Expense Amount	Column Titles				
Line Title	**1**	**2**	**3**	**4**	**Total general**
3	**16.500,00**	**27.500,00**	**15.500,00**	**15.500,00**	**75.000,00**
To implement protocols to prevent and manage adverse effects that modern biotechnology may generate in human health, food sovereignty and the conservation and use of biodiversity	**16.500,00**	**27.500,00**	**15.500,00**	**15.500,00**	**75.000,00**
73.02.07 Diffusion, information and advertising	5.000,00	16.000,00	4.000,00	4.000,00	29.000,00
73.06.01 Consultancy, counseling and specialized research	9.000,00	9.000,00	9.000,00	9.000,00	36.000,00
73.06.03 Training Services	2.500,00	2.500,00	2.500,00	2.500,00	10.000,00
Total general	**16.500,00**	**27.500,00**	**15.500,00**	**15.500,00**	**75.000,00**

6.2.4 Strategic Guideline 4

To promote research, education, training, coaching and communication on biosafety, biotechnology and genetically modified organisms in the country, a total of $75,000.00 is budgeted for activities related to consulting activities, diffusion, information, advertisement and training which are detailed in Table 9 for the next four years.

Table 9. Projected budget for the period 2017-2020, based on strategic guideline 4 of Policy 7.5 of PNBV

Expense Amount	Column Title				
Line Title	**1**	**2**	**3**	**4**	**Total general**
4	**16.500,00**	**27.500,00**	**15.500,00**	**15.500,00**	**75.000,00**
Promote research, education, training, coaching and communication on biosafety, biotechnology and genetically modified organisms	**16.500,00**	**27.500,00**	**15.500,00**	**15.500,00**	**75.000,00**
73.02.07 Diffusion, information and advertising	5.000,00	16.000,00	4.000,00	4.000,00	29.000,00

73.06.01 Consultancy, counseling and specialized research	9.000,00	9.000,00	9.000,00	9.000,00	36.000,00
73.06.03 Training Services	2.500,00	2.500,00	2.500,00	2.500,00	10.000,00
Total general	**16.500,00**	**27.500,00**	**15.500,00**	**15.500,00**	**75.000,00**

6.2.5 Strategic Guideline 5

Guideline for implementing measures and safeguards to promote the involvement and participation of communities, people and nationalities in the processes that affect their cultures and natural environments as a result of biotechnology handling practices; an amount of $75,000.00 is contemplated for activities related to consulting services, diffusion, information, advertising and training services which are detailed in Table 10.

Table 10. Projected budget for the period 2017-2020, according to strategic guideline 5 of Policy 7.5 of PNBV

Expense Amount	**Column Titltes**				
Line Titles	**1**	**2**	**3**	**4**	**Total general**
5	**16.500,00**	**27.500,00**	**15.500,00**	**15.500,00**	**75.000,00**
To implement measures and safeguards to promote the involvement and participation of communities, people and nationalities in the processes that affect their cultures and natural environments as a result of biotechnology handling practices	**16.500,00**	**27.500,00**	**15.500,00**	**15.500,00**	**75.000,00**
73.02.07 Diffusion, information and advertising	5.000,00	16.000,00	4.000,00	4.000,00	29.000,00
73.06.01 Consultancy, counseling and specialized research	9.000,00	9.000,00	9.000,00	9.000,00	36.000,00
73.06.03 Training Services	2.500,00	2.500,00	2.500,00	2.500,00	10.000,00
Total general	**16.500,00**	**27.500,00**	**15.500,00**	**15.500,00**	**75.000,00**

6.2.6 Strategic Guideline 6

According to the experience of budget execution obtained in the period 2011 - 2015, it is considered appropriate to include a sixth guideline, entitled: Lineament of administration and management for the strengthening of the implementation of the Cartagena Protocol and its Strategic Plan based on Policy 7.5 of PNBV, whose function is to cover the activities described in Table 11 and refer to topics related to recruitment services, travel expenses, subsistence, national and international air tickets, purchase of machinery, supplies of short and long duration, among others, with a required budget of $1,175,860.00 for the period 2017-2020.

Table 11. Projected budget for the period 2017-2020, based on the strategic guideline 6 of Policy 7.5 of PNBV

Expense Amount	**Column Titles**

Line Titles	1	2	3	4	Total general
6	**286.315,00**	**327.815,00**	**295.115,00**	**266.615,00**	**1.175.860,00**
Administration and management to reinforce the implementation of the Cartagena Protocol and its Strategic Plan based on Policy 7.5 of PNBV	**286.315,00**	**327.815,00**	**295.115,00**	**266.615,00**	**1.175.860,00**
71.02.03 Thirteenth salary	6.700,00	6.700,00	8.500,00	8.500,00	30.400,00
71.02.04 Fourteenth salary	1.500,00	1.500,00	2.000,00	2.000,00	7.000,00
71.05.07 Fees	2.500,00	2.500,00	4.000,00	4.000,00	13.000,00
71.05.10 Personal services under contract	80.000,00	80.000,00	90.000,00	90.000,00	340.000,00
71.06.01 Employer contribution to S.S.	8.000,00	8.000,00	9.000,00	9.000,00	34.000,00
71.06.01 Reserve Fund	3.000,00	3.000,00	7.000,00	7.000,00	20.000,00
71.06.02 Reserve Fund	5.000,00	5.000,00	5.000,00	5.000,00	20.000,00
71.07.07 Compensation for unused vacations due to termination of contract	4.000,00	7.000,00	7.000,00	7.000,00	25.000,00
73.01.05 TELECOMMUNICATIONS	5.000,00	5.000,00	5.000,00	5.000,00	20.000,00
73.01.06 Post office services	1.000,00	500,00	500,00	500,00	2.500,00
73.02.06 Public and Official Events	3.000,00	3.000,00	3.000,00	3.000,00	12.000,00
73.02.09 CLEANING SERVICES	3.000,00	3.000,00	3.000,00	3.000,00	12.000,00
73.02.10 Nursery services	15.000,00	15.000,00	15.000,00	15.000,00	60.000,00
73.02.35 Feeding services	6.500,00	6.500,00	6.500,00	6.500,00	26.000,00
73.02.99 Other services (Translations)	2.000,00	2.000,00	2.000,00	2.000,00	8.000,00
73.03.01 National air tickets	2.500,00	4.000,00	8.000,00	4.000,00	18.500,00
73.03.02 International air tickets	15.000,00	15.000,00	15.000,00	15.000,00	60.000,00
73.03.03 Local viatical and subsistence allowances	6.500,00	3.500,00	6.500,00	2.500,00	19.000,00
73.03.04 Viatical and subsistence allowances abroad	15.000,00	15.000,00	15.000,00	15.000,00	60.000,00
73.05.02 Buildings, stores and residences	2.000,00	2.000,00	1.500,00	1.500,00	7.000,00
73.06.02 Auditing services	2.000,00	2.000,00	2.000,00	2.000,00	8.000,00
73.06.03 Training services	2.500,00	2.500,00	2.500,00	2.500,00	10.000,00
73.07.02 Rental and Licensing of Computer Software Packages	1.000,00	1.000,00	1.000,00	1.000,00	4.000,00
73.07.04 Maintenance and repair of informatic systems and equipments	800,00	800,00	800,00	800,00	3.200,00
73.08.01 Food and beverages	5.000,00	5.000,00	5.000,00	5.000,00	20.000,00

73.08.04 Office supplies	4.000,00	3.000,00	1.500,00	2.500,00	11.000,00
73.08.05 Cleaning materials	215,00	215,00	215,00	215,00	860,00
73.08.10 Materials for laboratory and medical use	30.000,00	30.000,00	30.000,00	30.000,00	120.000,00
73.08.11 Construction, electrical, plumbing and carpentry materials	500,00	500,00	500,00	500,00	2.000,00
73.08.13 Spare parts and accesories			0,00		0,00
73.08.99 Other goods of use and investment consumption	400,00	400,00	400,00	400,00	1.600,00
73.14.09 Books and collections	1.000,00	1.000,00	1.000,00	1.000,00	4.000,00
77.01.02 General rates	500,00	500,00	500,00	500,00	2.000,00
78.02.04 For private Sector not financial	5.000,00	5.000,00	5.000,00	5.000,00	20.000,00
78.99.01 Assignment to be distributed to Transfers and investment grants	15.000,00		15.000,00		30.000,00
84.01.04 Machinery and equipments – long lasting goods	20.000,00	70.000,00	5.000,00	1.000,00	96.000,00
84.01.06 Tools – goods of use and investment consumption	4.000,00	13.000,00	4.000,00	4.000,00	25.000,00
84.01.07 Equipments, informatic systems and packages	4.700,00	4.700,00	4.700,00	4.700,00	18.800,00
99.01.03 OBLIGATIONS FROM PREVIOUS YEARS FOR OTHER EXPENSES	2.500,00		2.500,00		5.000,00
Total general	**286.315,00**	**327.815,00**	**295.115,00**	**266.615,00**	**1.175.860,00**

Total referential budget did consider continuing with the implementation processes of the Cartagena Protocol and its Strategic Plan for the period 2017-2020 amounting $1'856.260,00, which are being distributed in general items for each year as provided for in each of strategic guidelines (Table 12 and Figure 6 and 7).

Table 12. Referential Budget for the period 2017-2020, based on previously established six strategic Guidelines

Expense Amount	**Column Titles**				
Line Titles	**1**	**2**	**3**	**4**	**Total general**
To implement measures and safeguards to promote involvement and participation of communities, people and nationalities in the processes that affect their cultures and natural environments as a result of biotechnology handling practices	16.500,00	27.500,00	15.500,00	15.500,00	75.000,00
To develop and implement a comprehensive	16.500,00	27.500,00	15.500,00	15.500,00	75.000,00

national biosafety system for the control of potential hazards and risks in the transfer, handling, release and use of the results of biotechnology					
To promote research, education, training, training and communication on biosafety, biotechnology and genetically modified organis	16.500,00	27.500,00	15.500,00	15.500,00	75.000,00
To generate biosafety regulations based on the precautionary principle, to address and reduce the risks associated with the presence and use of living modified organisms	61.500,00	87.500,00	140.900,00	90.500,00	380.400,00
To implement protocols to prevent and manage adverse effects that can generate modern biotechnology in human health, food sovereignty and the conservation and use of biodiversity	16.500,00	27.500,00	15.500,00	15.500,00	75.000,00
Administration and management to reinforce the implementation of the Cartagena Protocol and its strategic plan based on Policy 7.5 of PNBV.	286.315,00	327.815,00	295.115,00	266.615,00	1.175.860,00
Total general	**413.815,00**	**525.315,00**	**498.015,00**	**419.115,00**	**1.856.260,00**

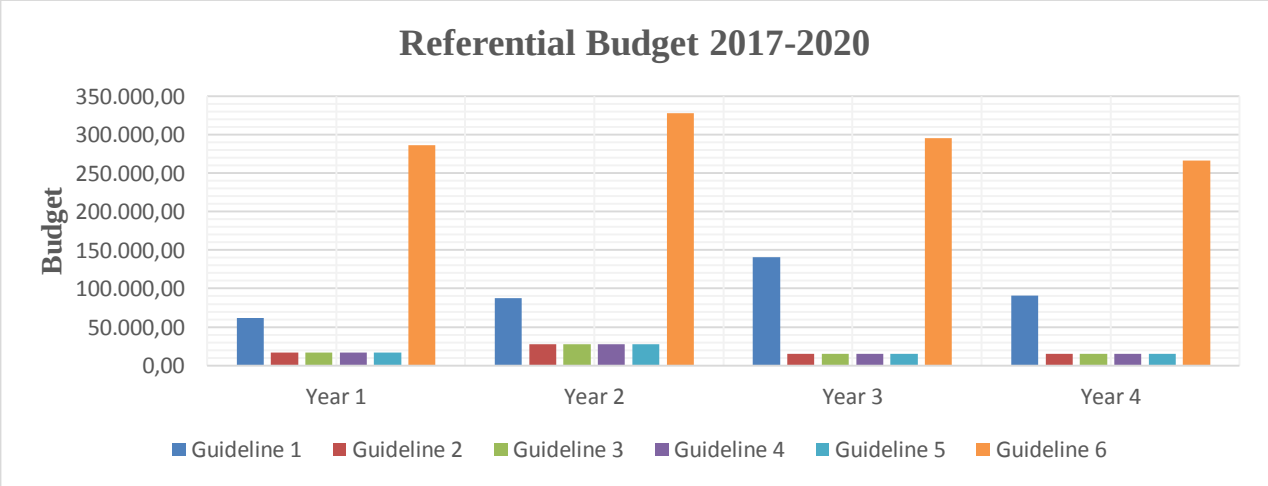

Chart 6. Referential budget for the period 2017-2020, based on previously established six strategic Guidelines.

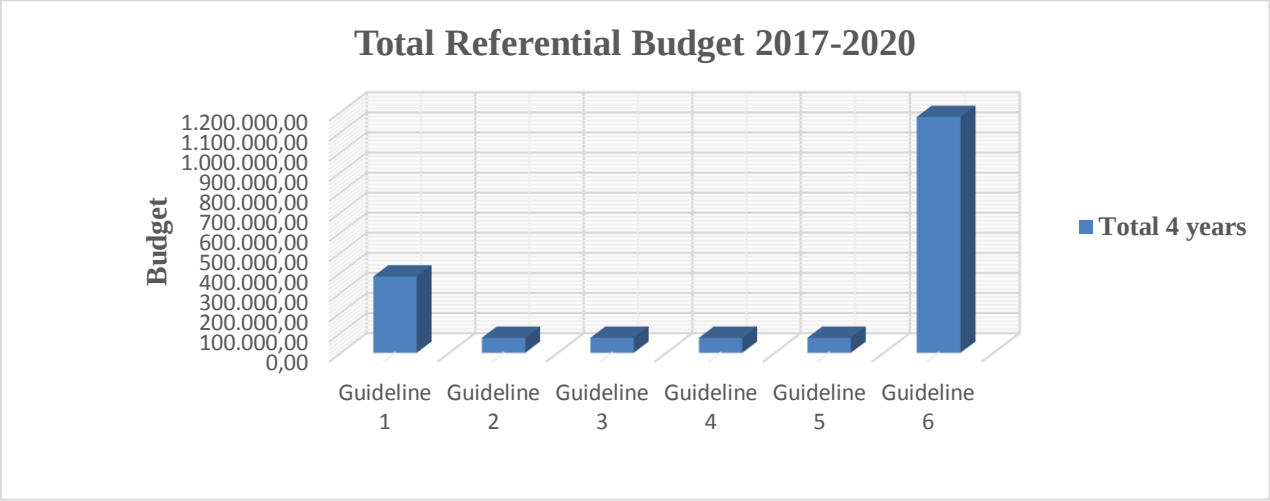

Chart 7. Total referential budget for the period 2017-2020, based on previously established six strategic Guidelines.

For the projection made, distribution, by budgetary allocations, for the next four years has been considered, which are referential or estimates and are subject to changes depending on the budget ceiling that is assigned to each year and the number of entities and/or institutions conforming part of the process. It is also important to emphasize that proposed budget is only a referential expenditure exercise done by the Ministry of Environment and other institutions participating in activities of implementation of the Cartagena Protocol for the period 2011-2015.

In general, it is recommended that estimated budget should be incorporated into the Plan of Action of the National Biodiversity Strategy and other institutional strategies of the country. In addition, it is important to generate a matrix for tracking targets set and achieved (generation of accomplished indicators), to develop a database to include monitoring of processes developed including technical and financial execution and, to perform a matrix of budgetary changes within project's implementation, on a monthly basis.

7. LESSONS LEARNED

Ecuador is in need of a specific regulatory regime for GMOs biosafety that would meet the provisions of the Cartagena Protocol and its Strategic Plan and adapt to local national reality. While there are legal documents related to the subject, which establish some measures for its management, the generation of specific and consensual regulations (Law and Regulations on Biosafety) is still necessary for an integral management of modern biotechnology and its products, thus enabling processes' regulators to have necessary tools for their decision-making.

Modern biotechnology and biosafety related to genetically modified organisms are still sensitive issues in Ecuador, demanding higher education, participation and public awareness, involving all related sectors, including non-governmental organizations, academic sector at all levels, community leaders, consumers, producers and farmers, so that, the country, in this way, will be able to have a clear position on the issue and obtain an active cooperation of these sectors with government and/or decision makers.

Work done by the Ministry of Environment in cooperation with other agencies responsible for biosafety in the country has been of great importance for the promotion and execution of several processes related to the regulation of genetically modified organisms. Therefore, it is necessary to continue with these initiatives, through the development and implementation of standards, administrative procedures, guidelines, manuals and biosafety protocols, based on experiences, at international level, but especially considering national needs.

The country counts with trained professionals in research topics, use, production and regulation of genetically modified organisms, either by the training received as part of the activities developed by the Ministry of Environment or by training received at national and international universities, which should be considered in order to generate scientific and technical information that would enable a substantiated decision-making, meet gaps in the field, guarantee the quality of products

resulting from the application of modern biotechnology, and, to determine real impacts of the use of technology from a social, environmental and economic point of view.

Progress made by the country in the implementation of the Cartagena Protocol have been possible thanks to the investment made by the Ecuadorian Government and international cooperation; however, resources are limited in a developing country like Ecuador and usually prioritized to areas needing greatest attention. It is still necessary to manage and obtain viable resources and to continue with the process of implementing a clear, applicable national system on biosafety that responds to the interests of all sectors involved.

The country still has no Plans or Sectoral Strategies with biosafety issues included or addressed, hence, the importance to build and implement Plans and Strategies involving all relevant sectors related to biosafety of GMOs.

The organization of spaces for discussion, exchange of information and points of view among different actors represent an important role on the processes under its competence, related to the regulation of GMOs, contributing significantly to obtaining additional and validated information for processes of evaluation of the implementation of the Protocol. Thus, in the events held for this study, the participation of 98 professionals and public authorities, private entities and representatives of civil society was taken into account.

8. RECOMMENDATIONS

- For an adequate development of actions that would contribute to the implementation of the Cartagena Protocol in the country, it is necessary to have clear guidelines on research, production and use of genetically modified organisms from public institutions and/or government.
- In reference to Article 401 of the Constitution: *"Ecuador is declared free of transgenic crops and seeds (……)"*. The interpretation of a limitation in the application of biotechnology in the field of genetically modified organisms (GMOs) has prevailed in the country. Discussion and analysis of this issue with all related sectors, including civil society, is still required.
- It is important to have regulations, defined and articulated with existing legal frameworks in order to avoid practices that violate or contradict the existing regulatory framework and deepen their dispersion.
- It is necessary to reactivate and promote the functioning of the National Biosafety Commission (CONABIO), since this will enable, in a better way, all legal and technical processes necessary to improve the handling of GMOs in the country. Nevertheless, if the mentioned commission will not get to be activated, the Ecuadorian Government should find other mechanisms which allow the management of the biosafety.
- It is important to continue developing specific regulations on biosafety (Law and Regulation) from a complementary, interdisciplinary and interagency coordination perspective, for the proper treatment of genetically modified organisms, also determining competencies, establishing appropriate administrative and technical processes, and, avoiding opposed and excessive legislation/regulation.
- To continue education and training processes in topics related to the regulation of genetically modified organisms, establishing further continuous processes and at long-term, directed to a larger number of professionals at government and academic institutions, as well as the inclusion of new players and thematic required in accordance to the needs of the country.
- To organize events open to the public for diffusion of programs on issues related to genetically modified organisms, in order to reinforce the understanding and treatment of the subject, at political and technical levels and directed to society in general.
- To promote education, training, communication and involvement of society in this field, considering the inclusion of actors from basic levels, such as primary and secondary education systems, also taking into account existing programs for environmental education and the toolkit from CEPA.

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10. ANNEXES

Annex 1. *Attendee registration to roundtable meetings held in the cities of Guayaquil, Loja and Quito, on July 15, 18 and 22 of 2016, respectively.*

REGISTRO DE ASISTENCIA MESA REDONDA GUAYAQUIL
Convenio MAE – IICA

Evento: Mesa Redonda sobre Implementación Protocolo de Cartagena **Hora:** 09h00 – 16h00
Fecha: 15 de julio de 2016

LISTA DE PARTICIPANTES

N°	NOMBRE	CARGO	INSTITUCIÓN /ÁREA	CORREO ELECTRÓNICO	TELÉFONOS	FIRMA
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Consultoría "Elaboración de un estudio sobre la implementación del Plan Estratégico 2011-2020 del PCSB en el país; Plan Nacional del Buen Vivir (PNBV) 2013-2017; Estrategia Nacional de Biodiversidad y su Plan de Acción (ENB-PA); y, Protocolo de Nagoya Kuala Lumpur (PNKL) sobre responsabilidad y compensación suplementario al PCSB".

N°	NOMBRE	CARGO	INSTITUCIÓN /ÁREA	CORREO ELECTRÓNICO	TELÉFONOS	FIRMA
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21						
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23						
24						
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26						

MESA REDONDA IMPLEMENTACIÓN DEL PROTOCOLO DE CARTAGENA

Lugar y fecha: Loja, 18 de julio de 2016

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1	Pablo Vivar	MAE - Zona 7	Responsable UCN	pablo.vivar@ambiente.gob.ec	
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MESA REDONDA IMPLEMENTACIÓN DEL PROTOCOLO DE CARTAGENA

Lugar y fecha: QUITO 22/07/2016

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MESA REDONDA IMPLEMENTACIÓN DEL PROTOCOLO DE CARTAGENA

IICA Oficina del IICA en Ecuador

Lugar y fecha: Quito, 22/07/2016

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Ministerio del Ambiente

MESA REDONDA IMPLEMENTACIÓN DEL PROTOCOLO DE CARTAGENA

IICA Oficina del IICA en Ecuador

Lugar y fecha: Quito, 22/07/2016

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Annex 2. *Matrix analyzed and validated in three roundtable meetings held in the cities of Guayaquil, Loja and Quito, on July 15, 18 and 22 of 2016, respectively.*

ELEMENTS OF THE STRATEGIC PLAN FOR THE CARTAGENA PROTOCOL ON BIOSAFETY 2011 - 2020							
Strategic objective	*Expected results*	*Operational objectives*	*Results*	*Indicators*	Results at National Level		
					Compliance indicators	*Evaluation*	*Means of verification*
Focal area 1: **To facilitate the establishment and further development of biotechnology safety systems for an efficient application of the Protocol** To establish other necessary instruments and guidance to fully implement the Protocol	Full implementation of the Cartagena Protocol on Biosafety by the Parties Improve performance of the Parties in order to reach general objectives of conservation and sustainable use of biological diversity	1.1 National Biosafety framework Allow all Parties to establish national safety frameworks on biotechnology for the application of the Protocol	• Decisions regarding the safety of a living modified organism are based on well-established regulatory and administrative regulations, in line with the Protocol. • The issues related to Biosafety and application of the Protocol on Biosafety are integrated into sectors - Pertinent	• Number of Parties, particularly centers of origin, whose national legislation on Biosafety and implementation of guidelines is still in effect but not later than 6 years after adhesion to the Protocol and ratification of same.	¿Has Ecuador, as center of origin of species, a legislation on biotechnology and application guidelines currently in force?	Yes X Partially No	Legal frameworks are available (Constitution, Organic Health Law, Organic Law on Food Sovereignty, Codification of the Environmental Management Act, National Plan for Living Well, National Strategy Biodiversity, etc. among others) which have included one or more regulations on biotechnology. However, Ecuador does not yet have an official biosafety law and regulation on biotechnology safety.
				• Percentage of Parties that have established administrative regulations and procedures for handling notifications and requests for approval of import of living modified organisms intended for direct use as food or feed or for processing; confined use and introduction into the environment	¿ Does the country have established regulations and administrative procedures for handling notifications and requests for approval of import of LMOs intended for direct use as food or feed or for processing; contained use and for introduction into the environment?	Yes Partially X No	• The country does not yet have regulations and procedures to handle notifications and approval requests to import GMOs.
				• Percentage of Parties that have designated national focal points and competent national authorities	¿Has Ecuador designated national focal points and national competent authorities?	X Yes Partially No	Ecuador has notified some national focal points (CDB, CPBS focal points) and national competent authorities (MAGAP, MAE, MSP, SENESCYT)
				• Percentage of Parties that have received notifications in accordance with Article 8 of the Protocol or with relevant national legislation.	¿Have notifications been received from exporting countries or from exporters prior to intentional transboundary movements of an LMO?	Yes Partially X No	• Records of notifications from exporting countries or exporters prior to transboundary movements inside of Ecuador are not available.
				• Percentage of Parties that have adopted important decisions in accordance with Article 10 of the Protocol or with relevant national legislation.	¿Have decisions been taken with respect to communications in response to notifications of LMOs imports?	Yes Partially X No	• No record of communications in response to notifications of LMOs' import is available.
		1.2 Coordination and support. To establish efficient mechanisms to develop safety systems on biotechnology with the necessary support for coordination, financing and supervision	• Better understanding of the capacity-building needs of the Parties that are developing countries and of Parties with economies in transition. • A coherent approach and efficient mechanisms for the creation of capabilities related to the biotechnology safety • Parties count with adequate and predictable financial and technical resources to allow them to comply with their obligations in line with the Protocol in a sustained and integrated manner. • Each of the Parties has established and applied national strategies and action plans related to biotechnology safety. • Existing resources and opportunities are being taken in advantage and are used more often. • Better coordination and cooperation among the Parties and entities that are financing or executing efforts for the creation of capabilities in the biotechnology safety. • Better coordination and cooperation among Parties importing and exporting LMOs.	• Number of Parties that have evaluated their needs for creation of capabilities, including institutional and training needs, which have submitted information to IECB, at the latest 3 years after adhesion to the Protocol or ratification of the same.	¿Have needs for creation of capabilities been evaluated in the country, including institutional training needs?	X Yes Partially No	Evaluation studies have been carried out on the needs of creation of capabilities (public perception study, study on situation of laboratories, five-year training plan)
					¿Has information been submitted to IECB on the needs for creation of capabilities?	Yes Partially X No	No information has been submitted to IECB on the topic.
				• Percentage of Parties that have prepared national action plans for the creation of capabilities on the biotechnology safety for the application of the Protocol.	¿Have national action plans been prepared for the creation of capabilities on biotechnology safety in application of the Protocol?	X Yes Partially No	Action plans, programs and training agreements have been developed (Five-year training plan; Cooperation Agreement MAE - USFQ, MAE IICA, Sponsorship for international training, Consultancy for Creating of Capabilities in BT, OGM, Bs; reversal notes, among others)
				• Percentage of Parties that count with training programs for the personnel who is in charge of issues related to the biotechnology safety and for training, at a long term, of professional staff in biotechnology safety.	¿Has the country training programs for staff in charge of issues related to biosafety and also for long-term training in biosafety for professionals?	Yes X Partially No	Regular and long term training programs are not available; however, some training initiatives in biosafety issues have been developed at different courses, workshops, events related to consulting agreements and implemented in the country under MAE coordination and with the participation of different institutions of public and academic sectors mainly.
				• Percentage of Parties that have established national mechanisms for the coordination of initiatives related to the creation of capabilities on biotechnology safety.	¿Has the country established national coordination mechanisms for initiatives for creation of capabilities in biosafety?	X Yes Partially No	Cooperation agreements with national institutions (USFQ; ESPOL, AGROCALIDAD), Cooperation with international institutions (IICA, CIBOGEM - México, CTNBio - Brasil, MINAGRI – Argentina, INTA Argentina, INVIMA – Colombia, ICA – Colombia, EMBRAPA – Brasil, UCONN/USDA – United States, ENGOV – European Union, University of Belgium.
				• New and additional financial resources obtained for the application of the Protocol.	¿Have new and additional financial resources been obtained for the application of the Protocol?	Yes X Partially No	Additional funding has been obtained for training on issues related to the management of BCH-BCH, GEF6 initiative and creation of capabilities to promote full implementation of CPBS
				• Number of Parties that count with predictable and reliable funding to reinforce their capacity to implement the Protocol.	¿Does Ecuador count with a predictable and reliable financing in order to reinforce its capacity for the implementation of the Protocol ?	Yes X Partially No	Funding was obtained under GEF6 initiative.
				• Number of Parties that have notified that their needs for creation of capabilities have been covered.	¿Are there any notifications informing that the needs for creation of capabilities have been met?	Yes Partially X No	There are no reports on this respect since the needs for creation of capabilities in the country are not considered, with a policy and operational framework for biosafety still under development.
				• Number of cooperation agreements notified involving importing Parties and those that export LMOs.	¿Are there any notified cooperation agreements with countries importing and exporting LOMs?	Yes Partially X No	• No cooperation agreements with countries importing and exporting LMOs have been notified.
		1.3 Risk assessment and management. To further develop and support the implementation of scientific tools on common approaches to risk assessment and risk management for Parties.	• Guidance on risk assessment and risk management, including guidance on new developments in modern biotechnology • Parties and other governments establish and adopt common approaches to risk assessment and risk management, as appropriate. " Guidance for risk assessment and risk management, including guidance on new advances in modern biotechnology. • Parties and other governments establish and adopt common approaches for risk assessment and risk management, as appropriate.	• Percentage of Parties adopting and using guidance documentation on risk assessment and risk management with the purpose of: □ To carry out their own risk assessment and risk management; □ To evaluate risk assessment reports submitted by notifies.	¿Has the country adopted or used guidance documents on risk assessment and risk management which were submitted by notifies for its own assessment?	Yes Partially X No	• Guidance documentation on risk assessment or risk management of LMOs has not been adopted.
				• Percentage of Parties adopting common approaches for risk assessment and risk management	¿Have any common approaches been adopted for risk assessment and risk management?	Yes Partially X No	• No common approaches for risk assessment and risk management of LOMs have been adopted.
				• Percentage of Parties undertaking a real assessment of risk in pursuit of the Protocol.	¿In which country are risk assessments carried out?	Yes Partially X No	• There are no risk assessment nor risk management procedures for LMOs.

ELEMENTS OF THE STRATEGIC PLAN FOR THE CARTAGENA PROTOCOL ON BIOSAFETY 2011 - 2020							
Strategic objective	*Expected results*	*Operational objectives*	*Results*	*Indicators*	**Results at National Level**		
					Compliance indicators	*Evaluation*	*Means of verification*
Focal area 1: **To facilitate the establishment and further development of biotechnology safety systems for an efficient application of the Protocol** To establish other necessary instruments and guidance to fully implement the Protocol	Full implementation of the Cartagena Protocol on Biosafety by the Parties Improve performance of the Parties in order to reach general objectives of conservation and sustainable use of biological diversity	1.4 LOM or features that may have adverse effects To develop modalities of cooperation and guidance in identifying LMOs or specific features that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.	• Modalities developed and put into practice • Parties can identify, evaluate and supervise LMOs or specific features which may have adverse effects.	• Guidance developed by Parties and available on living modified organisms or specific features that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.	The country has developed a guidance on LMOs or specific features that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health?	Yes X Partially No	• A Sanitary Regulation exists for the labelling of products and technical guidelines have been implemented for risk assessment.
				• Number of Parties who have the capacity to identify, evaluate and supervise living modified organisms or specific features that could have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.	¿Has Ecuador the capacity to identify, evaluate and supervise LMOs or specific features that may have adverse effects in the conservation and sustainable use of biologic diversity, taking into account risks for human health ?		Professional staff has been trained in the topic from AGROCALIDAD, INSPI, INIAP, ARCSA Laboratories and ESPOL.
		1.5 Responsibility and compensation Adopt and implement the Nagoya – Kuala Lumpur Protocol on liability and compensation supplementary to the Cartagena Protocol on Biotechnology Safety.	• Each Party adopts administrative and legal measures necessary to implement the Nagoya - Kuala Lumpur Protocol at national level on liability and compensation supplementary to the Cartagena Protocol on Biotechnology safety.	• The Nagoya-Kuala Lumpur on liability and compensation supplementary to the Cartagena Protocol on Biotechnology safety becomes in force prior to the 7th. meeting of the Conference of Parties acting as a meeting of the Parties in the Protocol.	¿Has Ecuador subscribed the Nagoya-Kuala Lumpur Protocol on liability and compensation supplementary to the Cartagena Protocol on Biotechnology Safety prior to the 7th. meeting of the Conference of the Parties acting as the meeting of the Parties in the Protocol?	Yes Partially X No	Ecuador has not subscribed the Nagoya-Kuala Lumpur Protocol on liability and compensation supplementary to the CPBS.
				• Percentage of Parties in the Nagoya-Kuala Lumpur Protocol on liability and compensation supplementary to the Cartagena Protocol on Biotechnology Safety that national administrative and legal frameworks have established including regulations and procedures on liability and compensation for damages derived from living modifies organisms.	¿Has the country established national administrative and legal frameworks including regulations and procedures on liability and compensation for damages derived from LMOs under the framework of the Nagoya-Kuala Lumpur Protocol on liability and compensation supplementary to the CPBS?	Yes Partially X No	Ecuador has not yet subscribed the Nagoya-Kuala Lumpur Protocol on liability and compensation supplementary to the CPBS.
		1.6 Handling, transport, packaging and identification. To enable Parties to implement the requirements of the Protocol and decisions of the COP-MOP regarding the identification and documentation requirements for living modified organisms.	• All shipments of living modified organism intended for direct use such as human or animal food or for its processing, confined use and intentional introduction into the environment are duly identified in the documentation attached to them in conformity with the requirements of the Protocol and the decisions of the COP-MOP. • Technical instruments of easy and reliable use to detect not authorized LMOs have been developed and are available. • Available guidance for the handling, transport and packaging of LMOs has been used.	• Percentage of Parties that have established documentation requirements for LMOs intended for direct use such as human or animal food or for processing	¿Have documentation requirements been established for LMOs intended for direct use such as human or animal food or for its processing?	Yes X Partially No	A regulation for labeling has been implemented (to substitute health regulations for labeling of processed food for human consumption, Official Register 2nd. S 318 published on August 25, 2014) and the Instructive of General Regulations to Promote and Regulate Organic Production - Ecological - Biological in Ecuador.)
				• Percentage of Parties that have established documentation requirements for LMOs intended for confined use and for intentional introduction into the environment.	¿Have documentation requirements been established for LMOs intended for confined use and for intentional introduction into the environment?	Yes Partially X No	• Documentation requirements have not been established for LMOs intended for confined use and for introduction into the environment.
				• Number of Parties with access to instruments capable of detecting not authorized LMOs.	¿Does the country have instruments capable enough to detect not authorized LMOs?	Yes X Partially No	Technical capacities are available in two laboratories within the country for detection of not authorized LMOs; however, administrative instruments are still under development for the monitoring on this field.
				• Number of Parties that are using available guidelines for the handling, transport and packaging of LMOs.	¿Are there any guidelines available for handling, transport and packaging of LMOs being used in the country?	Yes Partially X No	• Guidelines are not used for the handling, transport and packaging of LMOs.
		1.7 Socioeconomic considerations. Based on research and information exchange, provided relevant guidance on socio-economic considerations can be taken into account when making decisions on import of living modified organisms.		• Number of colleagues examining available research used by the Parties which are considering socioeconomic impacts caused by LMOs.	¿Are available researches examined and used when taking into consideration socioeconomic impacts of LMOs?	Yes X Partially No	In spite of a national study on key socioeconomic considerations for the assessment and management of risks prior to the use of LMOs, an evaluation analysis has not been made on this respect by some of the colleagues.
				• Number of Parties sharing their information with regards to socioeconomic considerations.	¿Has the country informed of procedures so that socioeconomic considerations can be taken into account?	Yes Partially X No	No notifications have been made on the topic.
				• Number of Parties notifying their experiences regarding socioeconomic considerations when making a decision on import of LMOs. modified	¿Are there any notifications on experiences made by taking into account socio-economic considerations in decision-making of import of living organisms available?	Yes Partially X No	• No notifications have been made on the topic.
				• Number of Parties that are using guidelines on socioeconomic considerations.	¿Guidelines on socioeconomic considerations are actually used in the country ?	Yes X Partially No	A consultancy has been made on the issue of socioeconomic considerations.
		• Percentage of Parties having procedures available to manage LMOs in transit.	• Parties can manage LMOs in transit • Guidelines have been developed to assist Parties in detecting involuntary release of living modified organisms and to implement procedures in response.	• Percentage of Parties that count with measures to manage LMOs in transit.	¿Does the country count with procedures to manage LOMs in transit?	Yes Partially X No	• No measures have been taken on this respect.
				• Percentage of Parties that count with procedures for confined use.	¿Are there any guidelines for confined use?	Yes Partially X No	• There are no measures available for confined use of LMOs.
				• Percentage of Parties using guidelines to detect involuntary release of living modified organisms which also have appropriate procedures in response.	¿Does the country use guidelines for detecting involuntary releases of LMOs and does it have appropriate procedures in response?	Yes Partially X No	• Guidelines are not used on this respect.

ELEMENTS OF THE STRATEGIC PLAN FOR THE CARTAGENA PROTOCOL ON BIOSAFETY 2011 - 2020

Strategic objective	*Expected results*	*Operational objectives*	*Results*	*Indicators*	**Results at National Level**		
					Compliance indicators	*Evaluation*	*Means of verification*
Focal area 2: **Creation of capabilities** 2. To further develop and reinforce capabilities of Parties in order to implement the Protocol	"Increased safety in transfer, handling and use of living modified organisms. The Parties establish regulatory, administrative, effective and efficient supervisory frameworks to implement the Protocol. The necessary mechanisms are established to enable Parties to carry out risk assessments science-based. Adoption of more transparent and expeditious decisions. Full use of systems for exchange of information".	2.1 National Biosafety Framework. Greater support to the development and implementation of national systems on regulations and administrative issues.	• National biosafety frameworks have been developed and implemented	• Number of Parties with regulation frameworks in force	¿Is there any framework on regulations currently in force?	Yes X Partially No	• Regulations within biosafety framework are available (Constitution, Organic Health Law, Organic Law on Food Sovereignty, Codification of the Environmental Management Act, National Plan for Living Well, National Biodiversity Strategy, among others).
				• Number of Parties with functional administrative arrangements	¿Administrative arrangements have been developed? Are they functional?	Yes X Partially No	A National Biosafety Commission is available which keeps a basic administrative and operational arrangement.
		2.2 Risk assessment and risk management. Empower Parties to evaluate, apply, share and conduct risk assessments and to establish, based on local science, capacities to regulate, manage, monitor and control risks of LMOs.	• Resources are available, including human resources, necessary to evaluate LOMS' risks and administrative mechanisms that have been established • Materials for training and technical guidance have been developed for risk assessment and risk management, which are used by Parties. • Administrative and infrastructure mechanisms have been established for the assessment and management of risks of LMOs, at national, subregional or regional levels.	• Relationship between summary of risk assessment reports and number of decisions on LMOs in the IECB	¿Has information on the relationship between summary reports on risk assessment and the number of decisions taken on LOMs been reported to IECB?	Yes Partially X No	• No information has been reported on this respect.
				• Number of summary risk assessment reports submitted to IECB that comply with the Protocol	¿Are summary reports on risk assessment available at the IECB which comply with the Protocol?	Yes Partially X No	• No summary reports are available.
				• Number of people trained on risk management, as well as in supervision, management and control of LOMs	¿Is there a number of people trained on risk assessment as well as in supervision and control of LMOs?	X Yes Partially No	Approximately 469 employees have been trained (technicians and authorities) of National Secretaries, Coordinator Ministries, Sectorial Ministries, Agencies of Control, public Research Institutes , among others, related to biosafety of genetically modified organisms.
				• Number of Parties that have infrastructure, including laboratories for supervision, management and control of LMOs.	¿An adequate infrastructure, including laboratories for supervision, management and control of LMOs is available?	Yes X Partially No	Support to AGROCALIDAD and ESPOL for the opening of a laboratory for detection of LMOs (reversal notes)
				• Number of Parties that are using developed training materials and technical guidelines.	¿Are training materials developed as well as technical guidelines being used in the country?	Yes X Partially No	Development of protocols for detection of LMOs (reversal notes, consultancies)
				• Number of Parties considering that training materials and technical guidelines are sufficient and effective.	¿In the country, is it considered that training materials and technical guidelines are sufficient and effective?	Yes Partially X No	They are not sufficient, generation of documents with specific guidance and focused on national reality should continue being generated.
		2.3 Handling, transport, packaging and identification. To develop capabilities for the handling, transport, packaging and identification of living modified organisms.	• Customs officers at border sites can apply Protocol requirements related to the handling, transport, packaging and identification of living modified organisms. • Personnel is duly trained and equipped for the testing, detection and identification of LMOs.	• Number of customs officers and laboratory personnel being trained.	¿Have some of Customs officers been trained?	Yes Partially X No	At current, there are no customs officers being trained on the topic.
					¿Have some of laboratory personnel been trained?	X Yes Partially No	Professional staff from AGROCALIDAD, INSPI, INIAP, ARCSA Laboratories and ESPOL have been trained on this topic.
				• Percentage of Parties that have established reliable laboratories for detection or having access to them.	¿Have some reliable laboratories for detection being established in the country or is there access to them?	Yes X Partially No	Support to AGROCALIDAD and ESPOL for the opening of a laboratory for detection of LMOs (reversal notes). I tis considered that these laboratories still require a reinforcement of capabilities to become completely reliable
				• National and regional certified Laboratories, capable of detecting LMOs.	¿Has the country some national and regional certified laboratories capable to detect LMOs?	Yes Partially X No	ESPOL and AGROCALIDAD Laboratories are not accredited.
				• Number of certified laboratories currently operating.	¿Are some certified laboratories operating?	Yes Partially X No	Two of available laboratories (ESPOL and AGROCALIDAD) are not accredited.
		2.4 Liability and compensation. To provide assistance to the Parties subscribed to the Protocol in their efforts to establish and implement regulations and procedures for liability and compensation due to damages resulting from transboundary movements of living modified organisms.	• A mechanism or institutional process has ben identified or established in order to facilitate the implementation of international regulations and procedures on liability and compensation, at local level.	Number of admissible Parties that counted with support for the creation of capabilities under liability and compensation scope related to living modified organisms.	¿Has the country received some support for the creation of capabilities in the field of liability and compensation related to LMOs?	Yes Partially X No	Training on liability and compensation has not been done.
				• Number of national legal and administrative instruments duly identified, amended or recently sanctioned that meet the objective of international regulations and procedures in the field of liability and compensation.	¿Does the country have a number of national legal and administrative instruments duly identified, amended or recently sanctioned that meet the objective of international regulations and procedures in the field of liability and compensation?	Yes Partially X No	• No administrative or legal national instruments are available.
		2.5 Awareness, education and public participation. To improve capabilities, at national, regional and international levels, to facilitate efforts to increase public awareness and promote education and participation regarding safe transfer, handling and use of living modified organisms.	• Parties have access to guidance and training materials on public awareness, education and participation concerning safe transfer, handling and use of LMOs • Parties have the capacity to promote and facilitate awareness, education and public participation concerning biosafety.	• Percentage of Parties that have mechanisms to ensure public participation in decision-making regarding LMOs not later than 6 moths after subscription of the Protocol or ratification of same.	¿Have some mechanisms been developed in the country to ensure public participation in decision-making with respect to LMOs?	Yes Partially X No	No mechanisms have been developed for public participation.
				• Percentage of Parties informing to the public about existing participation modalities.	¿Is public aware/informed about existing participation modalities?	Yes Partially X No	No activities related to the topic are being carried out.
				• Number of Parties with web sites and files with national search capability, national resource centers or sections in existing national libraries dedicated to educational materials on Biotechnology safety.	¿Does the country have websites and files with national search capability, national resource centers or sections in existing national libraries dedicated to educational materials on Biotechnology safety?	Yes X Partially No	Biosafety page, informative guides, brochures are generated in the IMNB Project.
		2.6 Exchange of information. To ensure that all interested key Parties, duly identified, especially those of developing countries and countries with economies in transition, have easy and full access to IECB.	• Increased access to IECB information and to exchange of information through IECB from users of developing countries and countries with economies in transition. • Easy access through IECB instruments to facilitate implementation of the Protocol. • Parties, including public in general, can easily access to IECB information.	• Number of informative reports submitted to IECB from developing countries and countries with economies under transition.	¿Has Ecuador sent information to the IECB?	Yes X Partially No	Some regulatory information has been updated and recently, the third report of the Protocol has been sent.
				• Number of IECB users' traffic from developing countries and countries with economies in transition	¿Is there information available related to IECB users' traffic in the country?	Yes Partially X No	Information on users' traffic is not available.
		2.7 Education and training on biotechnology safety. Education and training in biosafety. To promote education and training of professionals in biosafety through greater coordination and collaboration between academic institutions and relevant organizations.	• Availability of a sustainable group of professionals in biosafety with diverse expertise in national / international level • Better education and training programs in biosafety • Increased exchange of information, training materials and exchange of personnel and students between academic institutions and relevant organizations.	• Number of academic institutions, by region, offering educational courses and programs and training in biotechnology safety.	¿Have country's academic institutions, by region, offered any educational courses and programs for training in biotechnology safety?	Yes X Partially No	National universities have a professorship in biosafety within its curriculum (USFQ, ESPE) and fourth level programs (Masters) at ESPOL
				• Number of materials and training modules available on-line related to biotechnology safety.	¿Have materials and training modules on line in biotechnology safety been developed in the country?	Yes Partially X No	No materials have been developed.

ELEMENTS OF THE STRATEGIC PLAN FOR THE CARTAGENA PROTOCOL ON BIOSAFETY 2011 - 2020

Strategic objective	*Expected results*	*Operational objectives*	*Results*	*Indicators*	**Results at National Level**		
					Compliance indicators	*Evaluation*	*Means of verification*
Focal area 3: Compliance and review To achieve full compliance of Protocol and its efficacy	Parties comply with requirements of Protocol	3.1 Compliance with Protocol. To reinforce mechanisms in order to achieve compliance.	• Each Party fully implements its obligations and regularly monitors the implementation of its obligations under the Protocol • Improved reporting by Parties, including the submission of complete and timely national reports • All Parties can implement their regulatory frameworks and decisions • Sufficient financial resources are allocated to compliance • The Compliance Committee can thoroughly examine the fulfillment of obligations by the Parties and propose appropriate measures • The supportive role of the Compliance Committee is improved	• Number of Parties that have identified and addressed issues related to failures in compliance.	¿Have non-compliance issues been identified and addressed in the country?	Yes Partially X No	No work has been done on this issue
				• Number of Parties that count with legal, administrative measures and others approved and in force for the implementation of the Protocol	¿Does the country have legal and administrative measures as well as others approved and in force for the implementation of the Protocol?	Yes X Partially No	. Availability of legal frameworks (Constitution, Organic Law of Health, Organic Law on Food Sovereignty, Codification of the Environmental Management Act, National Plan for Living Well, National Strategy for Biodiversity, among others) which have included one or more articles for regulation of biotechnology. • The National Commission on Biosafety has been conformed. • However, Ecuador does not yet have an official biosafety law and regulation
				• Percentage of Parties that have designated national focal points	¿Has Ecuador designated all national focal points?	X Yes Partially No	All focal points have been designated (CDB, CPBS)
				• Number of Parties that count with an adequate system to handle requests, even for previous substantiated agreement	¿Does the country have a system for handling requests, even for previous substantiated agreement?	Yes Partially X No	• A system for handling of requests or previous substantiated agreements has not been developed.
				• Percentage of Parties that have published all mandatory information through IECB	¿Is the country publishing all mandatory information through the IECB?	X Yes Partially No	This activity has been duly complied.
				• Number of Parties that count with a system for supervision and implementation of regulations	¿Does the country have a supervision system for implementation of regulations?	Yes Partially X No	There are no systems or related activities in course.
				• Number of Reports received in each cycle of presentation of reports, at national level	¿Has the country complied with submission of national reports as requested?	X Yes Partially No	This requirement has been complied as far as number of reports and due dates is concerned.
		3.2 Evaluation and review. To improve effectiveness of Protocol, including by means of assessment processes and frequent reviews.	• Evaluation and review of Protocol is carried out regularly, including its procedures and annexes • The Protocol, including its procedures and annexes, fits even in the event that new developments in the field of modern biotechnology bring new challenges or it adapt to the challenges of implementation	• Number of Parties capable of having access to financial resources to comply with obligations pursuant to the Protocol.	¿Is the country capable of accessing to financial resources in order to comply with obligations pursuant to the Protocol?	X Yes Partially No	The country has professional capacities for management and access to financial resources.
				• Number of evaluation reports received and published reviews	¿ Are there records of numbers of evaluation reports received and of published reviews in the country?	Yes Partially X No	• No information is available.
				• Number of Parties modifying their national frameworks on biosafety to adjust to the amendments to the Protocol adopted to address new challenges	¿Are national frameworks on biotechnology safety modified, in the country, in order to comply with the amendments to the Protocol adopted to address new challenges?	Yes Partially X No	The country still has no specific legal frameworks available (law and regulation) on biotechnology safety.
Focal area 4: Exchange of information To enhance availability for the exchange of information Pertinent	Transparency in the development and use of LMOs. Increased compliance with national and international requirements. Adoption of substantiated decision-making Increased public awareness of Biotechnology safety	4.1 Efficacy of IECB To increase quantity and quality of information submitted to IECB and obtained from them	• IECB is recognized as the repository of most authoritative information on biosafety • The information sent to IECB is accurate, complete and timely • Increased number of countries send and retrieve information • Risk assessment reports are shared in a timely manner through IECB • Facilitating access to resources and experiences related to biosafety	• Relationship between summary reports of risk assessment and number of decisions taken on LMOs	¿Has the country established a relationship between summary reports of risk assessment and number of decisions taken on LMOs?	Yes Partially X No	• No information is available
				• Number of publications contained in the Information Resource Center on Biosafety (IRCB)	¿Are records of publications kept by the Information Resource Center on Biotechnology safety (IRCB) available?	Yes Partially X No	No information is available
				• Number of users' traffic to IECB	¿Have records on users' traffic been sent to IECB available?	Yes Partially X No	No information is available
				• Number of references to IECB	¿Have records of references been sent to IECB?	Yes Partially X No	This option has not been enabled
				• Number of countries with focal points registered in IECB	¿Has the country registered focal points at the IECB?	X Yes Partially No	Information has been submitted to IECB
		4.2 The IECB as a tool for online discussions and conferences. To establish IECB as a fully functional and effective platform for assisting countries in implementing the Protocol.	• Countries are better equipped with instruments offered through the BCH • The principles of inclusiveness, transparency and equity of IECB are applied consistently BCH • Discussions and negotiation processes related to the Protocol are facilitated through IECB • Increased awareness about IECB in different groups of interested Parties, direct or regional	• Number of countries/regionals that have published laws and/or regulations on biotechnology safety in the IECB	¿Has the country issued some laws and/or regulations on biotechnology safety in the IECB?	X Yes Partially No	Laws related to biotechnology safety have been issued.
				• Number of decisions taken over a national/prior substantiated agreement available through IECB	¿Has the country taken decisions over national/previous substantiated agreements available through IECB?	Yes Partially X No	No decisions have been implemented over the previous substantiated agreement at national level.
				• Number of IECB users requesting improvement in accuracy, completeness and timeliness of information	Does the country have a record of IECB users asking for an accurate, complete and timely information?	Yes Partially X No	No users have been involved in these processes because the country has not worked in depth on the subject, and further strengthening is required for the diffusion of IECB webpage and its usefulness.
				• Number of on-line discussions and real-time conferences made through the IECB platform.	¿Are there records of a number of on-line discussions and real-time conferences made through the IECB platform?	Yes Partially X No	No events have been carried out through on-line platform. Additionally, a reinforcement is required for diffusion of IECB webpage and its usefulness.
				• Percentage of Parties that are participating in on-line discussions and real-time conferences in IECB	¿Has the country participated in on-line discussions and real-time conferences in IECB?	X Yes Partially No	Participation in on-line discussions and real-time conferences has been done.
				• Number of participants in on-line discussions and conferences, considering diversity and background.	¿Is a record of participants in on-line discussions and conferences available, considering its diversity and background?	Yes Partially X No	There is no record of this type of information. In spite of that, it is known that some professionals have participated in on-line discussions and conferences.
				• Number of activities for creation of capabilities intended to increase transparency, inclusion and equity of participation in IECB.	¿Have activities been developed for creation of capabilities aimed at increasing transparency, inclusiveness and equity participation in IECB?	X Yes Partially No	Several workshops and courses, whose thematic aspects were related to IECB have been held. However, it is important to promote and encourage specific courses to improve knowledge and use of IECB.
		4.3 Exchange of information through different instruments of IECB. To increase comprehension through some other mechanisms for exchange of information.	• Exchange of information is increased at regional, national and international meetings on the topic of biologic diversity and biotechnology safety. • Different modalities and opportunities to share information related to biotechnology safety.	• Number of events organized in relation to biotechnology safety.	¿Number of events organized in relation to biotechnology safety?	X Yes Partially No	39 events have been organized (courses, workshops, working breakfasts meetings and national seminars)
				• Number of publications shared on biotechnology safety.	Has the country shared some publications on biotechnology safety?	Yes Partially X No	No shared publications are available.
Focal area 5: Diffusion and cooperation To expand the scope of Protocol and to promote Cooperation	Increased political support for the implementation of the Protocol. Increased support organizations, conventions and initiatives, and collaboration with them, for implementation of the Protocol.	5.1 Ratification of Protocol. To achieve worldwide recognition of the Protocol.	• All Parties included in the Agreement on Biologic Diversity become Parties in the Protocol.	• Percentage of Parties in the Convention on Biological Diversity which have become Parties of the Protocol.	¿Ecuador, as part of the CDB, has ratified its participation in CPBS?	X Yes Partially No	Ecuador ratified its participation in CPBS, in 2003.
		5.2 Cooperation. To enhance international cooperation and collaboration in Biotechnology safety.	• An official relationship is established with Secretariats of other conventions and organizations. • An invitation to the CBD Secretariat is extended as an observer to the Committees MSF and OTC of OMC.	• Number or relationships established with other agreements as reflected in joint activities.	¿Has the country established relationship with other agreements as reflected in joint activities?	X Yes Partially No	Work has been done with the CDB Secretariat

Annex 3. *Registration of attendees to the national seminar for authorities held in the city of Quito, August 11, 2016*

Convenio de cooperación técnica para fortalecer la capacidad del Ecuador en bioseguridad y promover la aplicación integral del Protocolo de Cartagena sobre Seguridad de la Biotecnología y la Convención sobre la Diversidad Biológica a nivel nacional

Seminario Nacional sobre la Implementación del Plan Estratégico 2011-2020 del Protocolo de Cartagena sobre Seguridad de la Biotecnología

Quito, 11 de agosto de 2016

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Seminario Nacional sobre la Implementación del Plan Estratégico 2011-2020 del Protocolo de Cartagena sobre Seguridad de la Biotecnología

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Convenio de cooperación técnica para fortalecer la capacidad del Ecuador en bioseguridad y promover la aplicación integral del Protocolo de Cartagena sobre Seguridad de la Biotecnología y la Convención sobre la Diversidad Biológica a nivel nacional

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Quito, 11 de agosto de 2016

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Annex 4. *Matrix of actions taken and future proposals for the implementation of the Cartagena Protocol on Biosafety and its Strategic Plan.*

ACTIVITIES FOR THE IMPLEMENTATION OF THE CPBS/STRATEGIC PLAN 2011-2020				
Policy 7.5 of Biosafety/PNBV 2013-2017: "To ensure biosafety thereby safeguarding the health of people, other living beings and nature"				
No.	**Strategic Guidelines**	**Accomplishments**	**Proposal**	**Activities**
1	*To generate safety regulations based on the precautionary principle, to address and reduce risks associated with the presence and use of living modified organisms.*	-Constitution of the Republic of Ecuador - Art. 15, 281- Numerals 8 and 9 and 401 - National Plan for Living Well (NPLW), 2013-2017 - Objective 7, Policy 7.5 (5 strategic guidelines) -Organic Law on Food Sovereignty - Art 26. -Organic Law for Defense of Consumer- Art. 13, 14 -Organic Law of Health, Art. 146, 149, 150, 151 -Codification of the Environmental Management Act - Art 8, 9. -Unified Text of the Secondary Legislation of the Ministry of Environment, Art. 179, 180, 181 and 182 -Ecuadorian Technical Regulation RTE INEN 022 - Item 5.2 of Numeral 5, Item 5.4 of Numeral 5 -Substitute Sanitary Regulations for Processed Food Labeling for Human Consumption - Art 22. -Regulation of the Normative for Agricultural organic production in Ecuador – Art. 13, 64 -Instructions of General Normative to Promote and Regulate Organic - Ecological - Biological Production in Ecuador – Art. 7, 88 **IN PROCESS** - Project of Organic Environmental Code, Art. 5, 21, 56 - Project of Organic Code of Social Economy of Knowledge, Creativity and Innovation, Art. 44, 450 - Proposed Organic Law for Agrobiodiversity and Seed, Art. 46 -National Biodiversity Strategy, 2015 - 2030 - Incorporates Policy 7.5 of NPLW.	To generate specific and consolidated biosafety regulations, from a complementary perspective and interdisciplinary and interinstitutional coordination.	-To promote treatment and analysis of the Proposed Biosafety Law and Regulation - To implement specific technical regulations for issues such as: 1. Monitoring and detection of GMOs in field and laboratory 2. Transboundary movement 3. Notifications and requests to approve or reject GMO imports 4. Process assessment and risk management.
2	*To develop and implement a comprehensive national biosafety system for the control of potential hazards and risks in the transfer, handling, release and use of the results of biotechnology*	-The National Biosafety Commission (CONABIO), is in charge of the coordination, formulation and implementation of National Biosafety Policies, conformed by: Ministry of Agriculture, Aquaculture and Fisheries; Ministry of Public Health; Ministry of Environment and, the National Secretariat of Higher Education, Science, Technology and Innovation, other ascribed and related entities.	-To activate and promote the operation of the National Biosafety Commission (CONABIO)	
3	*To implement protocols to prevent and manage adverse effects that modern biotechnology may generate in human health, food sovereignty and the conservation and use of biodiversity*	- Study on the status of biotechnology laboratories - Important database (National System of Laboratories) - Operating procedures, methodologies and protocols for detection of genetically modified organisms in crops, food, feed and other living things. -Establishment of laboratories for detection of genetically modified organisms – AGROCALIDAD and ESPOL	- To continue with generation processes of instruments and capacity for monitoring, management and control of GMOs.	To promote processes for accreditation/certification of AGROCALIDAD laboratories and ESPOL - To create a network of laboratories for detection, identification and quantification of GMOs, replicating the experience obtained with AGROCALIDAD and ESPOL. To generate procedure manuals and/or protocols for handling, transport, contained use, detection, evaluation and releases of GMOs into the environment, provided that they comply with relevant legal framework.
4	*To promote research, education, training, coaching and communication on biosafety, biotechnology and genetically modified organisms*	- Quinquenal training plan, 2012-2017 39 training events have been held (courses, workshops, seminars, working breakfast meetings, etc.) -Approximately 469 employees of National Secretariats, Coordinator Ministries, Sectoral Ministries, Agencies of Control, Public Research Institutes.	-To evaluate, update and implement Quinquenal Training Plan	- To carry out evaluation studies on training needs -To develop materials and modules for on-line training on biotechnology safety. - To hold events for reinforcing diffusion and usefulness of the Information Exchange Center on Biosafety (IECB).
5	*To implement measures and safeguards to promote the involvement and participation of communities, people and nationalities in the processes that affect their cultures and natural environments as a result of biotechnology handling practices*	- Communication Plan and Strategy on biotechnology, genetically modified organisms and biosafety 2013 -2014	-To update and implement Communication Plan and Strategy	- To build-up a database on knowledge and communication needs on biotechnology, GMOs and biosafety. - To identify key actors and different actions to communicate with each one of them. -To analyze and define communication strategies based on the Plan and the Communication Strategy and considering the relevance of its diffusion and, if it is the case, generate new formats suitable for each actor and/or activity, including the production of informative materials (printed and/or audiovisual).

Annex 5. *Photographic record of events held for socialization and validation of information related to actions taken in the country for the implementation of the Cartagena Protocol on Biotechnology safety and its Strategic Plan.*

Picture 1. Participants to the round table meeting held in the city of Quito on July 22, 2016.

Picture 2. Participants to the round table meeting held in the city of Guayaquil on July 15, 2016.

Picture 3. Participants to the round table meeting held in the city of Loja on July 18, 2016.

Picture 4. Participants to the National Seminar for Authorities held in the city of Quito on August 11, 2016.

Annex 6. ***Record of budget assigned according to source 001 and its execution during the period 2011-2015***

SOURCE	001									
	ColumnTitles									
Line Titles	2011		2012		2013		2014		2015	
	Amount ENCODED	Amount PAID	Amount ENCODED	Amount PAID	Amount ENCODED	Amount PAID	Amount ENCODED	Amount PAID	Amount ENCODED	Amount PAID
Food and beverages	2492	2178,28	5948	5512,94	160,57	160,57	0	0	0	0
Employer contribution to S.S.	1470,77	1421,46	4902,58	4445,9	4692,41	4621,76	5380,21	5380,21	938,32	625,54
RENTAL AND LICENSES FOR USE OF COMPUTER SOFTWARE PACKAGES							83,12	83,12	0	0
Compensation for unused vacations due to contract termination	399,17	0	3985,17	0	2869,33	1154,7	7912,86	7912,86	0	0
Consultancy, counseling and specialized research	0	0	0	0	1800	720	1080	1080	0	0
Fourteenth salary	220	220	1143,67	729,99	1242,91	1082,17	1750,06	1750,06	177	118
Thirteenth salary	649,17	359,07	3985,17	2766,67	4163,5	4138,85	5453,81	5453,81	2395,58	338,16
Diffusion and information	0	0	0	0	2040	1428	0	0	0	0
Informational diffusion and advertisement			1340	1338	0	0	0	0	0	0
Editing, printing, copying and advertising	0	0	12500	28	11470,4	6288	432	381,6	0	0
Buildings, offices and residencies	600	240	2186,8	1591,56	34	19,2	0	0	0	0
ASSIGNMENTS							0	0	0	0
Equipmets, software systems and packages	1805,36	1786,9	5227,45	4395,39	1890	0	127,92	127,92	0	0
Public and official events	0	0	0	0	0	0	0	0	0	0
SUPERVISION AND TECHNICAL INSPECTIONS							0	0	0	0
Reserve Fund	0	0	427,58	427,58	3855,33	3501,56	3999,12	3999,12	809,93	269,98
Fees	0	0	1329,07	1329,07	1336,6	690,2	0	0	0	0
Maintenance and repair of equipments and sofware systems	200	122	0	0	0	0	0	0	0	0
Machinery and Equipments	0	0	0	0	0	0	0	0	0	0
Machineries and equipments	150	104	0	0	500	500	0	0	0	0
Cleaning materials	50	49,91	106,21	95,81	215	211,8	0	0	0	0
Construction, electrical, plumbing and carpentry materials	0	0	0	0	48,83	48,83	0	0	0	0
Office supplies	1639,61	1514,27	1972,42	530,66	500,66	21,42	191,82	187,93	770	749
Materials for laboratory and medical use	0	0	0	0	10800	0	5130	5130	0	0
Financial obligations of previous years for personnel expenses	0	0	0	0	0	0	0	0	0	0
Financial obligations of previous years for other expenses	2140,2	2140,2	0	0	24931,74	24931,74	206,08	206,08	0	0
Other goods of use and investment consumption			854,65	685,11	0	0	0	0	0	0
Other services	2850	2457	0	0	0	0	0	0	0	0
International air tickets	786,7	786,7	0	0	2855	263,76	155,52	155,52	0	0
National air tickets	300	0	4498	4131	2113,53	1482,32	84,28	84,28	3000	1471,28
Publicity and Advertising in Mass Media	0	0	0	0	5400	3780	0	0	0	0
VARIABLE REMUNERATION FOR EFFICIENCY	170	138,84	0	0	0	0	0	0	0	0
Spare parts and accesories	50	35	0	0	0	0	0	0	0	0
Feeding service	0	0	0	0	5896,28	2633,88	0	0	0	0
CLEANING SERVICE	0	0	0	0	0	0	0	0	0	0
Auditing service	0	0	3908	3400	4787,74	3920	660	660	0	0
Nursery services	0	0	1224,4	1224,4	2015	1993,6	465	465	0	0
Training services	0	0	12128,58	0	0	0	0	0	0	0
Post office services	70	7,5	10	0	0	0	0	0	0	0
Personal services under contract	15150	15100,67	50804	46068,8	48626	47893	51911,7	51911,7	9723	6482
SUBROGATION							4713	4713	0	0
General rates	0	0	0	0	15,17	15,16	0	0	0	0
TELECOMMUNICATIONS	120	106,71	0	0	0	0	0	0	0	0
Viatical and subsistence allowance - abroad	1040,63	1040,63	1300	1282,05	0	0	0	0	0	0
Local viatical and subsistence allowance	700	590	4530	3748,5	740	460	795	520	2000	560
General Total	33053,61	30399,14	124311,75	83731,43	145000	111960,5	90531,5	90202,21	19813,83	10613,96

Annex 7. *Record of budget assigned according to Source 701 and its execution during the period 2011-2015*

SOURCE	701									
	Column titles									
Line titles	2011		2012		2013		2014		2015	
	Amount ENCODED	Amount PAID	Amount ENCODED	Amount PAID	Amount ENCODED	Amount PAID	Amount ENCODED	Amount PAID	Amount ENCODED	Amount PAID
To Private sector not financial	0	0	0	0	74870	74870	0	0	124734,98	74840,99
Food and beverages	2376	1592,69	8061,86	1826,85	0	0	0	0	0	0
Employer contribution to S.S.	2145,19	2038,08	2713,19	2713,19	3972,13	3154,89	0	0	0	0
RENTAL AND LICENSES FOR USE OF COMPUTER SOFTWARE PACKAGES							692,7	692,7	0	0
ALLOCATION TO BE DISTRIBUTED TO TRANSFER AND INVESTMENT GRANTS	0	0	0	0	0	0	0	0	0	0
SCHOLARSHIPS AND FINANCIAL AID	0	0	0	0	0	0	0	0	0	0
Compensation for unused vacations due to termination of contract	2732,5	0	0	0	3866,24	3866,24	0	0	0	0
Consultancy, counseling and specialized research	28727,81	10000	10000	9500	15000	6000	9000	9000	72634,23	0
Fourteenth salary	308	0	292	292	638,28	371	0	0	0	0
Thirteenth salary	2732,5	2640	2783	2783	3894	3304,97	0	0	0	0
Diffusion and information	0	0	0	0	17000	11900	0	0	0	0
Informational diffusion and advertisement			0	0	0	0	0	0	0	0
Editing, printing, copying and advertising	19600	0	16797,87	0	40500	6480	3600	3180	0	0
Buildings, stores and residencies	0	0	0	0	780	160	0	0	0	0
Equipments, software systems and packages							1066,03	1066,03	0	0
Public and Official Events	0	0	0	0	0	0	0	0	0	0
Reserve Fund	0	0	2783	2581,19	2319,17	1159,1	0	0	0	0
Tools – goods of use and investment consumption	0	0	13000	0	0	0	0	0	0	0
Fees	0	0	0	0	2597,47	2597,47	0	0	0	0
Books and collections	0	0	0	0	0	0	0	0	0	0
Machineries and equipments – long lasting goods	0	0	70000	0	0	0	0	0	0	0
Office supplies	370	0	430	116,05	480	0	1598,5	1566,06	0	0
Materials for laboratory and medical use	0	0	0	0	90000	0	42750	42750	0	0
International air tickets	3841,2	1231,1	4000	0	16408,63	5074,42	2373,64	1629,33	0	0
National air tickets	1500	660,28	1350	717,16	5650	2076,88	3000	719,99	0	0
Publicity and Advertising in Mass Media	0	0	0	0	45000	31500	0	0	0	0
Feeding service	0	0	0	0	713,9	618,3	0	0	0	0
Auditing service							5500	5500	0	0
Training services	3300	0	24000	18136,72	0	0	0	0	0	0
Personal services under contract	22230	21120	28116	28116	41162	32693	0	0	0	0
Viatical and subsistence allowances abroad	7608,8	3399,52	6750	1178,1	16800	8279,15	5308,4	5247,03	0	0
Local viatical and subsistence allowances	2400	0	1750	400	4500	1379,04	1109,45	0	0	0
General Total	99872	42681,67	192826,92	68360,26	386151,82	195484,46	75998,72	71351,14	197369,21	74840,99