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**HEMISPHERIC BIOTECHNOLOGY AND BIOSAFETY
PROGRAM (HBBP): FRAME OF REFERENCE FOR ITS
PREPARATION AND IMPLEMENTATION¹**

Preliminary version for discussion

Guayaquil, Ecuador

¹ Working document prepared by the IICA Directorate of Technology and Innovation, based on the recommendations made by the Task force of experts from 14 countries in the Americas that met in Cancun in March 2005 to map out the preparation of the Hemispheric Program. The document includes the technical inputs received from the Task force's technical subgroup, composed of specialists from CINVESTAV, INIA (Chile), Auburn University (USA) and IICA itself.

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ACRONYMS

AECI	Spanish International Cooperation Agency
ARS	Agricultural Research Service
BIOLAC	United Nations University - Biotechnology for Latin America and the Caribbean
CAC	Central American Agricultural Council
CABBIO	Argentine-Brazilian Biotechnology Center
CAF	Andean Development Corporation
Cambiotec	Canada-Latin America Initiative on Biotechnology for Sustainable Development
CARDI	Caribbean Agricultural Research and Development Institute
CAS	Southern Cone Agricultural Council
CATIE	Tropical Agriculture Research and Higher Education Center
CGIAR	Consultative Group on International Agricultural Research
CIAT	International Center for Tropical Agriculture
CIMMYT	International Maize and Wheat Improvement Center
CIP	International Potato Center
CIRAD	Center for International Cooperation in Agricultural Research for Development
CORPOICA	Colombian Agricultural Research Corporation
CPB	Cartagena Protocol on Biosafety
CTA	Technical Centre for Agricultural and Rural Cooperation, The Netherlands
EMBRAPA	Brazilian Institute of Agricultural Research
FAO	United Nations Food and Agriculture Organization
FONACYT	National Science and Technology Fund
FONTAGRO	Regional Agricultural Technology Fund
FORAGRO	Regional Forum on Agricultural Research and Technology Development
GEF	Global Environment Facility
GFAR	Global Forum on Agricultural Research
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit
HBBP	Hemispheric Biotechnology and Biosafety Program

IABA	Inter-American Board of Agriculture
IDB	Inter-American Development Bank
IDIAF	Dominican Agricultural and Forestry Research Institute
INIA	National Agricultural Research Institute
INTA	National Agricultural Technology Institute
IPPC	International Plant Protection Convention
LAC	Latin America and the Caribbean
LMO	Living Modified Organism
MUSALAC	Banana and Plantain Network for Latin America and the Caribbean
NABI	North American Biotechnology Initiative
OAS	Organization of American States
OIRSA	International Regional Organization for Plant and Animal Health
PROCI _s	Regional Research and Technology Development Systems
PROCIANDINO	Cooperative Agricultural Research and Technology Transfer Program for the Andean Subregion
PROCICARIBE	Caribbean Agricultural Science and Technology Networking System
PROCINORTE	Cooperative Agricultural Research and Technology Transfer Program for the Northern Region
PROCI TROPICOS	Cooperative Program for Technology Research and Transfer for the South American Tropics
PROCISUR	Cooperative Program for Agrifood and Agroindustrial Technology Development in the Southern Cone
PROMECAFE	Regional Cooperative Program for Technology Development and the Modernization of Coffee Cultivation in Central America, Dominican Republic and Jamaica
REDBIO	Network of Technical Cooperation on Biotechnology
SICTA	Central American Integrated Agricultural Technology System
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
UNEP	United Nations Environment Programme
WTO	World Trade Organization

1. INTRODUCTION

The countries of the Americas are faced with the common challenge of achieving the competitive and sustainable development of agriculture and agribusiness in a way that is compatible with conservation and sound natural resource management and the reduction of hunger and urban and rural poverty. This challenge also entails producing food that is more nutritious, safe and of a better quality. The world's scientific community is agreed that if conventional technology alone is used, it will be impossible to increase or diversify the quantity and quality of food production sufficiently to feed a population that will nearly double over the next 50 years.

To meet these challenges, the countries of the Americas must do more to incorporate the latest scientific and technological advances and findings. The performance and competitiveness of agriculture and trade in food are increasingly being influenced by the emergence of new knowledge, as is the case of agrobiotechnologies.

As has been pointed out in various studies and specialized forums, in some countries the adoption of agrobiotechnologies has resulted in higher agricultural productivity, lower costs and improvements in the conservation and sustainable management of the environment. The marketing of products developed using the new biotechnologies, such as living modified organisms (LMOs), raises not just production-related issues but also the questions of biosafety and intellectual property. An extensive international regulatory framework is in place governing the development, use and marketing of the new agrobiotechnologies. It includes the Cartagena Protocol on Biosafety (CPB), in force since September 2003; the agreements adopted at the World Trade Organization, such as the Agreement on Sanitary and Phytosanitary Measures and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); the agreements adopted under the International Plant Protection Convention (IPPC); and the principles and guidelines being developed under the aegis of the *Codex Alimentarius*.

Several countries in the region have made great strides with the development, incorporation and safe use of agrobiotechnologies, and in implementing the international agreements on the subject. However, there are also major differences and disparities between regions and countries with regard to their capabilities in this field. Mindful of the challenges that the new agrobiotechnologies pose, the opportunities they offer and the need to strengthen national capabilities in this field, IICA's member countries called for a hemispheric biotechnology program. It should lead to joint action aimed at integrating efforts, tapping opportunities and improving access to the technologies available, to find solutions to common problems and enhance national capabilities. This decision was set out in Resolution 386, of November 2003, of the Inter-American Board of Agriculture (IABA), which comprises the ministers of agriculture of the countries of the Americas. IICA was asked to set up a team of professionals, from the Institute itself and the Member States, to develop a plan for agrobiotechnology and biosafety in the hemisphere.

This document presents a proposed frame of reference for the preparation and implementation of a Hemispheric Biotechnology and Biosafety Program (HBBP). It draws on the guiding principles proposed and recommendations made at the first meeting of the Task Force of experts from 14 western-hemisphere countries and IICA, who met 10-11 March in Cancun. The design of this framework forms part of IICA's ongoing actions on institutional

aspects and policies, and in support of cooperation among the countries on agrobiotechnology. This framework will also boost and complement the actions already under way.

2. RECENT BACKGROUND

2.1. IICA's mandate and IABA Resolution 386 on Agrobiotechnology

IICA's 2002-2006 Medium Term Plan makes technology and innovation a strategic, priority area for technical cooperation with the member countries, to support the modernization of agriculture and the development of rural communities. The Institute has been implementing actions on several aspects of institution building for agrobiotechnologies and promoting reciprocal cooperation between countries on the subject under the PROCIs, PROMECAFE, SICTA, FONTAGRO and FORAGRO (Annex 1).

Specifically, Resolution 386 of the Inter-American Board of Agriculture, IICA's highest-level governing body, is consistent with IICA's mandate on the subject and is based on: i) the IICA member countries' recognition of the importance of biotechnology and its impact on agricultural development and trade; ii) the existence of the CPB and the fact that it permits agreements between "parties" and "non-parties" to meet the requirements governing the transboundary movement of LMOs and trade (e.g., the trilateral understanding involving Canada, the United States and Mexico, one of the first efforts to implement the CPB, in particular Article 18(2a)); and, iii) the existence of regional initiatives such as the one undertaken by the North American countries (NABI) and others that are being developed, such as those of Central America, the Caribbean and the Southern Cone.

Basically, the IABA Resolution instructs IICA:

- a. To convene meetings, in consultation with its Member States, to discuss the importance of agricultural biotechnology, and its impact on trade and development.*
- b. To disseminate among its Member States the arrangement signed by the three North American countries to facilitate trade and the transboundary movement of LMOs, with a view to considering the possibility of implementing such measures.*
- c. To establish a task force comprised of IICA staff and interested Member States to develop a plan for agricultural biotechnology and biosafety in the hemisphere.*
- d. To urge the Member States to contribute to IICA the additional resources necessary to support the activities considered under this resolution.*

The mandates contained in Resolution 386, IICA's regional platform of 34 country offices and the reciprocal mechanisms for cooperation on technology and innovation that the Institute supports, will make it possible to spur, coordinate and intensify regional and hemispheric reciprocal cooperation aimed at building the national capabilities needed to develop agrobiotechnologies.

2.2. Regional cooperation initiatives in agrobiotechnology and biosafety

For some time the issues of agrobiotechnology and biosafety have been a feature of the science and technology and agriculture agendas of the countries, and also of the hemispheric

agendas of regional and international technical cooperation agencies.² IICA, FAO and the OAS are some cases in point.³ In addition to its activities worldwide, in LAC in particular FAO supports cooperation on research between national biotechnology institutions and laboratories and information sharing, and has a regional database run by the REDBIO network.

IICA has been involved in actions on institutional aspects of biotechnology and biosafety since the early 1990s. More recently, the Institute has been supporting subregional initiatives, such as the cooperation provided to the Central American Agricultural Council (CAC) with CATIE and OIRSA, for the development of a regional agrobiotechnology strategy. The Institute has also been helping to develop a regional agrobiotechnology agenda in the Caribbean Region and to organize a regional advisory group on the subject. IICA has supported the implementation of regional research projects that make use of modern agrobiotechnology tools through regional cooperation mechanisms such as the PROCIs, PROMECAFE and FONTAGRO. The Technical Secretariat of FORAGRO has also promoted hemispheric dialogue and studies of the institutional situation with regard to agrobiotechnologies in LAC, with a view to developing a regional agenda on the issue, within to the Forum's mandate.

The new regional models for cooperation in agrobiotechnology include the North American Biotechnology Initiative (NABI). The NABI has an expeditious, informal governmental structure and promotes the development and appropriate use of agrobiotechnology products in North America. The NABI also encourages a cooperative approach to the regulation of agrobiotechnology and keeps senior agricultural officials informed of breakthroughs and agreements reached among the countries. The trilateral agreement for the implementation of Article 18.2(a) of the CPB is a case in point. Other regions of the hemisphere could benefit from the lessons learned from the NABI model.

2.3. Task force of country experts on the HBBP

Based on IABA Resolution 386, IICA convened a meeting in Mexico of a task force of experts in agrobiotechnology and biosafety from the different regions of the hemisphere,⁴ to discuss the conceptual and operational underpinnings needed for the design of the Program. During that meeting, the countries gave an overview of their actions in the field of biotechnology and biosafety, including some studies of the impact of implementing the CPB on transboundary trade in LMOs. Information was also presented about the new regional cooperation models being implemented, which the Program could help implement in other regions. IICA presented its actions in the field of biotechnology and biosafety, and the core elements for the design of the Hemispheric Program. The Task Force then discussed the Program.

² For further details of regional cooperation in agrobiotechnology, see documents prepared by the IDB (Trigo et al., 2002), Cambiotec (2002), FORAGRO/IICA and others.

³ The OAS has promoted information initiatives like SIMBIOSIS and efforts involving biotechnology indicators.

⁴ The Task Force was made up as follows: Southern Region: Chile, Argentina, and Brazil; Andean Region: Colombia, Ecuador, Venezuela; Central Region: Costa Rica, Nicaragua and Guatemala; Northern Region: Mexico, USA and Canada; Caribbean Region: Dominican Republic, Jamaica and Trinidad and Tobago (the last country did not take part). The list of participants is to be found in Annex 4 of this document.

The various presentations⁵ showed the diversity that exists in terms of the capabilities and activities of the different regions. This important body of knowledge will be very useful for developing the Program.

Recognizing the existence of subregional mechanisms and the need to promote dialog among the different subregions, the Task Force recommended that the countries proceed to formulate the HBBP and stated that:

- a. *IICA, through its Offices in the countries, should support the gathering and dissemination of information concerning the costs and benefits of agrobiotechnologies, to facilitate decision-making by policymakers and support the development of a positive public perception of agrobiotechnology in the Region*
- b. *IICA should conduct regional needs assessments, including existing studies, to determine how countries in the region could benefit from agrobiotechnology through the sale of products that could add value to the countries' domestic economies*
- c. *IICA should support, as soon as possible, the design and implementation of policy frameworks to assist countries that do not have national agrobiotechnology policies*

The Task Force also discussed and endorsed several types of actions that should be included in the HBBP. The main ones mentioned were as follows: i) development of specialized information on strategic issues (e.g., in the field of trade negotiations, to support decision-making processes); ii) actions to improve the public perception of agrobiotechnology, disseminating objective information about its costs and benefits; iii) support for the development of national biotechnology policy frameworks, focusing on countries that do not have them; iv) support for technology development and innovations, beefing up regional strategies and cooperative work between countries; v) strengthening of aspects related to the design and harmonization of regulatory frameworks and assessments of the economic impact of their implementation; and, vi) regional needs assessments of agrobiotechnologies for the countries and studies of ways they could benefit from them, as a development tool that adds value to the economy and improves the well-being of the population.

2.4. IICA Executive Committee meeting in Riberão Preto, Brazil, and the HBBP

At the IICA Executive Committee meeting held in May 2005, the Directorate of Technology and Innovation gave a presentation on the progress of the Institute's technical cooperation on biotechnology and, especially, the HBBP. The national delegations praised the work under way and again endorsed the Program and its lines of action. They also said it was important for the Program to facilitate follow-up to the work of *Codex Alimentarius* and support the development of the capabilities needed to negotiate international agreements on the subject, increase the private sector's involvement - with the public sector - in the development and marketing of agrobiotechnologies, and encourage actions to change the public perception, with a greater participation by civil society. The delegates also endorsed the importance of disseminating initiatives like the NABI and the transfer of this experience to other regions, such as the Southern Cone within the framework of the CAS. Another point highlighted was the importance of facilitating the application of new agrobiotechnologies for products other than

⁵ The presentations made at the meeting of the Task force in Cancun, Mexico are to found on IICA's Biotechnology and Biosafety Web page: www.iica.int/biotecnologia

commodities, which figure prominently in the current statistics on the use of LMOs in the Americas. Efforts are needed to promote the development and safe use of agrobiotechnologies in other economically important crops with great potential, such as quinoa, fruit trees, bananas and roots and tubers. Finally, they emphasized that more financial resources were needed to implement the Program, given the advantages offered by agrobiotechnologies. These points were set out in Executive Committee Resolution 428.

3. PURPOSE AND OBJECTIVES OF THE HBBP

3.1. Purpose

To contribute to the development, management and safe use of agrobiotechnologies and their products, by means of joint activities that the countries will carry out based on their common priorities and strategic efforts to achieve a competitive and sustainable form of agriculture in the Americas.

To achieve the above, the Program, through IICA, will promote dialogue among the different players involved, the efficient dissemination of information, training and the development of public policies, making use of the regional and national institutional channels available.

3.2. Objectives

- To help gather and disseminate information and studies to enable national officials to design policies and take decisions based on scientific and technical evidence, and provide the public with objective information on agrobiotechnologies.
- To conduct regional needs assessment to achieve the appropriate use of agrobiotechnologies and assess their current and potential positive impact on socioeconomic development.
- To support the design and harmonization of policies and regulatory frameworks, with emphasis on countries and regions that do not have them or that require specific assistance.
- To promote an objective public perception of agrobiotechnologies and encourage the authorities to make the issue of perception an important component of national agrobiotechnology policies and programs.
- To support the development of scientific and technological capabilities in the field of agrobiotechnology by means of regional strategies and cooperation among countries and regions, considering the solution to national and local problems.

4. SOME UNDERLYING PRINCIPLES OF THE HBBP

Both the formulation process and the implementation of the Program will be based on a series of principles. Among other things, the Program will:

- Work on opportunities and/or problems common to the countries that call for joint activities and an equitable distribution of the benefits.
- Acknowledge the existence of ongoing regional and hemispheric programs, projects and mechanisms, and implement activities that will strengthen the Program's actions and avoid the duplication of efforts.
- Gradually reduce the disparities among countries and regions, giving priority to further actions in the fields of policy and the development of institutions in the countries with the greatest needs.
- Provide the national authorities with the authoritative, timely and relevant information they need to take important national decisions and negotiate international agreements.
- Promote the implementation of concrete actions on the topics related to the Program that add value to national efforts, recognizing the countries' sovereignty and their right to decide the path of their agricultural and environmental scientific and technological development.
- Combine the formulation and management of the implementation of the Program with the promotion of ongoing technical cooperation actions on behalf of the users.
- Promote coordination and the establishment of strategic partnerships with public and private institutions of recognized excellence for the implementation of the Program, in line with its nature, objectives and activities.
- Integrate efforts with regional and international technical and financial cooperation organizations to secure the human, technical and financial resources needed for the actions to be implemented under the Program.
- Facilitate ownership of the Program by the member countries and their institutions, conducting participatory processes in the different stages of the formulation and implementation of the Program so that they contribute to its smooth operation and sustainability.

5. LINES OF ACTION

Based on the results of the deliberations of IICA's governing bodies (at the meetings of the IABA in Panama and the Executive Committee in Brazil) and the recommendations made by the Task Force at the meeting in Mexico mentioned in section 2.3 of this document, the HBBP will implement the following interrelated lines of action:

5.1. Needs assessments, benefits and opportunities

Proposed objective. To conduct regional studies of the countries' needs in regard to the development and safe use of agrobiotechnologies and the benefits to be derived from them, and in order to implement international agreements. The aim will be to carry out impact

priority actions under the Program. The activities will also promote the incorporation of agrobiotechnologies as an important tool for development and competitiveness and the well-being of the population.

General description. Although there has been an increase in agrobiotechnology research and development activities in the countries of the Americas, they cover a wide range of topics, operate in isolation and possess few resources. The efforts to focus multinational endeavors on concrete regional projects are also few and far between, and insufficient given the cost of work on biotechnology and the complexity and magnitude of the problems to be solved. As a result, the work is fragmented and the possibilities of achieving impacts in terms of production, the environment and trade are limited.

Another aspect to bear in mind in assessing needs is the region's enormous biodiversity and the conservation and sustainable use of these resources.⁶ Little work has been done on a large number of species used in agriculture as their presence in international markets is limited and buyers in developed countries find them largely unattractive. Known as "orphans," such underused crops are very important in the rural economies and diets of rural communities and in domestic trade and should not be overlooked. The Program will promote the analysis of needs based on the potential benefits of agrobiotechnologies and the role they can play in the agriculture of both the temperate zones and the tropical and subtropical regions. Most of the rural poverty in the Americas is to be found in the lowland and highland ecosystems of the latter.

The Program will also provide the countries with inputs for setting priorities and assigning resources to aspects of agrobiotechnology considered of national and regional importance. It will promote regional exercises aimed at identifying needs and the current and potential benefits and opportunities afforded by these techniques for the competitive and sustainable development of agriculture and to help reduce rural poverty.⁷

5.2. Information for policy-making, negotiations and public perception

Proposed objective. To support the development, management and negotiation processes related to agrobiotechnologies by compiling and preparing strategic information on the latest developments and biosafety and international agreements and their implications, to support policy-making and decision-making. Also, to help find, prepare and disseminate information that will contribute to the development of an objective, authoritative public perception of the Program subject-matter by different interest groups and society in general.

General description. At present, policy-making, the development, use and marketing of agrobiotechnologies and negotiations for international agreements are influenced by disinformation or a lack of credible, factual information based on scientific and technical evidence. This situation affects decision-making and the public's perception. The Program

⁶ For example, four of the eleven most important centers of origin and genetic diversity of crops are located in the Americas, including several of great strategic importance.

⁷ There are many examples in different parts of the world of needs being turned into opportunities. An obvious case in point is the use of the technology for producing alcohol from sugarcane that has now made Brazil a leader in the use of alcohol as fuel and to generate electricity.

aims to develop the capacity to provide information from sources that enjoy recognized credibility to support policy design, the negotiation and implementation of international agreements and decision-making on agrobiotechnologies. Part of the work will be entail providing information that can be used by all the parties interested in the development, safe use and marketing of biotechnologies.

The Program will compile scientific and technical information for policy-making and decision-making and monitor the trends and implementation of international agreements such as the CPB, WTO/TRIPS, Codex Alimentarius and multilateral agreements between parties and non-parties to the CPB. The information will be disseminated in printed form and electronically, and by means of forums, conferences, workshops and presentations in general. Advantage will be taken of IICA's current Web pages and information systems on science and technology, trade, health and safety, etc., facilitating links to other information systems. For the actions on public perception, the Program will enlist the aid of experts from the social and communication disciplines to prepare information tailored to different audiences, including schoolchildren. The studies of public perception already conducted in some countries will be disseminated throughout the region.

5.3. Impact of agrobiotechnologies on development, the environment and trade

Proposed objective. To generate information and analysis on the current and potential socioeconomic impact of agrobiotechnologies and the policies associated with them, specifically as regards their contribution to agricultural production and productivity, the environment, the sustainable use of natural resources (e.g., biodiversity), rural poverty reduction and agricultural trade. The Program will also promote forums and meetings on the impact of agrobiotechnologies in the Americas, fed with information generated by the Program on the aforementioned issues and the obstacles to their greater dissemination and use.

General description. More agrobiotechnology development work is now going on in the Region, particularly in the field of technology research and development. The countries have progressed from the use of relatively simple techniques -such as tissue culture- to more sophisticated ones like genetic engineering, especially in countries that possess more resources and capabilities. Nonetheless, it is surprising that, although such technologies have been developed in the Region for nearly 25 years, few processes and products have been marketed. Little information is available about the socioeconomic impact of agrobiotechnologies on production and trade and the distribution of the profits generated by their use, e.g., LMOs, among producers, agroindustry and consumers. Another important aspect is the need to intensify the analyses of the socioeconomic impact of implementing regulatory frameworks.

In some studies and forums, various explanations have been offered for the situation described. These include the high investment and time required to produce new products adapted to specific conditions and production systems, the lack of clear regulatory processes and the costs involved in complying with strict regulatory measures. This brings the need of integrating efforts among countries to support decision-making and negotiating processes.

The Program aims to design and/or apply existing impact measurement methodologies, and generate and disseminate information about the true costs and benefits, efficiency and

competitiveness of agriculture based on agrobiotechnologies. The Program will also promote biosafety workshops that will include aspects of risk analysis, management and communication. Studies of the implementation of international agreements and regulatory frameworks will also be promoted.

5.4. Policies and regulatory frameworks⁸

Proposed objective. To support the design and implementation of policies related to the development and safe use of agrobiotechnologies by means of conceptual and methodological elements and the sharing of experiences, placing special emphasis on actions in countries and regions that do not have such policies or that require specific assistance. Furthermore, to help enhance the countries' institutional capabilities for designing and implementing regulatory frameworks consistent with national conditions and international agreements, and the harmonization of frameworks among countries.

General description. The promotion of agrobiotechnologies must be underpinned by policies that favor their development, incorporation and safe use in production systems and trade. These policies must also have a positive impact on agricultural production in harmony with the environment and improve the conditions and quality of life. Such policies should include incentives to encourage the training of specialized professionals, investment in research and development, increased institutional and management capabilities, and, in particular, the creation and/or strengthening of biotech industries such as the seed industry.

In the regulatory field, such policies require the existence of a legal framework and functional systems to ensure that agrobiotechnology products are used safely, especially new ones such as LMOs. They must also cover intellectual property, access to genetic resources and aspects that facilitate technology transfer. Several countries have established broad regulatory frameworks and/or risk analysis mechanisms to ensure biosafety, but many more have yet to do so. It is not only of a question of introducing regulations and ratifying international agreements; countries must also possess the institutional capabilities, instruments, specialized human resources and financial resources needed to set up the respective units and enforce the measures included in such regulations.

As part of its support for policy frameworks and regulations, the Program makes provision for the analysis of the impact of intellectual property rights (IPR) on production, the management of technical change, the promotion of innovation and trade, etc. It will also support the management of intellectual property by compiling and disseminating information on instruments, methodologies, experience and the assessment of the impact of such rights on the development and marketing of agrobiotechnologies.

The Program is called upon to play a leading role in advising the countries of the Americas about the design and harmonization of agrobiotechnology policies and the development of institutional capabilities for the design, harmonization and implementation of legal frameworks, mainly on biosafety and intellectual property. This is especially important for countries and regions that still do not have policies of this kind or legal frameworks in place.

⁸ The term "regulatory framework" refers to the various forms and levels of legal and administrative instruments used by the different countries.

The HBBP also intends to foster the transfer of experiences through intra- and interregional technical cooperation on these issues and their impact, and the impact of regulations such as biosafety. In the latter field, major progress can be made by affording the countries access to existing databases on approval processes, legislation and regulations, and experiences of implementing international agreements related to the regulatory frameworks and methodologies, and instruments for applying them.

5.5. Institutional building through regional agrobiotechnology initiatives and technical cooperation processes

Proposed objective. To improve the countries' institutional capabilities for designing policies, scientific development and the management and safe use of, and trade in agrobiotechnologies, by means of comprehensive regional agrobiotechnology initiatives or strategies and reciprocal technical cooperation between countries in the regions of the Americas.

General description. The Program will focus on speeding up the processes used to formulate, build consensus on and implement regional initiatives related to the development, management and use of agrobiotechnologies and the development of institutional capabilities through cooperation among countries. Actions in this field will be consolidated in the Central American and Caribbean regions and similar development will be facilitated in the Andean Region. In the case of the Southern Cone countries, a regional biotechnology program was approved under the CAS. The NABI is also operational and links will be facilitated between this initiative and others such as the CAS. In general, the regional initiatives aim to develop a regional vision of agriculture and the role of agrobiotechnologies and related policies, the gathering and dissemination of strategic information, regulatory aspects, support for the marketing of agrobiotechnologies, the public perception and the development of agroindustry, and scientific and technological development. These initiatives are designed to meet the needs of the regional economic integration blocs, whose countries have similar development objectives; and, at the same time, to operate with a hemispheric perspective, developing close links and synergies with other countries in other regions.

In scientific and technological matters, the Program specifically intends to intensify scientific exchanges and training and the implementation of workshops and discussion forums, and provide databases of laboratories and researchers. Emphasis will also be placed on institutional aspects of research and technology development. Moreover, the Program will complement and boost the actions of important regional mechanisms such as REDBIO-FAO and research activities through the PROCIs, PROMECAFE, networks like MUSALAC and regional activities in the Americas of international research centers such as CIAT, CIP, CIMMYT, IFPRI and CATIE. It will also take advantage of the experiences of other cooperative efforts like CAMBIOTEC, CABBIO and BIOLAC.

Another important task will be to support the sharing of ideas and experiences and joint efforts between countries to promote the creation of biotech firms (e.g., seed and plant material multiplication, production of biopesticides, and biofertilizers, among others) to facilitate the incorporation of agrobiotechnologies into production systems and marketing. In this case, the Program will foster the discussion of these topics by producers and the private sector and institutions with experience in promoting rural agroindustry and financing. The idea is to complement national efforts to promote the development of rural

agroindustry through the sharing of regional experiences and joint activities under the regional mechanisms and strategies.

6. THE PROGRAM'S INTEGRATED APPROACH

The Program will adopt an integrated approach, inasmuch as it will add value to actions already under way in the Region, encompass regional lines of action and initiatives and involve actors of various kinds.

It will add value to ongoing actions, at both the national and regional levels, by focusing on aspects covered partially, or not completely, by existing regional activities. Hence, the inclusion of actions such as information gathering and dissemination aimed at supporting negotiations and decision-making; and the evaluation of the current and potential socioeconomic, environmental and commercial impact of the new agrobiotechnologies. Also, the creation of platforms to enable countries to share their experiences regarding the design and management of regulatory activities and the articulation of technical cooperation actions among the different regional initiatives under way and under development.

The Program is organized in the form of a matrix. On the one hand, there are the lines of strategic action that reflect common needs expressed by the countries; and, on the other, the regional initiatives for cooperation among countries. These initiatives have their own characteristics and specific objectives, but will also make it possible to implement the Program, taking into account the differences and specificities of the regions and the articulation of actions among them.

Furthermore, the Program will actively involve different actors who are a factor in the development, management and safe use of agrobiotechnologies and the trade in products obtained from them. They will be substantive actors drawn from governments, the private sector (e.g., agroindustry), academia and civil society in general. Figures 1 and 2 shows the elements described above and their interrelationships.

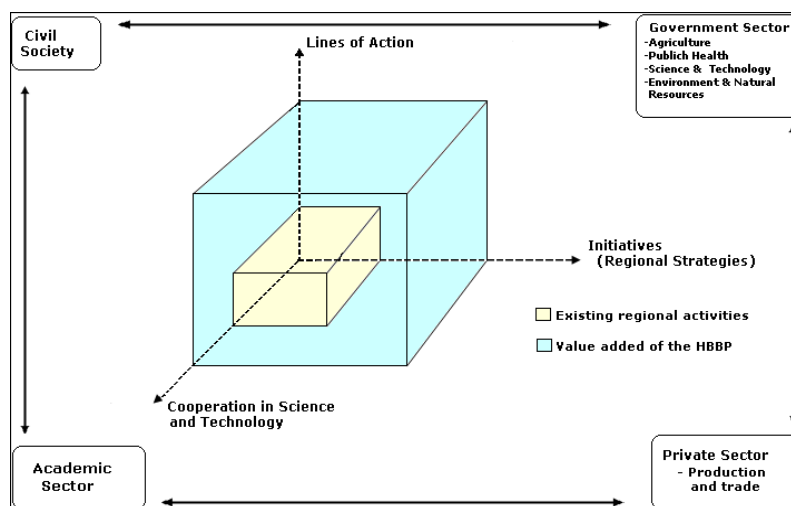


Figure 1: Value added of the HBBP according to the different dimensions involved in existing regional activities, within a framework of interrelated national actors.

Lines of Action Regional Initiatives	Hemispheric Biotechnology and Biosafety Program: Matrix View of Regional Activities and actions				
	Needs Assessments, Benefits and Opportunities	Information and Public Perception	Impact of Agrobiotechnologies	Policies and Regulatory Frameworks	Institutional Building and Technical Cooperation
Andean Region					
Caribbean Region					
Central Region					
Northern Región					
Southern Region					

Figure 2. Matrix view of the HBBP according to the strategic lines of action reflecting the common needs of the countries.

7. STRATEGY FOR FORMULATING THE PROGRAM

During the process of formulating the Program, some specific technical cooperation activities will be implemented consistent with its purpose and content and tailored to the needs of the countries. This section describes how the Program will be coordinated, oriented and prepared, and refers briefly to the specific activities.

7.1. Coordination, orientation, preparation and consultation

7.1.1. Coordination of the formulation of the Program

The Program will be coordinated by IICA's Directorate of Technology and Innovation, assisted by the Institute's other Thematic Areas, which will provide technical inputs on the subjects in which they specialize. A **cross-thematic** approach will be used, as promoted by the Directorate of the Technical Cooperation Secretariat. Figure 3. By adopting this approach, it will be possible to enhance the formulation, and then the implementation, of the Program, based on work in areas related to agrobiotechnologies, such as agribusiness, trade and food safety. The work will involve IICA's regional and national specialists and harness existing institutional capabilities, and coordinate the support of mechanisms like the PROCIs and regional research centers, such as CATIE and CARDI, and FORAGRO,⁹ which the Institute supports.

⁹ IICA is actively involved in the consolidation of the regional research system. In particular, it supports the subregional cooperative research programs PROCINORTE (North America), SICTA, PROMECAFE PROCIANDINO, PROCITROPICOS, PROCISUR, PROCICARIBE (under CARDI), the FORAGRO and FONTAGRO hemispheric mechanisms, and the regional research centers, CARDI and CATIE.

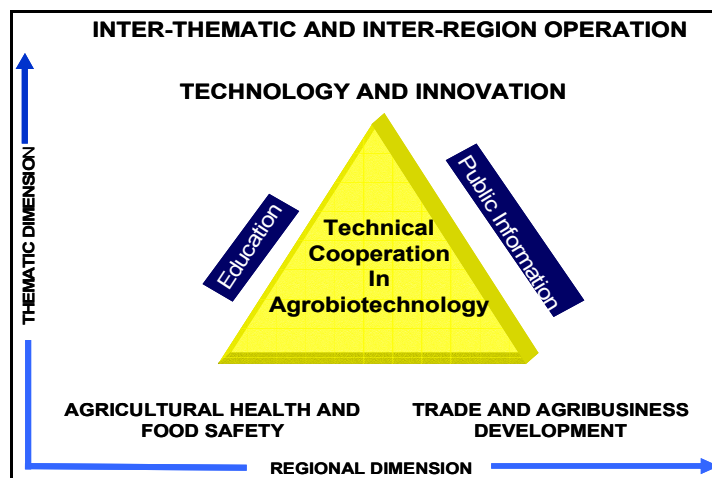


Figure 3. Vision of IICA's Cross-thematic Action in Agrobiotechnology under the Areas of Technology and Innovation, Policies and Trade, Agribusiness Development and Agricultural Health and Food Safety

7.1.2. Steering Task Force and technical subgroups by line of work

The steering Task Force set up to draft this Frame of Reference, comprising country experts and IICA professionals, as described in section 2.3, will continue to operate. It will operate **in the form of a network**, holding onsite meetings and interacting online. Its mission will be to guide the conceptual and operational aspects of the formulation process and review the intermediate outputs and the final one (the Program document). The Task Force's efforts will be complemented with the work of the specialists of the technical subgroups (on the Program's core topics) and specialized consultants, in specific cases.

7.1.3. Strategic partnerships

To prepare and implement the Program, technical capabilities in the scientific and technical, educational, institutional and financing fields will be required to complement those of IICA and the countries. Priority will be given to strategic partnerships with international and regional technical cooperation and financial agencies like FAO/REDBIO, the IDB, FONTAGRO, the World Bank, GEF, GFAR, the CGIAR's international centers, the OAS, USAID, CAF, the European Union and organizations in the countries and the cooperation agencies of developed countries. By mutual agreement with the countries, alliances will also be sought with private sector organizations recommended by the countries themselves that are compatible with the spirit, nature and objectives of the hemispheric Program. The partner organizations will be encouraged to take part in the meetings and workshops held to prepare the program, including work sessions of the donor support group.

7.1.4. Fundraising

Funds and in-kind contributions will need to be raised for the formulation and implementation of the Program. IICA will be allocating a specific budget that will be used as seed funding for

the formulation of the Program, and contributing its specialists in the subject-matter and its infrastructure (network of 34 Offices in its member countries). The funds available are insufficient, however; hence, in IABA Resolution 386, the member countries recognized that they would need to make additional contributions.

7.1.5. Operational stages

a. Identification of regional and national counterparts. Counterparts will be identified for each region for the formulation process, both in the needs assessment phase and for the review of the Program document. The Program will seek to involve leading professionals from the countries who are familiar with the agrobiotechnology situation in identifying the needs and regional priorities (people who are conversant with both the technical and institutional issues and their respective regions).

b. Workshops to identify needs and priorities. Several countries and regions already have national assessments of the problems and opportunities facing agriculture from the agrobiotechnology perspective, but many do not. The needs, problems and opportunities must be reviewed and fine-tuned, and priorities set for the implementation of joint activities, so that the Program produces impacts and adds value to national efforts. The needs and priorities will be identified by holding workshops in the Central American, Caribbean, Andean and Southern Cone regions. In the Northern Region, this work is already being done under the NABI initiative, and advantage will be taken of the information that now exists.

c. Drafting of the Program document. The fruit of the formulation process will be a programming document containing all the information required to implement the Program. It will also include a description of projects on specific aspects of agrobiotechnologies with great potential impact, to be implemented as multinational efforts. The unit in charge of coordinating the formulation of the Program within the Directorate of Technology and Innovation will produce a preliminary version of the document. In doing so, it will draw on the needs assessments produced at the regional meetings, secondary information sources, the documents prepared by the technical subgroups for the lines of action and the support of experts on specific topics.

d. Consultation and validation of the final document. The first draft will be circulated within IICA to obtain pertinent feedback and suggestions and, studied and discussed by the members of the Task Force at a regional workshop.

The final version will be submitted to the consideration of IICA's governing bodies, following the recommendations of the Institute's General Directorate.

7.1.6. Dissemination of information about the HBPP.

Details of the progress of the formulation of the Program, the end product and the actions under way will be disseminated widely among the governments of the countries and different interest groups related to the Program's objectives and activities.

7.2. Specific actions in the short term

- Continued efforts to formulate the regional agrobiotechnology initiatives (strategies) for Central America and the Caribbean, in close coordination with the Hemispheric Program.
- Support for the development of ties between the NABI and the Southern Cone countries and a joint work program, including support for the CAS Biotechnology Coordinating Unit, for the respective initiative agreed on by the countries.
- Efforts in the Andean Region to develop a regional agrobiotechnology strategy, similar to those in the other regions, linked to the goals of the Hemispheric Program.
- Follow-up to the meetings of the Cop/Mop of the CPB in Montreal and preparation and dissemination of an analytical summary of the results among government officials and interest groups, to reach agreement on the next specific actions to support implementation of the CPB.
- Continuous promotion of the Web page on biotechnology and biosafety, and dissemination of topics of interest and multilateral agreements for the transboundary movement of LMOs.
- Conclusion, publication and dissemination of the FORAGRO-sponsored study on the institutional situation of agrobiotechnologies in LAC.
- Strategic evaluations of the impact of policies and regulations: i) measurement of the impact of the implementation of the CPB by states parties that import LMOs; ii) instruments for the management of regulatory frameworks on biosafety; iii) the socioeconomic impact and distribution of the benefits of the agrobiotechnologies; and, iv) the design of training tools to enhance institutional capabilities. These studies will be carried out as and when resources are made available.

8. SCHEDULE

ACTIVITIES	Months										
	1	2	3	4	5	6	7	8/9	10	11	12
Identification of regional counterparts	X										
Collection and dissemination of information, development and maintenance of the biotechnology and biosafety web site	X	X	X	X	X	X	X	X	X	X	X
Conformation of a Task Force for the formulation of the HBBP		X	X								
Needs assessments				X	X						
Strategic studies				X	X	X					
Monitor compliance with international agreements such as CPB, support regional initiatives on biotechnology and biosafety, and continue current activities in this field.		X	X	X	X	X	X	X			
Consultation workshop on the draft HBBP							X				
Workshop for identification of funding sources for the HBBP						X					
Preparation of final HBBP document						X					
Validation workshop of the Program with stakeholders								X			
Final document submitted to the consideration of IICA's governing bodies for approval.									X		

9. ANNEXES

Annex 1

IICA's principal actions in the field of agrobiotechnology, 2002-2005¹⁰

Support for institution building through regional cooperation

- Promotion of a regional strategy in Central America under CAC/SICTA. IICA-CATIE-OIRSA.
- Design of the regional agenda and setting up of a Consultative Group in the Caribbean.
- Start of links between NABI and Southern Cone countries under CAS.
- Participation in NABI as observer.
- Institution building for agrobiotechnology R&D Andean Region PROCIANDINO.
- LOTASSA Project: PROCISUR/Six other institutions.
- Implementation of regional agricultural research projects using biotechnological techniques: FONTAGRO, PROCISUR, PROCIANDINO, PROMECAFE (CATIE-CIRAD).

Dissemination of the impact of biotechnology on agricultural development and trade

- *Global and Regional Forums and Conferences:* State of the art of Biotechnologies in LAC: Fourth FORAGRO Meeting (Panama); biotechnology and trade: PCCMCA annual meeting (El Salvador, Central America); Regional Conference, REDBIO/FAO; IDIAF (Dominican Republic); World Agronomy Congress (Brazil); IICA-IDB-PAHO Seminar (Washington); World Biotechnology Forum (Chile); IICA Technical Forum on Biotechnology (Costa Rica); Biotechnology strategy and MRF for LMOs, Joint Meetings CAC, CCAD, Health Min. (Guatemala, Belize, Costa Rica); Ministerial Science and Technology Conference in Central America (USDA-Costa Rica-IICA); Board of SICTA (El Salvador); IICA Executive Committee (Brazil).
- *National Forums and Conferences:* Washington: IICA-USDA meeting; Dominican Republic: Biotechnology Policies and Launching of REDBIO; Costa Rica: UCR Forum; UCR Radio Program; Seminar on environmental legislative issues; Chile: IICA Seminar on Biosafety Situation.

Support for the design of regulatory frameworks and implementation of international agreements

- Follow-up to the Cop/Mop meetings in Malaysia and Montreal (participation), analysis and dissemination.
- Support for technical meetings between countries on aspects of implementation of the CPB and trade: Buenos Aires (February 2004 and 2005); Montreal (March 2005); Montreal (May-June 2005).

¹⁰ Actions through partnerships with national organizations such as SAGARPA-Mexico, USDA-USA and Agriculture and Agri-Food Canada, and regional and international organizations.

- Follow-up to the implementation of actions under Codex Alimentarius (Area AHFS).
- Formulation MRF for LMOs for agricultural use in Central American countries.
- Analysis of the institutional panorama of biosafety regulation in LAC.

Information, dissemination and studies

- IICA Web page: www.iica.int/biotechnology
- INFOTEC: Biotechnology in the S&T Information System/weekly bulletin: www.infotec.ws
- New agrobiotechnologies: challenges, trends institutional considerations. COMUNIICA 2005
- Institutional Situation of Agrobiotechnologies in LAC. FORAGRO 2005

Hemispheric Biotechnology and Biosafety Program (HBBP)

- Consultation Meeting of the Working Group in Mexico
- Document - Frame of Reference for the Program's design and implementation
- Information to IICA's governing bodies and process of formulation with actions under way

Annex 2**RESOLUTION No. 386**
AGRICULTURAL BIOTECHNOLOGY AND BIOSAFETY

The INTER-AMERICAN BOARD OF AGRICULTURE, at its Twelfth Regular Meeting,

CONSIDERING:

That at the Second Ministerial Meeting on Agriculture and Rural life, held in Panama on November 11-12, 2003, the Ministers recognized the importance of agricultural biotechnology and its impact on the trade in goods, especially with regard to the transboundary movement of Living Modified Organisms (LMOs);

That the Cartagena Protocol on Biosafety (CPB) recognizes that Parties and non-Parties may reach arrangements for the purpose of complying with the regulations governing trade and development;

That, in this regard, efforts have been made in the Region to establish strategic partnerships, such as the initiative undertaken by the Central American countries with support from IICA, as well as the high-level discussions among the countries of the Southern Cone;

That Canada and the United States of America (non-Parties to the CPB) and Mexico (Party to the CPB), signed a trilateral arrangement which constitutes one of the first global initiatives to emerge from this Protocol; and

That the ministers of agriculture have expressed interest in learning of the contents of this document,

RESOLVES:

1. To entrust IICA with convening meetings, in consultation with its Member States, to discuss the importance of agricultural biotechnology, and its impact on trade and development.
2. To ask IICA to disseminate among its Member States the arrangement signed by the three countries of North America to facilitate trade and the transboundary movement of LMOs, with a view to considering the possibility of implementing such measures.
3. To establish a task force comprised of IICA staff and interested Member States to develop a plan for agricultural biotechnology and biosafety in the hemisphere.
4. To urge the Member States to contribute to IICA the additional resources necessary to support the activities considered under this resolution.

Annex 3**RESOLUTION No. 428**
AGRICULTURAL BIOTECHNOLOGY AND BIOSAFETY

The EXECUTIVE COMMITTEE, at its Twenty-fifth Regular Meeting;

CONSIDERING:

That by IICA/JIA/Res.386(XII-O/03), the Inter-American Board of Agriculture (“IABA”) entrusted IICA with convening meetings, in consultation with the Member States, to discuss the importance of agricultural biotechnology and biosafety and their impact on trade and development;

That by that same Resolution, the IABA encouraged horizontal cooperation among the IICA Member States in the area of agricultural biotechnology and biosafety, and urged them to contribute additional resources for furthering IICA’s work in that area;

That the development of biotechnology and biosafety in the Member States requires the establishment of the corresponding legal frameworks;

That the General Directorate has made proposals to the Executive Committee for strengthening IICA’s role in supporting cooperation in biotechnology and biosafety,

RESOLVES:

1. To thank the Member States for their offers to share, through horizontal cooperation coordinated by IICA, their experiences and best practices in the area of biotechnology and biosafety.
2. To thank the General Directorate for its proposals for strengthening horizontal cooperation and other activities to advance the development of biotechnology and biosafety in the Americas.
3. To renew the request made by the IABA at its Twelfth Regular Meeting for the Member States to contribute additional resources to support IICA’s activities in the biotechnology and biosafety area.
4. To ask the Director General of IICA to allocate the resources needed to implement IABA Resolution 386, from funds collected as the result of the payment of quota arrearages.

Annex 4

**LIST OF THE WORKING GROUP OF NATIONAL EXPERTS THAT MET
IN MEXICO IN MARCH**

LIST OF PARTICIPANTS

PARTICIPANTS	COUNTRY	INSTITUTE	PHONE	EMAIL/FAX
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