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Directorate of Technical Leadership and Knowledge
Management**

**HEMISPHERIC
Biotechnology
and Biosafety
PROGRAM (HBBP)**

**San Jose, Costa Rica
2006**

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Editorial coordination: Paul Murphy
Mechanical editing: Assefaw Tewolde
Layout: Maria del Pilar Castillo
Cover design: Ana Catalina Lizano
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EXECUTIVE SUMMARY

IICA facilitated the formulation of a Hemispheric Biotechnology and Biosafety Program (HBBP) based on a mandate by the Inter American board of Agriculture (IABA), which comprises the ministers of agriculture of the countries of the Americas, through its resolution IABA-386. This resolution also called for the formation of a specialized hemispheric task force in biotechnology and biosafety, which has been in place since 2005. This task force, together with IICA, guided the HBBP process and developed this program. It is important to note that task force members are represented by all the sub-regions of the hemisphere.

The HBBP outlines the importance and need for the incorporation of new technologies such as agricultural biotechnologies into national policies so that they can contribute towards the competitiveness of the agricultural sector of IICA's member countries. It also states that agricultural biotechnology has significant implications in trade and transboundary movements of live modified organisms (LMO's) that have been reflected in international agreements such as the Cartagena Protocol on Biosafety. Such international agreements raise not only trade and production-related issues but also questions of biosafety regulatory, risk assessment and management, intellectual property, liability, redress, and capacity building issues.

During the formulation process, the HBBP also recognizes the regional cooperation initiatives in agricultural biotechnology and biosafety that have already been under development. Such initiatives include the Central American regional strategy in Biotechnology and Biosafety as well as the Caribbean Regional Biotechnology Initiative that IICA has been developing. These initiatives have been in collaboration with other regional and international organizations such as CATIE, OIRSA in the case of Central America and CARDI in the case of the Caribbean. Similarly, the program recognizes the need to consolidate and share experiences between other regional technical cooperation models in biotechnology. These include the North American Biotechnology Initiative that involves Canada, the United States and Mexico and the Biotechnology Group of the Southern Agricultural Council which functions as a mandate of the Ministers of Agriculture of Argentina, Bolivia, Brazil, Chile, Paraguay and Uruguay. As IICA continues

to develop the hemispheric program, it will also work closely with these regions and in the Andean region, where initial steps have already been taken.

The purpose of the HBBP is to facilitate mechanisms for the development, management and responsible use of agro-biotechnology in order to promote competitive and sustainable agriculture in the Americas. Its mission is to identify and promote opportunities for the execution of activities between all interested parties, utilizing available resources and existing institutional (national and regional) channels.

The objectives of the HBBP include: (1) support the gathering, analysis and dissemination of existing information 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; (2) support member countries in conducting needs assessment at the national and regional levels, to determine the development and appropriate use of agro-biotechnologies; (3) support the development, implementation and communication of transparent, science-based policies and regulatory frameworks and, where appropriate, facilitate regional harmonization; (4) promote transparent communications on the risks and benefits of agro-biotechnology, and encourage the authorities to make the issue of public perception an important component of national agro-biotechnology policies and programs; (5) support the development of scientific and technological capabilities in the field of agro-biotechnology by means of regional strategies and cooperation among countries and regions, considering the solution to national and local problems; and (6) promote studies, discussions and analyses of the implications of national and international norms and regulations, as well as international negotiations and agreements, on matters related to agro-biotechnology and biosafety, with special emphasis on their impact on trade.

The objectives outlined above will be achieved by the implementation of specific activities that are outlined in this document -- activities are associated with each objective. Similarly, the program recognizes some underlying principles under which it will be implemented. These include: (1) the acknowledgement of the existence of ongoing regional and hemispheric programs, projects and mechanisms to ensure that the program avoids a duplication of effort; (2) provide the national authorities with the authoritative, timely and relevant information they need to take important national decisions and participate in international fora; (3) 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; (4) solicit support for the Program from member countries and their institutions, conducting participatory processes in the different stages of the implementation of the Program so that they contribute to its smooth operation and sustainability.

The Directorate of Technical Leadership and Knowledge Management will coordinate the implementation of the program through its area of Biotechnology and Biosafety pooling when necessary, existing expertise from within IICA through its thematic areas and the

regional offices through which it will develop, as the need arises, regional working groups. It will also continue to work with the task force members through networking or meetings while it will also work to establish strategic alliances with centers of excellence and other entities with similar interests.

Small budget needed to achieve the above outlined objectives and implement their associated activities has been approved for the period of 2006 – 2008. Accountability of the progress made by the program will be given to the respective authorities of IICA and the task force members as per the institutional guidelines.

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 agrees 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. This will directly influence the food security of many countries, particularly the developing countries where the demands will be higher.

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 with agrobiotechnologies. Agrobiotechnology is influencing the agricultural sector in several ways. For example, in addition to improving productivity, it is enabling the alternate use of agriculture, such as in the pharmaceutical industry and bio-energy and-bio fuels industry.

The adoption of agrobiotechnologies has been shown to result in higher agricultural productivity, lower costs, improvements in the conservation and sustainable management of the environment, and safer foods. However, the marketing of products developed with the use of new biotechnological tools, such as living modified organisms (LMOs), raises not only production-related issues but also questions of biosafety, regulatory, risk assessment and management, as well as intellectual property and capacity building issues. Because of this, an extensive framework of international agreements exists, with science-based regulatory systems that have implications for these new agro biotechnologies. It includes: the Cartagena Protocol on Biosafety (CPB), in effect 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 standards adopted under the International Plant Protection

Convention (IPPC); and the principles and guidelines being developed under the aegis of the *Codex Alimentarius*.

Recognizing the significant regional differences that exist in the hemisphere in this field and 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 the need for a hemispheric agro-biotechnology program. Such a program should lead to joint action aimed at sharing information, 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, adopted by the Inter-American Board of Agriculture (IABA), which comprises the ministers of agriculture of the countries of the Americas. IICA was instructed 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 the Hemispheric Biotechnology and Biosafety Program (HBBP). This program 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 2005, in Cancun, Mexico. The Task Force met for the second time in San Jose, Costa Rica, May 3-4 of 2006 at which time the program was formulated and adopted by consensus among members. The CAS Biotechnology Group participated in this Task Force.

2. BACKGROUND

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

The IABA Resolution 386 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 informing Member States when they consider 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 Offices in the countries, the reciprocal mechanisms for technical cooperation available to the Institute and other support received, will make it possible to stimulate, coordinate and intensify regional and hemispheric reciprocal cooperation aimed at building the national capabilities needed to develop agro-biotechnologies and use them responsibly.

2.2 Regional cooperation initiatives in biotechnology and biosafety

For some time the issues of agro biotechnology and biosafety have been a feature of the science and technology and agriculture agendas of the countries and of the

hemispheric agendas of regional and international technical cooperation agencies.¹ IICA, FAO and the OAS² are cases in point. In addition to its worldwide activities, FAO supports cooperation on research between national biotechnology institutions and laboratories and information sharing, and has a regional database run by the REDBIO network in LAC.

IICA has been involved in the institutional aspects of agro-biotechnology and bio-safety since the early 1990s. More recently, the Institute has been supporting sub regional 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. Initial steps have been taken to work in the Andean Region as well as the southern cone in this area. Similarly, the Area of Biotechnology and Bio-safety, under the Directorate of Technical Leadership and Knowledge Management, has been working closely with the biotechnology group of CAS and the North American Biotechnology Initiative (NABI). In addition, 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.

The new regional and specialized models for cooperation in agrobiotechnology include the North American Biotechnology Initiative (NABI) that comprises Canada, the United States and Mexico. This model has an agile informal governmental structure and promotes the exchange of information and ideas regarding research and technology transfer, regulatory issues and trade as well as communications in agricultural biotechnology and biosafety in North America. The NABI promotes efforts to work cooperatively to share common experiences and approaches. The Trilateral Arrangement 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 through intraregional technical cooperation mechanisms that this program will promote, as called for under resolution IABA-386, as indicated earlier.

Another model of regional cooperation in agrobiotechnology is the Southern Cone model which functions as a mandate of the Ministers of Agriculture of Argentina, Bolivia, Brazil, Chile, Paraguay and Uruguay. These ministries have a ministerial forum for consultation and coordination of regional activities, known as the Southern Agricultural Council (CAS), which has been in operation since 2003. Within CAS, there

¹ For further details on regional cooperation in agrobiotechnology, see documents prepared by the IDB (Trigo et al., 2002), Cambiotec (2002) and others.

² The OAS has promoted information initiatives, such as SIMBIOSIS and efforts involving biotechnology indicators.

is the Agricultural Policy Network (referred to as REDPA in Spanish) that serves as the regional technical support system for CAS. One of the technical groups established under REDPA is responsible for public policies in biotechnology and bio-safety. This group has been active and has made regional progress on (Resolution CAS/RES. 10-2004 of July 30 of 2004) the harmonization of regulatory frameworks and possible synchronization of the approval of transformation events, marketing aspects and international negotiations, research and information sharing as well as communication.

The HBBP presented here will work closely with all regional initiatives mentioned in this section, but will also respond to the need to promote the appropriate and safe use of agricultural biotechnology. It will also coordinate the implementation of activities with current and potential regional initiatives, the aim being to have a positive impact on the public's perception of the safe use of agricultural biotechnology through science-based information made available to different sectors of the population. Intraregional cooperation in agricultural biotechnology will also be greatly enhanced by these initiatives, especially in policy and information sharing issues that can improve the positioning of the hemisphere in international and global fora.

2.3. Task force of country experts on the HBBP

Pursuant to 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, to discuss the conceptual and operational underpinnings needed for design of the Program. During that meeting, the countries described overall what they were doing in the field of biotechnology and biosafety, reported on studies of the impact of implementation of the CPB on transboundary trade in LMOs (www.iica.int/biotechnology). Information was also presented on the new regional cooperation models being instituted, which the Program could help apply in other regions. IICA reported on its activities 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.

Recognizing the existence of sub regional mechanisms and the need to promote dialogue among the different sub regions, the Task Force recommended that the countries proceed to formulate the HBBP:

- 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 to assist in building a positive public perception of agrobiotechnology in the Region.*
- b. IICA should conduct regional needs assessments, which should include the use of existing studies, assessments to determine how countries in the region can benefit*

from agricultural biotechnology through the marketing of products that will add value to domestic economies.

- c. IICA should assist, as appropriate, in the development and implementation of policy frameworks to support countries in the region that do not have a national domestic policy on agricultural biotechnology.*

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

At the IICA Executive Committee meeting, held in May 2005, IICA gave a presentation on the technical cooperation in agro-biotechnology and, especially, the HBBP. The national delegations commended IICA on its ongoing effort and again endorsed the Program and its lines of action. They also said it was important that the Program facilitate follow-up of the work of *Codex Alimentarius*, 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's perception of the issue of agrobiotechnology, with greater participation by civil society. The delegates also endorsed the importance of supporting initiatives like the NABI and of transferring 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 grains, 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 that have 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. Through Executive Committee Resolution 428, the delegates recognized IICA's technical cooperation in agro-biotechnology and bio-safety.

2.5 The strategy for preparing the HBBP

Following the first task force meeting held in Cancun, Mexico, IICA developed a general framework document on the hemispheric biotechnology and bio-safety program, based on the set of recommendations given by this group. This document was then circulated to member countries, and the members of the Task Force, including the biotech group of CAS, sought suggestions and comments to be incorporated into the document. With input from all concerned parties, IICA developed the framework document. This served as the working document in developing the program on agro-biotechnology and bio-safety during the second task force meeting, held in San Jose, Costa Rica, on May 3 and 4 of 2006.

The Program will be coordinated by IICA's Area of Biotechnology and Biosafety under the Directorate of Technical Leadership and Knowledge Management. It will be assisted by other thematic areas, such as agribusiness, technology and innovation, agricultural health and food safety among others. These areas will provide technical input on the subjects in which they specialize and that are relevant to the specific activities included in this program. The implementation of the program will necessarily involve IICA's regional operations offices, regional specialists and will involve the use of mechanisms for technical cooperation between countries via PROCIS, SICTA, and regional and international research centers, such as CATIE and CARDI, among others.

Furthermore, the Program will actively involve different entities working in the development, management and safe use of agrobiotechnologies and trade in products obtained from them. They will be substantive actors drawn from governments, the private sector (e.g., agro-industry), academia and civil society in general.

2.6 Dissemination of information about the program

Details of progress with the Program and its outcome will be disseminated widely among the governments of the countries and different interest groups associated with the Program's objectives and activities. The Program will be evaluated and modified, as needed, over time, taking into account the developing situation with respect to agrobiotechnology and the changing dynamics in both national and international fora..

3 PURPOSE, MISSION AND OBJECTIVES OF THE PHBB

3.1. Purpose

To facilitate mechanisms for the development, management and responsible use of agrobiotechnology in order to promote competitive and sustainable agriculture in the Americas.

3.2. Mission

Identify and promote opportunities for the execution of activities between all interested parties, utilizing available resources and existing institutional (national and regional) channels.

To achieve the above, IICA through the HBBP, will coordinate joint activities among interested parties in order to promote efficient information sharing, capacity building and consulting in public policy development and decision making.

3.3. Objectives

1. To support the gathering, analysis and dissemination of existing information 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.
2. To support the member countries in conducting needs assessment at the national and regional levels, to determine the development and appropriate use of agrobiotechnologies.

3. To support the development, implementation and communication of transparent, science-based policies and regulatory frameworks and, where appropriate, facilitate regional harmonization.
4. To promote transparent communications on the risks and benefits of agrobiotechnology, and encourage the authorities to make the issue of public perception an important component of national agrobiotechnology policies and programs.
5. 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.
6. To promote studies, discussions and analyses of the implications of national and international norms and regulations, as well as international negotiations and agreements, on matters related to agrobiotechnology and biosafety, with special emphasis on their impact on trade.

3.4. Activities to be undertaken by the program as specified under each objective

This program contemplates the bellow indicated activities that deal with either policy and regulatory framework issues, information dissemination and sharing, impact assessment of agricultural biotechnology or needs assessment including benefits and opportunities.

At its second meeting, held in San Jose, to formulate the program with IICA, the hemispheric task force in agro-biotechnology and bio-safety, outlined the following activities identified under each objective to be carried out by the program. These are:

- 3.4.1 Objective 1.** To support the gathering, analysis and dissemination of existing information to enable national officials to design policies and take decisions based on scientific and technical evidence, and provide the public with objective information on agro-biotechnologies.

Activities:

- 3.4.1.1** The publication of periodic reports that highlight the status of agro-biotechnology in the Americas, as compared to other regions of the world, especially those that have dynamic biotechnological development. This publication is to be disseminated to the different stakeholders of IICA, namely, governments of member countries for their use in the

development of national policies and regulatory frameworks related to agro-biotechnology, academia, social organizations and the general public. Distribution will be via hard copies and electronically.

3.4.1.2 To consolidate an information and communication system specializing in agro-biotechnology and bio-safety as a basis for achieving all of the above, which has a direct impact on public policies, decision makers and those who form public opinion, and to have access to an up-to-date system for monitoring advances and developments in biotechnology.

3.4.2 Objective 2. To support the member countries in conducting needs assessment at the national and regional levels, to determine the development and appropriate use of agro-biotechnologies.

Activities:

3.4.2.1 IICA continues to conduct regional needs assessments, which includes the use of existing studies, assessments to determine how countries in the region can benefit from agricultural biotechnology through the development and marketing of products that will add value to the countries' economies

3.4.3. Objective 3. To support the development, implementation and dissemination transparent, science-based policies and regulatory frameworks and, where appropriate facilitate regional harmonization.

Activities:

3.4.3.1. Identify key elements that could be considered for the development of policies and regulatory frameworks, taking into account existing models and experiences in other countries.

3.4.3.2. Facilitate the sharing of experiences in the implementation of policies and regulatory frameworks between countries and regions.

3.4.3.3. Support initiatives to establish regional groups for cooperation on agro-biotechnology and bio-safety.

3.4.3.4. Organize capacity-building activities, when appropriate, based on the needs assessment.

3.4.4. Objective 4. To promote transparent communication on the risks and benefits of agro-biotechnology, and encourage the authorities to make the issue of public perception an important component of national agro-biotechnology policies and programs.

Activities:

- 3.4.4.1** Gather and analyze available information and studies related to public perception of agro-biotechnology and bio-safety in the region.
 - 3.4.4.2** Identify and utilize key spokespersons and mechanisms /methods for communicating to the public accurate information on agro-biotechnology and bio-safety.
 - 3.4.4.3** Provide authorities in the region with information regarding the impact of public perception on the acceptance of agro-biotechnology and its products, and promote the incorporation of this issue into national agro-biotechnology policies and programs.
- 3.4.5 Objective 5.** To support the development of scientific and technological capabilities in the field of agro-biotechnology by means of regional strategies and cooperation among countries and regions.

Activities:

- 3.4.5.1** To implement activities aimed at strengthening institutional capabilities, with an emphasis on scientific and technological aspects related to: intellectual property, bio- and agri- trade, knowledge management, quality and food safety, research and infrastructure, to the extent that they have been identified as national or regional needs, using IICA's regional technical cooperation instruments.
- 3.4.6 Objective 6.** To promote studies, discussions and analyses of the implications of national and international norms and regulations, as well as international negotiations and agreements, on matters related to agro-biotechnology and bio-safety, with special emphasis on their impact on trade.

Activities:

- 3.4.6.1** Production and distribution of analytical documents that can assist countries in understanding the implications of the implementation of norms, regulations, and decisions etc., under the CPB, WTO, and standard setting bodies, among others.

- 3.4.6.2** Continue to facilitate strategic meetings to discuss the implications of international negotiations on matters related to agro-biotechnology and bio-safety.

4 SOME UNDERLYING PRINCIPLES OF THE PROGRAM

Implementation of the Program will be based on a series of principles. The Program will:

- Acknowledge the existence of ongoing regional and hemispheric programs, projects and mechanisms, and implement activities that will strengthen the Program's actions and avoid a duplication of effort.
- Provide the national authorities with the authoritative, timely and relevant information they need to take important national decisions and participate in international fora.
- 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.
- Solicit support for the Program from 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 Strategy For Implementing The Program

This section describes how the Program will be implemented including strategic partnerships, monitoring and evaluation, funding and mechanisms for networking with the steering committee as well as the establishment of future trends in agricultural biotechnology and biosafety and accountability.

5.1. Steering Committee

The Task Force, comprising country experts and IICA professionals, which drafted the Frame of Reference and formulated the program, will continue to operate in the form of a network, holding on-site meetings and interacting on-line to provide guidance and feedback as the program evolves over time. The Task Force will continue to explore efficient mechanisms for implementation of the HBBP, including nodes.

5.2 Strategic partnerships

To implement the Program, technical capabilities in the scientific and technical, educational, institutional and financing fields will be utilized from IICA, member countries and both regional and international organizations (FAO, ISAAA, etc.) with a demonstrated interest in promoting the responsible use of agricultural biotechnology. Priority will be given to strategic partnerships with international and regional technical cooperation and financial agencies. The partner organizations will take part in the meetings and workshops held to implement the program, as appropriate.

5.3 Funding

Funds and in-kind contributions will be necessary for the formulation and implementation of the Program. IICA will allocate a specific budget that will be used as a

seed fund for the formulation of the Program. It will also contribute its specialists in the subject matter as well as its infrastructure (network of 34 Offices in its member countries). Adequate core budgetary funding should be reflected in IICA's medium-term plan (2006 – 2010), which is currently being developed. Additional contributions from member countries and other partners may be sought to sustain the program over the long term, in accordance with their recognition of this reality in IABA Resolution 386.

5.4 Future trends

IICA, along with the countries, should consider and anticipate future trends in agricultural biotechnology at future Task Force meetings.

5.5 Accountability

IICA will report to its Members and the Task Force and to the corresponding authorities on implementation of the HBBP and on the objectives of the Program have been advanced in order to assess its effectiveness..