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# **The new agro-biotechnologies**

**Challenges,  
trends and  
institutional  
considerations**

# Latin América and the Caribbean: The new agro-biotechnologies, challenges, trends and institutional considerations

*An analysis of the challenges and trends that affect the development and marketing of new agro-biotechnologies in the Latin American and the Caribbean countries.*

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## 1. Introduction

In recent years, food production in the region of Latin America and the Caribbean (LAC) has, on average, increased at a slightly higher rate than the growth of its population (almost 1% annually). However, this has not occurred in the same way in all regions and is below the world trend (Figure 1). To improve the situation, a major effort is required to transform agriculture, making it more competitive while at the same time reducing the levels of rural poverty and conserving natural resources. Such efforts should also aim to increase the region's share of world trade, both in terms of supplying the necessary volumes and providing better quality, more nutritious and safe foods. In this regard, technical change in agriculture, based on research and technological innovation, becomes a strategic variable of growth and agricultural development (Ardila and Seixas, 2003).

Taking advantage of the opportunities and challenges created by the new environment, both those mentioned above and others— changes in consumers' perceptions of food quality, trends in demand for food products and the transformation of the food industry— requires countries to participate in the new scientific and technological revolution. There is consensus among the international scientific community that conventional technology, alone, will not be sufficient to increase food production, in terms of quantity and quality, to feed a population that will almost double in the next 50 years. In this context, it is becoming clear that agricultural output and the food trade are increasingly influenced by the emergence of new fields of knowledge, such as the new agro-biotechnologies.

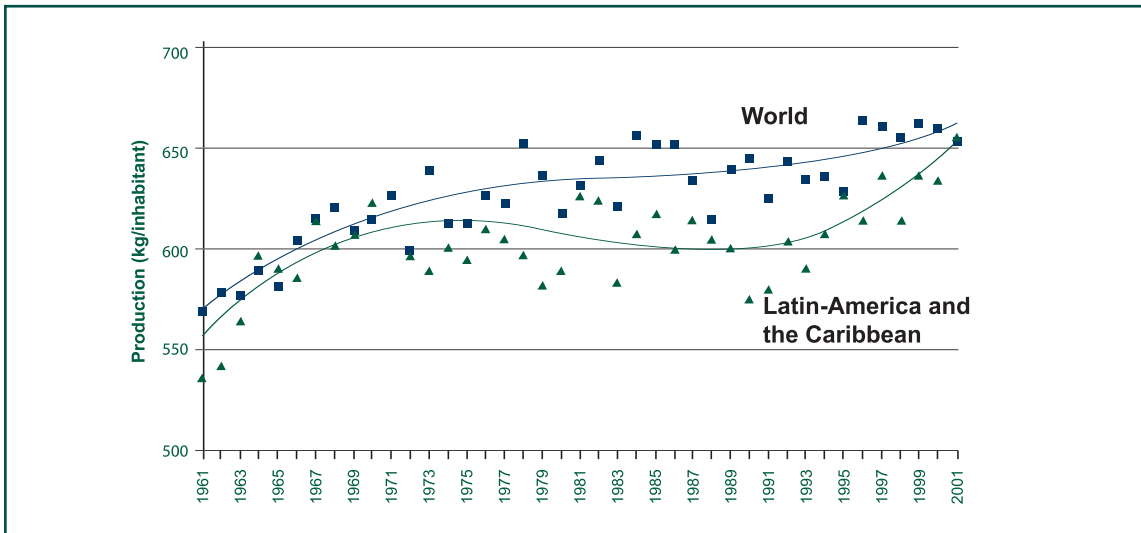
There is little argument about the indisputable advantages offered by new biotechnologies in their application to human health, or in the study and use

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IICA, San Jose, Costa Rica. February 2005. We are grateful for the valuable comments and improvements to this document made by Agustin Lopez, Jorge Cabrera, Marta Valdez, Viviana Palmieri, Jorge Ardila, Assefaw Tewolde, Eduardo Rojas y Tim O'Bryan.

## Production of food crops per capita, 1961 - 2001.



Source: Data FAO, preparation T and I Area, TGS, IICA  
Food crops: cereals, roots and oil seeds.

of molecular markers to identify genotypes with desirable characteristics for genetic improvement. However, their application in genetic engineering for the development and production of genetically modified live organisms (LMO) for use in agriculture and food has become the focus of an intense, and sometimes emotional, debate. Biotechnologies contribute to improvements in production and productivity, to the genetic characterization of lesser-known species; it helps reduce the use of agrochemicals that pollute the environment and reduces production costs. There are also several examples of how molecular techniques may be used to limit the spread of diseases, through the development of new vaccines. Recently, vitamin A (beta carotene) and iron have been incorporated into rice - the so-called "golden rice" -, which can improve the health of many poor communities. Nevertheless, these techniques may also give rise to products with potentially adverse effects for the conservation of genetic diversity, the environment and human health.

In the area of livestock, major progress has been made in the application of biotechnology, for example, in pharmaceutical applications of transgenic technology for human and animal health. Production of transgenic animals has been on a smaller scale than for plants, for technical and economic reasons, among others. The new biotechnologies may accelerate the process to identify genes with desirable effects on characteristics such as the growth, production and quality of livestock products. Molecular techniques make possible the

use of pronucleus from fertilized ovules and animal cloning; they also help determine paternity in animals. Another significant advance is the application of food "traceability" techniques, especially to meat products, an aspect with major implications for trade. At the same time, the application of molecular genetics to determine the quality of milk (e.g. casein) has a significant impact on milk prices in the world market.

It is important to emphasize that as a result of scientific advances, a new generation of technologies is emerging with a different approach to transgenesis, the basis of the current LMOs. These technologies are based on a knowledge of the characterization and functioning of genes, which make it possible to activate or deactivate genes from the same individual, or insert the genes of individuals that are very closely related taxonomically, in order to express characteristics that are desirable from the point of view of producers and consumers. This new technological era, leading to the control of genetic expression - principally the genetic use restriction technologies, such as those at the level of variety or characteristics, known as "GURTS" (Genetic Use Restriction Technologies) - may bring benefits for different types of agriculture. However, to achieve this it will be crucial to ensure the ethical, equitable and transparent management of these innovations.

This document summarizes some aspects of the agricultural context in relation to biotechnology, particularly LMOs, trends in their use and some consider-

*Agricultural output and the food trade are increasingly influenced by the emergence of new areas of knowledge, such as the new agro-biotechnologies.*

ations on institutional models, including aspects of biosafety and trade. It also includes some thoughts on the institutional management of the new agro-biotechnologies.

## **2. Important contextual aspects of biotechnology**

In relation to the points discussed above, we emphasize four important aspects for improving agricultural production by promoting technological change using the new agro-biotechnologies.

The first aspect concerns the need to modernize agriculture, given its impact on socioeconomic growth (in its expanded conception, agriculture contributes nearly 25% of the region's total gross domestic product (GDP)) and its key role in food security. Making better use of the existing agricultural area, breaking through yield ceilings, controlling pests, ensuring better crop adaptability to climatic and biotic stress, improving their nutritional quality and protecting the environment, are challenges that are more easily faced if the new agro-biotechnologies are used in combination with conventional technologies.

The second aspect is that the most significant impacts on the production and productivity of commercially grown crops, using genetic engineering techniques to produce LMOs, have occurred mainly in a few crops, largely for the production systems of temperate ecosystems. The challenge is to intensify existing efforts to apply these techniques and obtain benefits for the products and socioeconomic conditions of agriculture in the tropical belt. This zone contains the planet's greatest biological diversity and yet it also suffers from the highest levels of rural poverty. Despite some efforts by the international research system, and by a few countries, the development and production of new plant and animal genotypes obtained using new techniques, that are specifically adapted to local ecosystems and that also conserve the existing genetic diversity, has yet to materialize in a systematic manner.

The third aspect has to do with the development of new agro-biotechnologies and their application in the sustainable use of genetic resources in LAC –a region that contains four of the 11 international centers of origin and/or diversity. The new techniques bring an unprecedented increase in the strategic value of genetic resources, since they enable us to

better understand their true diversity and expand their use. Being able to better characterize the diversity of existing genes, knowing how they work and gaining a better insight into their expression, through advances in biotechnology, emerges as a great opportunity.

The fourth aspect is the comprehensive international regulatory framework that influences the development, use and marketing of new agro-biotechnologies. Of particular importance is the Cartagena Protocol on Biosafety (CPB), which entered into force in September 2003, in the context of the Convention on Biological Diversity; the World Trade Organization agreements, such as the Agreement on Trade Related Intellectual Property Rights (TRIPS) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS); the agreements reached under the International Plant Protection Convention (IPPC) and the guidelines of the Codex Alimentarius; and, more recently, the International Treaty on Plant Genetic Resources, aimed at promoting the conservation and sustainable use of these resources and the equitable distribution of the benefits derived from their use in agriculture and food security.

## **3. Trends in the development and use of LMOs**

In LAC, there have been major advances in the commercial application of biotechnology, particularly in the agricultural sector. However, when compared with other regions of the world, it is clear that the use of biotechnology for commercial purposes has been slower and only began towards the end of the eighties with the application of modern biotechnology. In recent years, some companies have developed recombinant proteins, monoclonal bodies and animal vaccines, which are marketed worldwide. Nevertheless, the lack of consistent national policies to support innovation, technology transfer and marketing, together with certain regulatory measures, have meant that the region's biotechnology industry has not experienced a sustained development. The "first generation" biotechnologies are the most widely applied in the Latin American and Caribbean countries: micro-propagation, the use of materials produced in the industrialized nations and bio-fertilizers and bio-pesticides. In 2002, studies by CamBioTec identified 432 biotechnology companies in 14 countries of the region, corresponding to the sectors of human health, animal health, agriculture, food, environment and industry.

*The use of biotechnologies and genetic engineering techniques for the development and production of genetically modified living organisms (LMOs) for use in agriculture and food has become the focus of an intense, and sometimes emotional, debate.*

In the case of the new agricultural biotechnologies based on genetic engineering, we see a changing situation, both in the world as a whole and in the region. The marketing of LMOs is not only affecting the production and productivity of some crops, but it is also changing the characteristics of the agricultural supply itself. The value of the world trade in these crops went from US \$75 million in the mid-1990s to nearly \$4.700 million in 2004, representing almost 15% of the value of commodities traded and 16% of the world trade in seeds (Clives, 2004). The region presents a contrasting situation in terms of the adoption and marketing of LMOs for agricultural use. On the one hand, large areas of the region are planted with transgenic crops, accounting for nearly 28% of the total cultivated worldwide and occupying second place after the United States and Canada together, which represent 65% of the area planted. On the other hand, few LAC countries grow these crops commercially. At present, commercial plantations are reported only in Argentina, Brazil, Mexico, Uruguay, Honduras, Colombia and Paraguay (Clives, 2004; Runge, 2004). The largest producer is Argentina, with nearly 16 million hectares and the predominant crop is soybean, and to a lesser extent, maize and cotton.

In general terms, the transgenic crops that have been commercially planted in some countries of the region in the last five years, with annual variations, have been soybean, cotton, maize, carnations, potato and canola. Here, work has essentially focused on four dominant characteristics: tolerance to herbicides, resistance to insects, resistance to viruses and resistance to fungi/bacteria. In other countries, research is carried out and/or mother seeds are produced by way of “contra-season” planting for re-export, without being used commercially in the domestic sphere. This is the case, for example, of maize in Chile, and soybean and cotton in Costa Rica.

At the same time, some LAC countries have achieved advanced levels in research to develop the processes of genetic engineering, transformation, development and testing of materials derived from transgenic plants. Although the LMOs on the market come from private transnational companies of developed countries, in the developing countries it is public research centers that are beginning to make major strides in the field of genetic engineering based on recombinant DNA for applications in agriculture. For the most part, these studies do not contemplate public-private alliances, but rather partnerships between public institutions. An IFPRI study of 15 developing

countries around the world, on the pipeline of stable transformation events based on recombinant DNA technology, found that such partnerships accounted for 40% of a total of 201 events. (Cohen, 2005).

In the region, major strides in agro-biotechnology research are evident in Brazil, Cuba, Argentina, Mexico, Chile, Costa Rica, Puerto Rico, Colombia, Uruguay, Jamaica and the Dominican Republic, among others. In LAC there are nearly 700 laboratories working in the general field of agricultural biotechnology; nearly 2000 researchers (Redbio/CATBIO, 2004); and more than 800 field assays in transgenic crops during the last ten years, accounting for nearly 20% of the world total (Trigo, et al (2002). This research work covers crops such as banana, coffee, tomato, potato, rice, maize, sunflower, papaya, yucca, vegetables, sugar cane, forestry species, canola, sweet potato, alfalfa, fruits, flowers, tobacco, squash, some forest species and sorghum, among others. In addition, several agricultural research centers of excellence are carrying out highly advanced work in the new agro-biotechnologies in countries such as Argentina, Brazil, Costa Rica, Mexico, Cuba, Colombia, Chile, Jamaica, the Dominican Republic, Venezuela and Uruguay, to mention some (CamBiotec, 2003). Similarly, the region participates in and benefits from biotech programs and projects applied to agricultural species by the international centers of the CGIAR based in LAC: CIAT, CIMMYT, CIP, and regional centers such as CATIE, among others.

Nevertheless, the problem of under-investment in science and technology that affects LAC is also reflected in the field of the agro-biotechnologies. Although it is difficult to quantify national investment exactly, based on the figures reported in studies for some countries, we may infer that these are low. A rough estimate —combining figures from different sources and making a hypothesis— suggests that regional investment in public research on agricultural biotechnology does not exceed US\$ 30-40 million annually; in other words, it represents only 5% of total public investment in research. This situation deserves to be explored further. Research intensity in agro-biotechnology in the region is low

compared with developed countries. ESA/FAO studies for some nations of the world show very low research levels for developing countries in general. For example, in Colombia and Mexico investment levels in agrobiotechnology research account for around 1.2 to 6.8% of total national investment in agricultural research (Cohen et al, 2004). At the same time, investment by private industry in developing nations is minimal when compared with the developed countries. LAC faces an enormous challenge to allocate more resources to these activities, given that the region as a whole on average assigns less than 0.40% of its agricultural GDP to research, in contrast with the investments made by developed countries, which exceed 2.5%.

#### 4. *The institutional model of the new agro-biotechnologies*

The institutional model that characterizes the development of the new agro-biotechnologies - in this case commercial LMOs - differs from that of conventional technologies. In essence, the new agrobiotechnologies are being developed in the context of technological innovation processes and the privatization of knowledge, which link research with industry and the markets. Furthermore, the institutional model is characterized by a complex and demanding regulatory framework.

**Technological innovation.** Knowledge and products derived from conventional technologies, such as high-yield crop varieties produced in the context of the green revolution, occurred under a technological change model based on a traditional and lineal process of generation and transfer of technology. Research products, both at the national and the international level, were considered as public, national or international goods, respectively. National research institutes and international centers were the principal, if not, the only source of technology. In the case of the LMOs marketed until now, although these are derived from scientific and technological work carried out in public institutions — mainly universities and centers of excellence— since the 1990s these have been produced mainly by the private sector. In practice, LMOs are produced by five large multinational firms and, therefore, are not goods of the international public domain. In fact, the new biotechnologies, together with the information and communication technologies, are clear examples of the global trend toward the privatization of knowledge.

The development of LMOs for the markets has essentially occurred in the context of a new para-

digim, based on technological innovation, which began in the industrial sphere but is increasingly applied in agriculture. Under this paradigm, innovations are not only the result of public research, but come from new and varied sources, such as partnerships between public-private institutions. Their vision is based on agroindustrial chains and the premise that innovation really happens when knowledge is taken to the marketplace.

**Industrial development.** Largely as a result of the situation described above, the development and marketing of crops with LMOs has some features in common with the development of products by the pharmaceutical industry, although there are also major differences. Just as patients wish to know how drugs are used, their composition, effects and contraindications— in the case of LMOs, consumers and society in general have begun to take an interest in obtaining more information about their characteristics, risks, safety and effects on health, among other aspects. At the same time, the process to develop these products – from research, to laboratory tests, field trials and validation exercises- is very costly for scant public budgets. Equally, ownership of the components of genetic construction and of processes to obtain LMOs, is governed, above all, by patents in the countries that develop them, and is also protected in several other countries. This contrasts with the conventional plant varieties, for which property rights are granted under a sui generis system, as in the case of Plant Breeders' Rights (PBR). However, the companies that produce LMOs argue that this system does not appear sufficiently robust to protect the final transgenic product or the components used in the engineering and transformation processes, since its scope is not as wide. For example, the specific protection of new genes introduced into a modified variety would not necessarily be assured under the PBRs.

**Regulatory process.** Agricultural research products based on conventional genetic improvement techniques are governed by more simple and less costly regulatory requirements, than those derived from genetic engineering, such as LMOs, given their novelty and biological nature. The regulations are related to biosafety in its different dimensions and intellectual property, an area with its own regulatory framework under the World Trade Organization's TRIPS Agreement, as mentioned earlier. Biosafety regulation extends to all links of the agrifood chain, beginning with the production base, i.e., the natural resources and, in this case, the existing genetic diversity, through primary production, the product processing and transformation stages and finally the consumer of the product or commodity. Figure 2

shows the scope of biosafety regulation, both in primary production per se and in its backward linkages with natural resources and the supplies sector, and forwards with industry and consumers.

Biosafety regulations contemplate risk analysis of a product's possible impacts on agriculture itself, the environment, genetic diversity and human health. In the case of research using LMOs, this must be authorized by the competent national authorities on biosafety. For the subsequent release and formal launch of an LMO into the marketplace, in addition to traditional requirements, risk evaluation and marketing permits are required. Furthermore, under the Cartagena Protocol (CPB) LMOs must also be identified. Table 1 shows a comparison between the regulatory processes required for materials obtained through conventional improvement techniques and for those based on LMOs. It is estimated that the regulatory process to launch a new transgenic material could cost between US\$ 0.1 and 0.8 million per event per year, depending on the country (Atanassov, et al, 2004). These aspects have yet to be determined in the field of livestock. Not all institutions in LAC are able to cover such costs.

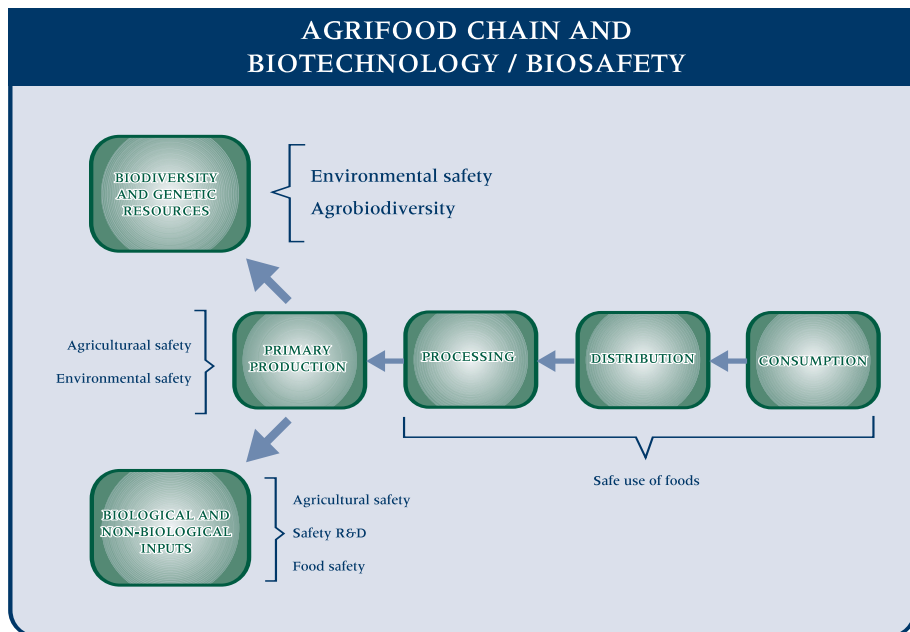


Figure 2 Scope of biosafety in the agrifood chain

## 5. Biosafety and trade

The implementation of the CPB, to which 22 countries of the region are party, requires a set of institutional and technical conditions to be put into place in the signatory countries. These are aimed at guaranteeing the safety of biotechnology within their national jurisdiction and preventing possible adverse effects from the transboundary movement of new biotech products (for example, adverse effects on conservation and sustainable use of biological diversity, the environment and human health).

The CPB is undoubtedly a very important global initiative for the regulation of transboundary movements of LMOs and biodiversity protection. However, as with all international agreements based on consensus, when it comes to their implementation, there are always a number of issues that must be clarified and specified. In the LAC countries varying degrees of progress have been made in regulating products derived from the new agro-biotechnologies. An IICA study shows that 23% of countries have specific biosafety laws for LMOs; 40% have regulations contained in other laws, for example, on plant health or seeds; and 37% lack such regulations (Alarcón, 2002). In the last two years, as a result of

### REGULATORY ADMINISTRATION OF RESEARCH PRODUCTS THAT INCORPORATE THE DEVELOPMENT AND DELIVERY OF LMOs FOR AGRICULTURAL USE, COMPARED WITH CONVENTIONAL TECHNIQUES

PROCESS / MATERIAL	PRODUCTION REGISTRATION	BIOSAFETY (ENV. RISK)	BIOSAFETY (SAFETY)	PROTECTION INTELLECTUAL PROPERTY RIGHTS	MARKETING (identification; etiquetado??)
IMPORTED TRANSGENIC VARIETY (2 YEARS)	<b>V</b>	⊗	⊗	⊗	⊗
TRANSGENIC VARIETY PRODUCED ENDOGENOUSLY (10 YEARS)	<b>G-V</b>	⊗★	⊗★	⊗★ <sup>PBR</sup>	⊗★
VARIETY PRODUCED WITH CONVENTIONAL TECHNIQUES	<b>G-V</b>	?	?	⊗★ <sup>PBR</sup>	?

- ⊗ Infrastructure and regulatory framework in the country
- ★ Additional costs
- GyV** Generation - Validation

Table 1. Regulatory administration of research products that incorporate the development and delivery of LMO's for agricultural use, compared with conventional techniques.



national efforts, support from projects financed by the GEF and international cooperation, the LAC countries have made progress on regulatory aspects as part of the implementation of the CPB.

Although the CPB in its entirety is of interest from the standpoint of trade, for the purposes of this document we will focus in particular on Articles 18 and 24. Article 18 refers to the handling, transport, packaging and identification of LMOs, and clause (2a) covers aspects related to LMOs intended for direct use as food or feed, or for processing, and the measures required for the documentation that accompanies LMOs subject to transboundary movement. Article 24 refers to trade arrangements between Party and non-Party States, and establishes that transboundary movements of LMOs between countries that have ratified the CPB and those that have not done so, should be consistent with the objectives of the CPB, and that "Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements".

In essence, under the CPB's legal framework, the Parties can decide whether or not to allow the entry of commodities and by-products that may contain LMOs, notifying the international community of their decision through an information exchange mechanism via the Internet. Making progress on the implementation of the CPB agreements is a complex matter, given that there are Parties and non-Parties among the developed countries and also among the developing nations. This is not simply an issue of North-South points of view, as some see it, but also South-South. One fact is clear for at least two commodities - maize and soybean - and that is that the signatory countries (Parties to the CPB) export low proportions of these crops, while the non-Parties are the largest exporters. A similar situation arises with imports (Table 2).

It is therefore understandable that there should be concerns over the possible consequences of implementing the CPB between countries that are Parties and non-Parties. To avoid a possible impasse in trade, some

countries have drafted provisional measures, such as the trilateral agreements signed by Canada, Mexico and the United States, in the context of the provisions of Article 18. 2.a of the CPB, on the transboundary movement of commodities that contain or might contain LMOs. The impact of this agreement and the experience derived from its implementation will be important aspects to analyze. As a result of the Meeting of the Parties to the CPB held in Malaysia, in 2004, groups of experts have been established to analyze specific aspects of its implementation and to issue technical recommendations to facilitate the discussions and decisions of the forthcoming Conference in Canada, which will take place in mid-2005.

In synthesis, it will be up to countries and their trading partners to determine the procedures for conducting transactions in accordance with the purposes of the CPB, while at the same time adhering to the agreements adopted in the context of the WTO, in particular, the SPS Agreement and the Code on Technical Barriers to Trade. Analysis of these agreements is essential to find the best possible way of reconciling the measures, in accordance with the different agreements, in order to prevent or restrict the entry of LMOs into the country, or on the contrary, authorize it. As Cabrera (2004) notes, we have yet to determine the contradictions or complementary nature of the applicable regulations and jurisprudence, based on the measures to be adopted—to ban the entry and use of LMOs in a country— especially if the precautionary principle were to be applied. This is an issue of potential conflict.

WORLD PRODUCTION (2004) AND TRADE (1997-2002) IN MAIZE AND SOYBEAN BETWEEN PARTIES AND NON-PARTIES TO THE CPB IN THE AMERICAS AVERAGE ANNUAL PERCENTAGE			
	Share World Production (%)	Exports (%)	Imports (%)
<b>Maize</b>			
Parties	31	1.1	66
Non-Parties	69	98.8	33
<b>Soybean</b>			
Parties	32	31	82
Non-Parties	68	69	18

Source FAOSTAT. Figures prepared by Trade Policy and Negotiations and Technology and Innovation Units of IICA: Oswaldo Segura and Enrique Alarcón with the collaboration Eduardo Rojas

Table 2. Maize and Soybean imports between Parties and Non-Parties to the CPB in the Americas.

Another aspect that deserves special attention in policymaking associated with the implementation of the CPB is related to the budgetary implications of the regulatory processes. On the one hand, appropriate budgets must be allocated to establish and operate regulatory activities. On the other, it is necessary to assess the impacts of applying these measures, not only for research, as already mentioned, but also for the trade of LMOs. Some studies have examined the costs related to the detection of LMOs in shipments at the points of export, which vary according to their degree of specificity, and whether detection is also required at the point of import. (Kalitzandonakes, 2004). It is important to intensify cost analyses and the evaluation of socioeconomic impact, coordinating technical efforts between Parties and non-Parties to the CPB, to provide a basis for decision-making. In this regard it is very important to consider who absorbs the increased costs in the agrifood chain, as well as the future impact that this might have on food prices.

*The new biotechnologies, together with the information and communications technologies, are clear examples of the global trend towards the privatization of knowledge.*

## 5. Some thoughts on institutional aspects

The opportunities afforded by the new fields of agricultural biotechnology when used in combination with conventional technologies, and efforts to ensure their safe use, implies increasing institutional efforts in the national and hemispheric spheres in various aspects, including the following:

- Establish explicit policies, based on needs, visions and impact analyses, and form teams to conduct a prospective analysis of the role of biotechnology in development and to monitor the impact of international agreements;
- Improve processes for identifying and setting priorities in order to take better advantage of limited resources and achieve high-impact results in a context of equity;
- Move towards processes that focus on innovation, creating the conditions to promote national and regional public-private enterprises that link research with the markets;
- Strengthen the institutional frameworks of research centers and regulatory bodies, through institutional capacity-building efforts towards the development and use of agro-biotechnologies;
- Implement a rational regulatory environment to create confidence among the different stakeholders, promote scientific-technological progress and evaluate the impact of the measures;
- Work towards the harmonization of policies and regulations among countries in aspects related to agricultural biotechnology and biosafety;
- Reverse the trend of under-investment in science and technology, and therefore in agro-biotechnology in general, in most countries and in the region;
- Create appropriate conditions for the development of agribusiness and agroindustry, including small-scale agriculture to make better use of agro-biotechnologies;
- Intensify technical cooperation efforts between countries, utilizing existing regional mechanisms and promoting the development of a hemispheric strategy to integrate visions and efforts in the Americas in a context of global competitiveness.

*To develop the biotechnology industry requires national policies to support innovation, technology transfer and marketing, as well as regulatory measures to promote agroindustry.*

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