The multinational biosafety project of the Organization of American States

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Financial support: Grant from the Organization of American States.

Keywords: Biosafety Protocol, Caribbean, Latin America, needs, regulations.

The Organization of American States is supporting the project "Biosafety Regulations in Latin America and The Caribbean within the framework of the International Biosafety Protocol". The general objective is to strengthen national skills for the assessment and management of risks of biotechnology food products, and to build up public awareness about their benefits and risks in the participant countries, with the ultimate goal to promote their safe and sustainable use within a protective and trusting environment for the public. The first phase has been focused on the evaluation of the political and regulatory systems in Chile, Peru and Colombia, identification of needs, and development of a

series of biosafety seminar-workshops in the three countries, with the participation of distinguished foreign experts. The second phase, which started in March 2003, has been extended to six countries of Central America and The Caribbean. The project is helping to identify the weaknesses and needs for the establishment of the biosafety protocol in each participating country. It has also establish the specific training needs and is given the bases for the design of general outlines of biosafety training plans, which will contribute to an efficient implementation of the International Biosafety Protocol. The project it is also allowing to coordinate actions between the countries for

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implementation of the protocol at a regional level. On the other hand, the project has allowed to assemble, around discussion tables, international experts with the main representatives of regulatory and academic institutions, business enterprises and NGOs, as well as with congressmen in scientific and technological matters and the protection of biodiversity. Thus, the project has permitted the establishment of cooperation linkages and has contributed to reinforce the notion of the importance of biosafety for national development and the preservation of local biodiversity.

The capacity of countries to carry out risk assessments based on scientific knowledge, is a key factor to determine whether the new living modified organisms (LMOs) and the products derived from them will be harmless to both the consumer and the environment, without imposing unfair limitations on international trade. In the face of this challenge, the United Nations Convention on Biological Diversity held long negotiations ending up on January 29, 2000, when the Conference of the Parties held in Montreal adopted the Cartagena International Biosafety Protocol which regulates the transborder movement of LMOs and derived products so as to preserve the environment and biodiversity.

By the end of July, 2001, 105 states had signed the Cartagena Protocol, including Canada and 18 Latin American and Caribbean countries (among them Chile, Colombia, and Peru); and 51 countries had ratified the Protocol. Therefore, the Cartagena Protocol entered into force on September 11, 2003. According to Article 22 of the Protocol, cooperation mechanisms will be implemented to "develop and strengthen the human resources and the institutional competences in biosafety, including biotechnology" in less developed countries, with the financial support of the Global Environmental Facility (GEF). The emphasis on capacity building will include scientific and technical training in the adequate and safe management of biotechnology, in the practice of biosafety risk assessment and management, and in the improvement of technological and institutional biosafety skills. On this purpose, some organizations in Latin America have been advancing capacity strengthening activities in biosafety, as an additional support to national GEF projects which were only initiated in the year 2002.

Since 1995, and thanks to the financial support from the International Development Research Centre-IDRC and the sponsorship of other international institutions, the CamBioTec Initiative has been working on the issue of strengthening capacities in biosafety and public awareness in the Latin American region, having organized several seminars and courses on biosafety in Argentina, Chile, Colombia, Cuba and Mexico. CamBioTec experience on this issue, up to 1999, has been summarized in a journal article (Verastegui, 1999).

During years 1998 and 1999 CamBioTec designed and implemented a biosafety and public awareness project in Argentina and Chile, based on the transfer of Canadian experience. It aimed at reinforcing skills for the assessment and management of risks derived from LMO products at the Argentinean and Chilean biosafety regulatory agencies. This tri-national project was financially supported by the Canadian International Development Agency (CIDA), and included a number of activities, such as: 10 internships of Chilean and Argentinean experts in Canada; a comparative study on the biosafety regulatory systems in the three countries (Flint et al. 2000); six courses on risk assessment and management: four seminars on biosafety and public awareness; wide dissemination of a Canadian book to enhance public education (Grace, 1998); and the publishing of two books containing the lectures presented during the two seminars held in Argentina (Dellacha and Verastegui, 2000), and the two seminars held in Chile (Gil and Irarrazabal, 2001). The final completion report describes in detail all activities performed under the scope of this CIDAsponsored project (Verastegui, 2000).

In other countries of the Andean Subregion, rich in biodiversity, there is also great interest in participating in training projects for reinforcing their capacities to implement the clauses of the Cartagena Protocol. The Protocol urges the Andean countries to examine their current situations related to biosafety regulation policies, and to identify future needs in their regulatory systems, institutional infrastructure and human resources. Thus, based on its previous experiences, in March 2001 CamBioTec organized, coordination meetings with the higher authorities of CONICYT (Chile), CONCYTEC (Peru), and COLCIENCIAS (Colombia). The result of these coordination meetings was the agreement to design a multinational project proposal which would include the already mentioned issues, with the purpose to submit it to the Inter- American Agency for Cooperation and Development (IACD) of the Organization of American States (OAS).

Thus, the proposal "Biosafety Regulations in Latin America and the Caribbean within the framework of the International Biosafety Protocol" was submitted and approved by the OAS in January 2002 with a donation of US\$ 57,000 for the first year and US\$ 25,000 for the second year. The first phase was carried out between April and December 2002, under the general coordination of Dr. Lionel Gil, CamBioTec Coordinator in Chile, and the advisory assistance of the CamBioTec Executive Secretariat. This first phase was focused on the evaluation of the political and regulatory systems in Chile, Peru and Colombia, identification of needs, and development of a series of biosafety seminar-workshops in the three countries, with the participation of distinguished foreign experts. The second phase, which started in March 2003, has extended the scope of the project in order to include six other countries from Central America and the Caribbean.

The first phase of the project has contributed to identify the weaknesses and needs for the establishment of the Biosafety Protocol in each participating country. It has also allowed to coordinate actions between the countries for a better implementation of the protocol at a regional level. The results will be shared with other countries of the Region, thus contributing to the development of other projects from both the public and private sectors.

In Brazil [i], initiatives of the Brazilian Biosafety Association-ANBio, a scientific society, established in 1999 have been implemented with the support of Brazilian funding agencies. During the period 1999-2003 around 1.500 people have been trained on risk assessment and risk management of GMOs. Also on the field of public awareness, ANBio has launched its programme of "Science to the Society" which aims to inform the general society and policy makers about the new developments of biotechnology in order to reduce fear.

OBJECTIVES

The general objective of this project is to strengthen national skills for the assessment and management of risks of biotechnology food products, and to build up public awareness about the benefits provided by these foods in Chile, Colombia and Peru, with the ultimate goal to promote their safe and sustainable use within a protective and trusting environment for the public. Furthermore, efforts are being made to create a basis on which Latin American regulations will conform to international agreements, already signed or under negotiation, that will push the need to reform national regulations. These objectives will be achieved by means of promoting the exchange and transfer of technical knowledge and international experiences.

Among the specific objectives of the OAS-funded project, the following can be stressed:

- 1. To evaluate the legal and institutional infrastructure existing in Chile, Colombia, Peru, Panama, El Salvador, Costa Rica, Jamaica, Grenade and Trinidad and Tobago in compliance with the International Biosafety Protocol.
- 2. To establish the training needs of the different social actors with the purpose of ensuring their proper qualifications for enforcing the International Biosafety Protocol of Cartagena.
- To organize biosafety seminar-workshops in Chile, Peru and Colombia for the purpose of making the institutions in charge of the implementation of the biosafety regulations and of the Cartagena Protocol become consciously aware

- of the existing problems and of the need for training of their personnel.
- 4. To elaborate the general outlines for national training programs in biosafety specific for Chile, Peru and Colombia, taking into consideration the training opportunities existing in Canada and Latin America.

PARTICIPATING ORGANIZATIONS

Chile

Participants institutions from the public sector were CamBioTec, CONICYT, SAG, INIA, CONAMA and FIA, which collaborated in organizational, logistic and cofinancing activities. The parliamentary sector, represented by the Senate Commissions for Agriculture and the Environment, actively participated in the organization of an International Seminar held in Santiago. The private sector participated through ANPROS in organizational activities. Furthermore, the United States Embassy collaborated in the co-financing of the international seminar.

Colombia

Participants from the public sector were, COLCIENCIAS, and the Colombian Agriculture and Livestock Institute (ICA), which collaborated in activities related to project development, as well as logistic organizational and co-financing aspects. Collaboration from the private sector came from TECNOS Foundation, the focal point of CamBioTec. Also FAO, the IICA, AgroBio, the Andean Development Corporation (CAF) and the Andres Bello Agreement provided financial support for carrying out the seminar which took place in Cartagena de Indias.

Peru

Participants from the public sector were CamBioTec, CONCYTEC, SENASA and INIA, (organizational, logistic and co-financing activities). The private sector collaborated through ADEX and several enterprises. Furthermore, the International Potato Center – CIP collaborated a lot, both in national coordination and technical assistance.

METHODOLOGY, ACTIVITIES AND RESULTS

The project has been designed in such a way as to promote both North-South and South-South cooperation. Starting from the characterization of the national regulatory systems, the identification of training supply and demand and the levels of public awareness in each country, biosafety training programs were developed as well as public education and communications programs, based on the existing capacities within the participating countries.

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Considering their higher level of development and expertise in biosafety and commercial agri-food biotechnology, the main training effort relied on institutions and experts from Canada, the United States, Argentina, Brazil, México and France mainly through seminars, courses and workshops. Besides this, valuable collaboration was provided by well-known national experts. Complementary technical knowledge in areas which need to be reinforced are being transferred to the corresponding national institutions.

Evaluation of the legal and institutional infrastructure in biosafety:

Specialized consultants developed studies in Colombia, Peru and Chile. They identified the national institutions and organizations related to the formulation of biosafety regulations, to the implementation of regulatory systems and to the process of risk assessment and management derived from the use of LMOs in human health, agriculture, food, livestock, animal health sectors and the environment. Furthermore, the national studies included analyses on the interpretation and use of the precautionary approach in the country and a revision of the experiences and methodologies employed in other countries for the evaluation of LMO-derived socioeconomic impacts. During 2003 similar activities are carrying out in Panama, El Salvador, Costa Rica, Jamaica, Grenade and Trinidad and Tobago.

The Colombian study identified the institutions and organizations related to the design and implementing biosafety regulations, regulatory systems, and assessing and managing the risks derived from the use of LMOs in the human health, agriculture and livestock, food and environmental sectors. A comparison was carried out between the Colombian provisions in force and the articles of the Biosafety Protocol, and the shortcomings of the national norms to comply with the requirements of the Protocol were identified. An analysis on the interpretation and use of the precautionary approach was performed and, finally, the methodological experiences of other countries for the evaluation of socioeconomic impacts derived from the use of LMOs were revised.

Peru presented a study in which the legal and institutional biosafety infrastructure in the agricultural, livestock and forestry sectors are characterized. A comparative study with the legislation of other Latin American countries, among them Argentina, Bolivia, Brazil and Colombia, was also carried out. Finally, a revision on the use of the precautionary principle in the legislation and on the methodologies used for the analysis of the socioeconomic impact in Brazil, Argentina and the U.S., was carried out.

In the case of Chile, the study included a revision of the biosafety regulatory frame, both at the national and the international level. A comparison was made between the Chilean provisions in force and the clauses of the Biosafety Protocol. The shortcomings in the national legislation were

identified so as to comply with the demands of the Protocol. Concerning the precautionary principle, its enforcement was reviewed in the Chilean law and some case studies were examined. Finally, three studies were carried out that partly analyzed the socioeconomic impact derived from the cultivation of LMOs. The results were most satisfactory. In the three countries it was possible to establish a biosafety regulatory baseline by means of the revision of the legal and institutional infrastructure. The regulatory shortcomings vis-à-vis the Biosafety Protocol were identified and proposals were conceived to improve them. The application level of the precautionary approach to LMOs was established (in general, none of the three countries presents cases of direct application of this principle to LMOs).

Concerning the socioeconomic impact, all three countries were able to identify the requirements for the establishment of appropriate methodologies at the national level. In the case of Colombia, the study proposes an overall, clear policy within a national regulatory frame that must consider the country's inherent conditions and also be congruent with the different international agreements signed in different sectors. A dispersed normativity was detected, which might produce negative effects when applied, leading to a breach of provisions. In Peru, the existence of a Biosafety Law and Regulation was confirmed, although some articles need to be revised to comply with the Protocol.

In Chile there is also a great dispersion both in the regulations and in the responsibility related to the subject of biosafety in LMOs. Although no national policy for biosafety exists, according to the initiatives that are being carried out, the Chilean option seems to become a country that produces, imports and exports LMOs (ANPROS). The developed regulations comprise only the agricultural sector and do not regulate all phases of LMO development. Finally, it has been concluded the convenience of including the concept of precaution as an approach but not as a general legal principle, since the Precautionary Principle is limited to environmental matters.

The studies carried out in each country were:

Colombia: "Biosafety Regulations in Colombia within the framework of the International Biosafety Protocol." Authors: Efrén Danilo Ariza, María Susana Carrizosa and Juan Carlos Rodríguez.

Peru: "Legal and Institutional Infrastructure in Peru." Author: Dora Pariona.

Chile: "Biosafety Regulations in Chile within the framework of the Cartagena Protocol." Authors: Lionel Gil, Victor Martínez, CamBioTec-Chile.

Biosafety training needs

Assessment studies were carried out in the three countries in order to determine the training needs. The Colombian study assessed the capacities related to risk assessment and control. Information management and public perception of biotechnology were also considered. The analysis was based on information generated by the Interministerial Working Group in Biosafety.

In Peru, the results of a survey to researchers and representatives of institutions (members of the National Biosafety Group) allowed the detection of specific needs in public and private institutions in the area of implementation of biosafety regulation systems for LMOs, risk assessment and management, technical and scientific assistance services and systems of information exchange.

In Chile, the training needs of human resources and the existing biosafety infrastructure were assessed. Data was obtained identifying the needs in information management. Pre- and postgraduate professional and academic careers in the subject of biotechnology were evaluated. It was also established that one of the main handicaps of in research and development on biosafety is the limited infrastructure and human resources in the areas of plant and animal molecular biology and genetic engineering.

In Colombia, it was identified the need to work based on target institutions, such as ministries and regulatory institutions, the National Technical Biosafety Councils (agricultural and livestock), technical teams, opinion forming groups, civil society and non-governmental organizations (NGOs). Among the training tools are informative courses, high level courses, training courses, internships and workshops. Risk assessment capacities have not reached the required level, and the structuring of a node of institutions of excellence is needed to support the regulatory agencies.

In Peru, the most important training needs include the new science and technology knowledge related to LMOs, risk management in all spheres (environmental and health), methods for detecting LMOs and for determining socioeconomic impacts. The needs for regulations related to the transborder movement of LMOs and for improving communication with the public were also detected, and, finally, the importance of developing short- and long-term training programs for regulatory agencies and for the reinforcement of secondary and university education, respectively, were established.

In Chile, the training requirements are related to those individuals who are in charge of training in the regulatory agencies, who will use the regulatory tools put at their disposal. This type of work calls for professionals with a full-time dedication to biosafety and biotechnology within these agencies. Competence is also lacking in information handling. Shortcomings were also found in risk communication and in the benefits of biotechnology to

society. The studies carried out in each country are listed below.

Colombia: "Biosafety Regulations in Colombia within the framework of the International Biosafety Protocol". Authors: Efrén Danilo Ariza, María Susana Carrizosa and Juan Carlos Rodríguez.

Peru: "Training needs in Peru". Author: Iris Verastegui.

Chile: "Overview of Biotechnology in Chile. Chapters: 'Requirements for Implementing the Protocol' and 'Training of Human Resources'". Authors: Lionel Gil, Utz Dornberger, and Víctor Martínez.

Seminar-Workshops

An itinerant seminar was carried out in Chile, Peru and Colombia, with the participation of nine foreign experts from Argentina, Brazil, the United States, France and Mexico. The experience of national researchers and academics, who presented a special view of the situation of biotechnology and biosafety in each of their countries, was also included in the local agendas.

In Chile the objectives were: to make information available to decision-makers, to assess Chile's strong and weak points concerning the Biosafety Protocol, and to train officers, decision-makers and researchers, by means of the event itself and two satellite courses. A point worth stressing was the ample coverage of the event by the communication media, a fact which contributed to improve the public's level of perception about biotechnology and the LMOs. The target public were controllers, inspectors, researchers, the media and the general public.

In Peru, the main objective was to train professionals, researchers and technicians in the principles of risk assessment and management of transgenic materials and in the regulatory frames that support them. Main participants were government officers, i.e. professionals from **SENASA**, **INIA**, and other institutions belonging to the National Biosafety Group.

In Colombia, the workshop was aimed at government officers, especially at members of the institutions responsible for biosafety legislation, at members of the National Technical Biosafety Committees, both agricultural and livestock, and at members of the academic and productive sectors. The main objective of the workshop was that of opening spaces for discussion between government organisms and the academic and productive sectors.

The series of three events was attended by approximately 360 people (100 in Colombia, 60 in Peru and 200 in Chile). For each of the events a CD was recorded with the presentations of the experts attending the seminar. This will expedite spreading of the information to the public. The final discussion tables in each country, allowed for the

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elaboration of recommendations which may serve as backup documents in decision-making related to the biosafety of LMOs. Press covering was greater in Chile, where national and international experts were interviewed by written, radio and television media, allowing for a greater coverage of the event's objectives. The importance of the participation of members of Congress and of Government representatives in the Seminars must be stressed, as it provides evidence of the national interest for taking effective measures in biotechnology matters. In Chile, the satellite courses permitted the training of approximately 30 professionals in the subject of detection of LMOs in foods and seeds and in the evaluation and management of risks derived from the use of LMOs.

General outline for national biosafety training programs

On the basis of the consultancy studies and the conclusions and recommendations of the national seminars, additional recommendations were formulated to complement the existing biosafety regulatory system model, by filling in gaps, omissions or lapses. Furthermore, a specific biosafety training program is being designed for Chile, Peru and Colombia taking into consideration the national objectives in biotechnology, adapting the needs to the potential training offer existing at the local, regional, and more developed countries' level, mainly Canada. Specially, the proposed program includes training in:

- (i) The implementation of regulatory systems for LMOs and by-products;
- (ii) Risk assessment and management, related to the use of LMOs and their by-products;
- (iii) Technical and scientific assistance in risk assessment and management due to the use of LMOs and by-products;
- (iv) Systems of information exchange, information dissemination and public education in biosafety of LMO by-products.

DISCUSSION

Precautionary Principle: Due to the absence of relevant experiences in the participating countries, the studies related to the application of this principle described general aspects in other countries, or were limited to cases related to species not genetically modified (*i.e.* introduction of *Fusarium oxysporum*, bivalves of the family Pteriidae, and variaties of Tilapia in Colombia).

Socioeconomic Impact: Due to the absence of legislation and experiences relevant to the subject in the participating countries, the analyses on methodologies were limited to statements of a general character in Colombia, to a brief revision of the situation in other American countries on the part of Peru, and to the economic and labour impact of transgenic seed production in Chile.

Interinstitutional Coordination: Some difficulties in interinstitutional coordination at a national level were observed for the design of policies, the carrying out of studies and the provision of consultantships to decision-makers, due to scanty communication between agencies and the public sector. There is a need to reinforce the carrying out of permanent interinstitutional workshops aimed at defining clear overall policies at a national level in matters related to LMOs. At this respect, we draw attention to the recent creation, in Chile, of the National Commission for the Development of Biotechnology.

CONCLUDING REMARKS

The project "Biosafety Regulations in Latin America and The Caribbean within the Frame of the International Biosafety Protocol" has given rise to the first coordinated and systematic effort of training in biosafety, thus becoming a pioneering project, complementary to the GEF (Global Environmental Facility). The OAS project which started in Chile, Colombia and Peru has been extended to six other countries from Central America and Caribbean. It has also provided the possibility of drawing up an inventory of the strengths and weaknesses of the national regulatory systems, determine the specific training needs and design general outlines of biosafety training plans, which will contribute to an efficient implementation of the International Biosafety Protocol or Cartagena Protocol, once the three countries have ratified it. On the other hand, the project has allowed to assemble, around discussion tables, international experts with the main representatives of regulatory and academic institutions, business enterprises and NGOs, as well as with the best informed congressmen in scientific and technological matters and the protection of biodiversity. Thus, the project has permitted the establishment of cooperation linkages and has contributed to reinforce the notion of the importance of biosafety for national development and the preservation of local biodiversity.

The technical and scientific institutions involved in biosafety are expected to offer congressmen all technical assistance needed so as to guide them in well grounded decision-making, specially in the following: determination of the general principles on which a biosafety policy and a national legislation in this matter must be based: assessment of the competences and faculties of public authorities; establishment of the authorization mechanisms corresponding to each activity involving LMOs; the possible adoption of an identification and labeling system; and the adoption of a liability system for the presumable damages that can be caused through LMOs.

At this respect, the discussions of the seminar-workshop carried out in Peru supported the recommendation of the National Biosafety Group to the Congress of the Republic to rule out the project of law that forbid the import, use, marketing and sowing of LMOs. During the development of the project, the Chilean government, with the purpose of

boosting biotechnology in the country, created the National Commission for Biotechnology Development (August 2002), a fact which allows the results of the project to be a good source of information for defining a national policy in biotechnology which will integrate political, social, ethical, health, environmental and biosafety aspects.

In Colombia, the consultancy studies allowed to review the *ex-ante* or *ex-post* methodologies and experiences used in other countries to assess the socioeconomic impacts of LMOs on the biodiversity, considering the values of the indigenous and local communities.

The biosafety regulations must not be converted into coverup barriers for the trade of LMOs, and also they must be in accordance with other legal bodies which regulate related aspects. These regulations must be flexible and dynamic to be able to respond to both the national and the international demands. The experience in other countries indicates that the more general aspects of biosafety must be regulated by a law, while the more technical aspects (and which consequently are subject to greater possibilities of change), should be regulated administratively. It is also necessary to determine the coverage of this legal framework (general application or by specific sectors). Regulations must take into account both the risks and the potential benefits involved by LMOs. Ecological, economic, scientific, cultural, religious and other impacts must be considered. The concept of "acceptable risk level" must be incorporated into the legislation to confront the probability of the occurrence of a risk and its consequences. Also, it is convenient to incorporate the concept of "precaution" as a perspective, and not as a general legal principle, because Precautionary Principle is circumscribed environmental matters and is not of a general nature.

It is absolutely necessary to base the invoking of the precautionary principle or approach on an analysis of previous risks, based on scientific evidence, which allows a case to case identification of the existence of risks that cannot yet be determined. If sufficient scientific evidence does not exist, provisional precautionary measures could be adopted, which would be exceptional and subject to revision. It is important to involve the opinion of all actors during decision processes. For this purpose, it is crucial to establish a strategy of clear communication between civil society, the scientists, regulatory organisms and decisionmakers. Therefore, a wide-ranging, unrestricted. unprejudiced debate has to be encouraged, which will cover all relevant matters. Biosafety is a discipline which is rapidly evolving, and which is fundamental for the development of biotechnology on a national level. Therefore, training in this matter is of the utmost importance, considering the special needs of the Latin American countries, both in relation to native biodiversity and the local environmental setting as to the need of promoting national biotechnological innovations.

It is recommended to support the establishment of national biosafety information networks which should include institutions from the public and private sector and universities. It is also convenient to support the development of biosafety training programs aimed at such areas as: introduction to biosafety of LMOs, molecular and phenotypic characterization of LMOs, interaction between LMOs and the environment, interaction between LMOs and health, biosafety of genetically modified microorganisms and social, economic and legal aspects of LMOs. Research in the areas of biosafety must have common objectives and follow the general guidelines established by the national policy of each country. The studies carried out show that the public has been induced to perceive LMOs in a negative form. However, important international institutions such as FAO. WHO and the national academies of science of several countries have concluded that the foods derived from LMOs are as safe or safer than their traditional counterparts.

The cultural factor is of great relevance when establishing the strategy with which the public will be faced. Thus, it is important to work with the communicators, who should be qualified to comprehend the scientific facts, and thereafter, to transmit the information in a way that will be easily understood by the general public. In order to improve information to the public, it is necessary to elaborate a communicational strategy based on simple messages. These must explain the potential that biotechnology represents to the benefit of the country.

Information on the biosafety system must also be provided, especially about: who are responsible, how are decisions made, how is information updated, and how the public can participate. Within this strategy, it must be acknowledged that the debate is not only about science, but also covers political, ideological, religious and ethical aspects. It must be stressed that in the development of this project communication channels have been opened with decision-makers so as to obtain the updated scientific and technical information needed as best support for the policies and legislation related to biotechnology and biosafety.

It is necessary to continue the studies on public perception of modern biotechnology in order to compare the facts and the evolution that this matter has undergone through the years. Research on LMOs in Latin America and the Caribbean must be promoted starting now, so as to have a timely access to the market at the moment when marketing of this type of crop be massified. The global trend leads toward a greater acceptance of LMO cultivation, a reason why we cannot wait until the last moment for carrying out research in our countries.

The biotechnological and organic options do not seem to be necessarily exclusory, as has been set out so far. International experience shows that all these options are

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feasible and complementary. Market recesses which exist for these two options can be taken advantage of, thus improving profit margin of agricultural production. The needs and possibility have to be studied for implementing segregation of these crops. These studies have to be carried out considering the characteristics of the variety (type of pollinization, distance, existence of wild relatives, etc.).

Countries having similar characteristics must work on a regional biosafety model, with the purpose of standardizing procedures. Thus, the information that each one of the parties delivers at the moment of confronting situations not contemplated in the Biosafety Protocol, can be validated. Various strategies have been set forth to make the most of the different advances in regulatory aspects, human resources and physical infrastructure. For this purpose it is necessary to develop international North-South cooperation and, very specially, regional cooperation. It is convenient to explore the possibility of establishing an aligned and officially approved system with neighboring countries for the evaluation and acceptance of LMOs, so that the high costs of the required experimental trials do not constitute a barrier to the development of LMOs in the region. Taking into account that the International Biosafety Protocol enter into force. during the year 2003, it is urgent to establish national regulatory systems and build up national competence for successfully taking on the new challenges demanded by these circumstances, which have deep implications in international trade.

The OAS Biosafety Project provides an excellent opportunity for training the different actors involved in this area in the participating countries, and opens new possibilities of cooperation at a regional level to strengthen the biosafety programs. At the same time, the experience acquired may act as a model for other countries of the region that urgently require to reply to the implementation of the protocol. Conscious of this responsibility, CamBioTec and the OAS are working on the initiative of implementing a training program based on the information and experience acquired during the development of this project. Finally as a project product, a book entitled: Biosafety and the International Commerce of Transgenics Food in the Americas: Decisions and Challenges, Eds: L. Gil and V. Martínez. Andros Impresores, ISBN 956-291-992-7, 433 pp, has been published in December 2003, which provide a wide overview of the work done in this project. The book addressed to industry, government regulators, parliament members, academia and consumers groups contains 34 articles written by experts from: Argentina, Brasil, Colombia, Chile, France, Mexico, Peru, and USA, covering aspects such as: Biosafety Framework and Policies, The Cartagena Protocol and the National Regulatory Systems, Risk Management and Risk Assessment, GMOs introduction and Socio-economic Impacts, Building Capacity in Agricultural Biosafety and Public Awareness and Communication.

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