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Biosafety policy, law and administration in Latin America and the Caribbean

Conservation and sustainable use of tropical rainforests of Latin America and the Caribbean

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ECONOMIC COMMISSION FOR LATIN AMERICA AND THE CARIBBEAN (ECLAC)
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Biosafety policy, lay and administration in Latin America and the Caribbean

Dr. Raúl Brañes (Mexico)
Dr. Orlando Rey (Cuba)

Mexico, City; December 1999

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Foreword

This document has been prepared by the Latin American Association of Environmental Law (ALDA) at the request of the Economic Commission for Latin America and the Caribbean (ECLAC) and the Regional Office for Latin America and the Caribbean of the United Nations Environment Programme (UNEP/ROLAC).

It examines biosafety policy, law and administration in Latin America and the Caribbean with special emphasis on factors related to living modified organisms resulting from modern biotechnology and the conservation and sustainable use of biological diversity.

This document is the third version of a revised and expanded study that ALDA has been conducting on this topic. The first version of the study was presented to the governments that participated in the Fourth Meeting of the Inter-Sessional Committee of the Forum of Environment Ministers of Latin America and the Caribbean (Lima, 2 October 1999), and the second version was presented to a meeting of experts convened by UNEP and ECLAC (Santiago, Chile, 29 and 30 November 1999) in response to a decision adopted at the Fourth Meeting mentioned above. This third version, which has benefitted from results of the aforementioned meeting of experts, will be submitted to the Twelfth Meeting of the Forum of Environment Ministers of Latin America and the Caribbean, to be held in March 2000 in Bridgetown, Barbados.

The version of the document presented here is divided into five chapters, just as the previous versions. The first chapter, which serves as an introduction, examines biotechnology development and the biosafety issues that such development poses. The second chapter provides an overview of the way in which a policy on biotechnological safety has been developing in a selected group of eight countries in Latin America and the Caribbean and how this policy has been implemented through law and administration. The third chapter analyses the international context in which biosafety policy, law and administration in Latin America and the Caribbean is developing. The fourth chapter examines the role being played in this field by the Protocol on Biosafety being negotiated at the world level in the framework of the Convention on Biological Diversity. Finally, the fifth chapter formulates some conclusions and recommendations.

Mexico City, December 1999

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Chapter I

Introduction

1. Environmental safety, biological safety and biotechnological safety

Safety is a situation in which a person or human group is free from harm that threatens their existence or the danger of being a victim of such harm. From a philosophical standpoint, safety is one of the so-called "situation values", because it is a benefit that is fully enjoyed in a situation: the situation of an individual or human group that is free from harm or the threat of harm. Many human activities are dedicated to the enjoyment of this benefit. Safety is a matter of great importance to human beings, since it is one of their most basic needs.

For some years now, environmental safety has emerged as one of the topics that should be addressed in the more general idea of safety. In fact, continuous warnings from the international scientific community regarding the risks that growing and alarming environmental deterioration pose to the individual and collective safety of human beings have given rise to the concept of "environmental safety".

Environmental safety can be defined, in a preliminary approach, as "the situation in which a person or human group is free from environmental damage that threatens their existence or deteriorates their quality of life, and free from the danger of being a victim of such damage". It is an approach that gives priority to survival and the quality of life of human beings, but that can and should be extended to other forms of life.**(1)**

Environmental safety is a topic which, from a political point of view and in an international context, has been present at least since the United Nations Conference on the Human Environment (Stockholm, 1972). Furthermore, an important bibliography has developed in relation to this topic, dealing not only with the so-called "resource wars", which was the initial topic of environmental safety, but also the safety that States should provide their citizens from many other points of view.**(2)**

Biological safety, or biosafety, is an important component of environmental safety and is related to the risks that people and living organisms, in general, are exposed to by biological factors that can affect their health and even their lives.

Biotechnological safety is, in turn, an important component of biological safety, which, in accordance with what has been previously stated, can be defined as the situation of a person or a human group and, in general of living organisms, that are free from harm stemming from biotechnology that threatens their existence or deteriorates their quality of life, as well as the danger of being a victim of such harm.

The concept of biotechnological safety is logically associated with the development of biotechnology and, consequently, usually refers to the set of activities aimed at

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(1) *Cf.* Raúl Brañes, *Seguridad ambiental en América del Sur: los principales problemas y los nuevos desafíos a la soberanía*, Comisión Sudamericana de Paz, Santiago, Chile, 1990.

(2) One of the pioneering works in this field is an essay by Arthur H. Westing entitled "An expanded concept of international security", which can be consulted in Arthur H. Westing (ed.) *Global resources and international conflict. Environmental factors in strategic policy and action*, Sipri-Unep. Oxford University Press, New York, 1986.

controlling the management, use and transfer of living modified organisms (LMOs). In this document, however, a broader viewpoint is assumed; that is, a concept of biosafety that includes the introduction of exotic species not modified by biotechnology, bearing in mind that these intentional or accidental introductions have been much more devastating than those that can so far be attributed to LMOs. Nevertheless, reference is also made to the impact of biotechnological development on food security and on other fields.

2. Biological safety or biosafety

Biological isolation is considered one of the main factors that have enabled the evolution of species, since when they are isolated, species evolve from common ancestors and build special ecological relationships and unique ecosystems.**(3)**

Prior to the advent of the modern world, a mixture of species from different places in the world was produced slowly and primitively, and was naturally limited by geographical barriers. This situation has been radically changed through colonization and human migration, particularly in the past two centuries.

The greatest threat to biological diversity, surpassed only by the loss of habitats, is the introduction of exotic species; that is, species that are introduced into an area to which they are not native.**(4)** Although the problem is usually approached in terms of the introduction of exotic species from other countries, the adverse impact of introducing such species can certainly take place through movements from one place to another within the same country, particularly when they are introduced into protected areas. In fact, it is recognized that political borders, above all on continents, bear no relationship to ecosystemic differences and other environmental parameters, so there may be greater differences between the regions within a single country than between two bordering countries.

The introduction of species may be voluntary or accidental. The former are easier to control – at least officially – through related regulatory mechanisms. The question of controlling the accidental introduction of species is more complicated, although some mechanisms have been suggested, such as controlling the discharge of ships' ballast water in coastal areas and requiring a permit for the possession, transport and sale of exotic organisms, once they enter a country.

The adverse effects attributable to introducing such species includes their competing with other species for space and food and their becoming predators of the native species, as well as their destroying or degrading crops and habitats, interrupting natural processes and transmitting pests and diseases.**(5)** In that regard, the effects are not only environmental, but also economic, and, of course, social and cultural, since – particularly in reference to agriculture – traditional crops and techniques are replaced when exotic crops are introduced.

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(3) An important collection of articles on the topic of invading species may be found in the IUCN journal, *World Conservation*, Double Issue 4/97-1/98, "Invaders from Planet Earth".

(4) *Cf.* Lyle Glowka *et al., Guía del Convenio sobre la Diversidad Biológica*, UICN, Gland y Cambridge, 1996, pp. 53 to 55.

(5) The impact of these species is greater in oceanic islands, as has occurred, for example, with the introduction of brambles (Rubus ssp.) in the Chilean islands of Juan Fernández. A similar incident occurred through the introduction of an African cichlid fish in Lake Gatún in Panama, where it eliminated six of the eight species previously common there, drastically reduced the population of the seventh species and eliminated aquatic invertebrates, algae and birds that fed on fish above and below it on the food chain. (*Cf.* WRI, UICN and PNUMA, Estratégia Global para la biodiversidad, 1992, pp. 45 and 46.

Once an invading species has taken root, it becomes very expensive, if not impossible, to eradicate it, especially in the case of small mammals and plants. Furthermore attempts to introduce species for control purposes have frequently led to even greater problems, so here, as with other environment-related topics, preventive rather than corrective measures are preferable.

In Article 8, item h), the Convention on Biological Diversity stipulates that each Contracting Party, in so far as possible and as necessary, "shall prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species". In the national sphere, this should translate into the policies, legislation and institutions needed to prevent or control the introduction of exotic species, always bearing in mind that preventive measures are not only preferable, but also the only measures that can produce acceptable results, both in environmental and economic terms. Although related bodies of laws generally exist in the region and have even existed for some time – as will be seen further on – they do not seem to have been effective, since the uncontrolled introduction of species and their harmful effects continue to be a tangible reality.

But a balanced view of reality should also take into account the benefits that have been derived from the introduction of exotic species in the form of crops, livestock and other species, which constitute the agricultural and industrial base. A large part of our daily food consists of cultivated or domesticated exotic species.

It is not a question of preventing the introduction of an exotic species, but rather of making it subject to appropriate regulatory policies and frameworks. In relation to these frameworks, the measures proposed are, in general, very similar to those in the entire legal system on biosafety and include, among other elements, the existence of prior and substantiated information, the use of pertinent environmental and risk assessments and a system of licenses and permits.

Specific guidelines to be taken into account in considering the introduction of exotic species have also been proposed,**(6)** such as an evaluation of the benefits expected for human beings and natural communities, the absence of a native species that could serve the same purposes and the prohibition of introducing species in habitats that have not been perceptibly modified by man, among others.

3. Biotechnological safety. Traditional and modern technology.

Both traditional biotechnology and modern biotechnology exist. The former includes diverse techniques used throughout history to cross closely related organisms through relatively lengthy processes that produce new genetic varieties.

In contrast, modern biotechnology includes techniques created over the past three decades to generate new genetic varieties by directly introducing the genes of quite different species (including bacteria and viruses), using processes that are rapid and give rise to what are called "transgenic" organisms.**(7)** These genetic modifications are

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(6) *Cf. Op cit.* in the previous footnote.

(7) This group includes organisms modified by directly influencing their genetic material – as occurs with recombinant DNA technology – or, more generally, all organisms in which the genes and genetic material are modified through means that do not take place naturally through birth or natural recombining. Recombinant DNA technology, which is the base that allows genetic material to be transferred through biochemical methods, has developed over the past three decades and enabled spectacular modification of plants, animals and microorganisms to take place.

also carried out by introducing, eliminating or multiplying genes in the same species. The new organisms produced are called "living modified organisms" (LMOs).[8] Biotechnological activities, as well as the introduction of exotic species, have always given rise to concern regarding the effects they could have on human health and the environment.

This concern has increased notably with advances in modern biotechnology and has spread beyond the realm of the scientific community to State spheres (through biotechnological safety policies, law and administration), as well as to debate in civil society regarding the risks that LMOs pose for human health and the environment.

An expression of these recent concerns is the still unsuccessful effort being made to gain a consensus on an international agreement on biotechnological safety that would regulate transboundary border movements of LMOs.

4. The debate on modern biotechnology

The debate on modern biotechnology is strongly polarized in many parts of the world. In fact, there are those who refer only to the benefits of LMOs without mentioning their risks and there are those who refer only to their risks without mentioning their benefits.

Between these two sectors, however, there are positions that oscillate among those who admit the benefits of using LMOs, but advocate more regulated and safe management, and those who reject at least some of the possible benefits of LMOs because they consider the magnitude of their risks to be much greater than such benefits.

The debate is far from being purely scientific. Modern biotechnology has been developed by increasingly powerful transnational companies that have successfully placed their products on the market and have brought about significant and accelerated changes, particularly in agriculture. These changes have, in turn, caused a social reaction based on fear of modern biotechnology risks, and that social reaction has been growing rapidly and giving rise to political and even judicial measures that are moderating the changes encouraged by biotechnology.

This document reviews certain factors in the controversy under way, not to take any position on it, but only to underscore the issues that should be taken into account in policies for biotechnological safety and, in more general terms, biosafety, as well as law and administration in this field.

Furthermore, this document gives priority to the approach that recognizes the risks that modern biotechnology poses for the conservation and sustainable use of biodiversity, but without failing to mention other approaches to the same topic.

5. The benefits of modern biotechnology

The benefits of modern biotechnology have been described many times. The important advances made by biotechnology in the field of medicine by changing the traditional bases of the pharmaceutical industry, for example, are obvious. Since 1997, the number of pharmaceutical products obtained through biotechnology has been greater than that obtained with traditional methods. In this area, the principal developments have been aimed at the production of vaccines and diagnostic and therapeutic

(8) At the beginning of the Protocol negotiations, these were called "genetically modified organisms" (GMOs).

methods. In the field of industry, cleaner industrial processes that involve a reduction in the use of toxic products or the solution to pollution problems (environmental bio-remedies for water, biological pest control, etc.) are expected to be reached through bio-remedies.

However, the most rapid advances in modern biotechnology and, at the time, the most disturbing to world public opinion, owing to their role in food, seem to lie in the field of agriculture, specifically in the production of farm products that are marketed directly, such as cereals, fresh fruit and vegetables, and products obtained from them, such as flour and oil. These developments have been particularly notable in the United States and in Canada, where a significant number of LMOs in crops have been approved for release into the environment and for consumption (maize, soybeans, tomatoes, potatoes, etc.). Thus, for example, an area planted with genetically modified maize increased in these countries from 160,000 hectares in 1996 to 1.2 million hectares in 1998.

The most frequently mentioned benefits in these changes are: greater food production in the same area, which, in addition to the economic benefits that it may have, also implies a reduction in the pressure on wild areas, forests and marginal lands, which consequently results in the protection of biological diversity; smaller food losses after harvesting and greater quality in fresh and processed foodstuffs; less consumption of energy and resources such as fertilizers and pesticides; and the encouragement of better agricultural practices, including integrated crop management.

6. The risks of modern biotechnology

In contrast with the discourse on the benefits of modern technology, concerns have multiplied regarding the risks that these processes involve or could involve for human, animal and plant health, as well as for biological diversity in general.

If, for the time being, we concentrate on the risks that modern biotechnology poses for biological diversity, the first point that should be underscored is that this diversity has always been endangered by a set of factors such as deforestation, forest fires, the invasion of exotic species and other factors, which now have been joined by the risks that would be posed by releasing LMOs into the environment. Consequently the risks that modern biotechnology poses for biological diversity should simply be considered another threat to such diversity, and a biological diversity conservation policy should therefore take into account all these factors as a whole.

Among biotechnology risks, the possible flow of genes from the cultivated plants to their wild relatives, which could have an adverse effect on them, is mentioned time and again. The same thing occurs with gene flows within the same species. What is more, even if it were impossible for this flow to take place, the release of LMOs into the environment would have to be considered equivalent to the introduction of exotic species, with effects that could be equally adverse.

Another risk that should be taken into account are the modifications in wild fauna that could result from the LMOs introduced as crops, since they may significantly affect their habitat. No less important are the effects that LMO dissemination may have on genetic diversity, by accentuating the characteristics of genetic homogeneity that is typical of large-scale commercial production and, therefore, accentuating the risks that such homogeneity poses.

The degree of concern regarding LMOs varies in magnitude. As long as their use takes place in field research (contained use), LMOs cause no fear, since it is recognized that there are fairly consolidated rules that enable them to be managed safely. In fact, it is

admitted that, in general, work with LMOs in laboratory conditions presents no special difficulties, since there are well-established methods and procedures to guarantee a general safety system.

In contrast, the risk is greater when LMOs are released into the environment, owing to various factors, including the difficulty of predicting potential risks because of the wide range of complex behaviours that may take place.

Some related concerns are unforeseen and unimaginable changes in the competitiveness, virulence and other characteristics of the species modified, the possibility of undesirable changes in other species, and variations in the stability of the genes inserted.

A typical case is that of weed resistance. We all know there are weeds that reduce crop productivity and require the application of diverse chemical products that present some degree of specific toxicity and remain in the environment for long periods of time, polluting land and water. Modern biotechnology has developed new wide-spectrum weed killers that have few of these drawbacks, but, in addition to the weeds, they also eliminate other beneficial plants that are essential to land conservation and plant diversity.

The problems being debated are numerous and very complex, especially in the field of agriculture, where the introduction of LMOs is linked to the risks of invasion, the propagation of the characteristic traits introduced, the possible development of pesticide-resistant organisms (superweeds or superpests), the production of toxic residues in food and associated genetic erosion processes, all of which would result in the consequent loss of biological diversity, land degradation and an increase in the need to use external inputs, thereby weakening traditional sustenance systems and subordinating them to the interests of big industry, in addition to the possible adverse impact on animal and human health.[(9)]
It has also been argued that the less favoured nations would become dependent on imported seeds, losing their capability for self-sustenance and burying native varieties that genetically guarantee the preservation of biological diversity. Furthermore, if success is achieved in using biotechnology to plant commercial tropical crops in temperate zones or to produce in laboratories the substances usually obtained from these crops, this would have a strong impact on incomes in many of these countries.

From the standpoint of food,[(10)] the debate is also very intense. The defenders of genetic engineering point out its capacity to feed an increasingly numerous world population, others insist that the causes of hunger in the world do not lie precisely in the lack of food, but rather in problems of access to and distribution of food that already exists or could be produced, and that these problems are caused by the existence of political and economic systems that are basically unjust and inequitable.

Another argument that has been set forth is that a large part of genetic engineering research and application related to food is directed more at meeting the commercial needs of the food processing industry than at the food needs of consumers. It is also pointed out that a large part of the transgenic crops are for livestock feed, which is the case with 90 to 95 per cent of the soybeans and 60 per cent of the maize grown in the United States.

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(9) Although these effects may occur with traditional modification, they are generally associated with LMOs.

(10) Foods are considered transgenic when they are prepared using raw material that has been genetically modified, either by introducing a gene from another species through genetic engineering or by changing the expression of the genes themselves without introducing genetic material.

Finally, biotechnology is also being questioned on the basis of ethical considerations, according to which man must not violate the integrity of species or interfere with natural processes.

7. Bisafety and environment in Latin America and the Caribbean

An important component of biosafety in our region has been concern regarding the effects that these factors could have on the environment, since Latin America and the Caribbean is a region characterized by its mega-diversity and is a centre of origin and diversity.

In fact, Latin America and the Caribbean offers extraordinary wealth in natural resources of all types, with a great variety of both species and ecosystems. The region now has five major types of ecosystems, 11 major types of habitats and 191 ecoregions.

Although biological diversity studies in the region are incomplete – the truth is they are also incomplete, to a greater or lesser extent, in all the regions of the world – Latin America and the Caribbean is, in fact, the world's most richly endowed continent in terms of mammals, amphibians and reptiles, while it shares the greatest diversity in birds with Central Asia. The number of plant species is estimated at 120,000, a figure that increases to 180,000 if ferns, moss and lichens are included. Our region contains 40 per cent of the plant and animal species in the world's tropical forests and 90,000 of the 250 known higher plant species, as well as 36 per cent of the main species for food and industrial use.

The marine and coastal ecosystems of Latin America and the Caribbean are particularly diverse because of the dissimilar influences from the Caribbean Sea and the Atlantic and Pacific Oceans. Estuarine ecosystems are abundant and contain great biological diversity. Mangroves in the region cover 5.8 million hectares.

The Caribbean islands show a contrast between the great wealth of biological diversity in the coastal ecosystems and less wealth in inland areas. The characteristics of these island coasts are richly endowed with coral reefs, mangroves and marine grasses. The conservation of biological diversity is particularly complex in the highly populated Caribbean islands, owing to the significantly small size of some areas and habitats, the high degree of endemism and great vulnerability to natural disasters.

The region's potential in genetic resources, both for agriculture and for pharmaceutical purposes, is especially important. Approximately 1,000 known plant species in Amazonia are considered to have economic potential, and at least 300, forestry potential.**(11)**

The coverage of protected areas in the region has expanded approximately 13 per cent in the past five years, which is equivalent to an increase of 160 million hectares. Nevertheless, ecological deterioration rates are notable, and particularly the loss of

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(11) In the pertinent bibliography, reference is usually made to the tomato native to the Peruvian Andes that was collected by a United States scientist in 1962 and which, after ten generations of crossing hybrids, is now producing various new species of tomato of a larger size, redder colour and 2.5 per cent sweeter than the original tomatoes. It has been calculated that this Peruvian tomato contribution represents a benefit of approximately 20 million dollars a year for the United States tomato industry. A minimum percentage of these benefits could serve as a decisive contribution for conservation in Peru (*Cf.* the article "La semilla de un millón de dólares: diversidad genética y afán de lucro" by Stacey Anderson, published in the UNEP journal *Nuestro Planeta*, Tome 4, Number 1, 1992).

biological diversity resulting from the destruction caused by splitting up habitats. At the present rate, it is estimated that between 100,000 and 300,000 species could disappear in the next 30 years.

The causes of this deterioration are quite similar to those that prevail in other regions, particularly in the developing countries, and they are basically associated with the action of human beings. Some of the causes are deforestation, desertification, erosion and other forms of land degradation; poaching, expansion of the agricultural frontier and expanded livestock breeding; the introduction of exotic species; agricultural, industrial and household pollution; and vulnerability to catastrophes.

Of all the ecoregions in Latin America and the Caribbean, 18 per cent are considered critical, 30 per cent endangered and more than 30 per cent vulnerable. Losses in biological diversity in the region have been greater during the second half of this century than in the nearly five centuries that preceded it.

Latin America and the Caribbean is the centre of origin for species of such importance to the world as maize, potatoes, cassava, tomatoes and peanuts, among other foods. Five of the world's ten countries with the greatest wealth in terrestrial plants and animals are in the region: Brazil, Colombia, Ecuador, Mexico and Peru.[(12)]

Some 34.4 per cent of world production is founded on strains that originated in Latin America and the Caribbean, including 40 per cent of North American agricultural food production and 39 per cent of such production in Mediterranean Europe. More than 65 per cent of the germ plasm of the current 20 most important food crops comes from Latin America and the Caribbean and from Central-Western Asia. Of the seven main modern agricultural crops, four originated in Latin America and the Caribbean (maize, potatoes, cassava and sweet potatoes).

8. Biosafety policy, law and administration in the countries of Latin America and the Caribbean

Biosafety is an element whose inclusion dates back many years in the policy, law and administration in the countries of Latin America and the Caribbean to address problems associated with the risk posed by the invasion of exotic species and developments in traditional biotechnology.

Today, these risks have been joined by those posed by modern biotechnology, which calls for the adoption of precautionary criteria regarding their possible effects on the environment. And these criteria should be used to conduct scientific assessments of such risks on a case-by-case basis.

These recent circumstances pose the need for major changes in what could be called traditional biosafety policy, law and administration in our countries in a very complex international context. Moreover, this need puts to the test the institutional capacity of our countries to respond appropriately to the new concerns posed by modern biotechnology.

To date, the development of policies on modern biotechnological safety in Latin America and the Caribbean has been modest. In most cases, they are responses to external causes, such as specific requests formulated by transnational companies to release modified organisms for field tests or for transgenic crops themselves. This incipient development contrasts with the rapid growth of land area covered by

(12) The case of Colombia is particularly outstanding, since it occupies 0.77 per cent of the world's land area, and shelters 10 per cent of its plant and animal species.

transgenic crops (such as soybeans, maize and canola), growth that is taking place at a faster pace than in other parts of the world.

Part of this policy has begun to be implemented through regulations and even special laws enacted for that purpose, and they are examined in the following chapters. The new legislation falls within the framework of previous provisions included in numerous and diverse bodies of law, including particularly the general laws on environment that our countries have been adopting since 1974, owing to their links with the topic in question, as well as in sectoral legislation for the protection of certain natural resources. However, most of the provisions in force are found in bodies of law dealing with public health and plant and animal health, as well as agricultural production, which are also examined in the following chapters. In fact, the codes or laws on public health and food, as well as laws on plant and animal health, agrochemicals and even trade, especially international trade, are some of the laws that have been regulating biosafety in general. And the pertinent areas of these laws is precisely where new provisions are beginning to be introduced to deal with modern biotechnological safety, while comprehensive regulations in this field are being developed.

The development of policy and law on biotechnological safety has been taking place alongside the development of administration to deal with the effects of LMOs, generally on the basis of existing structures in the field of health, agriculture and environment. Some of this development was under way while this document was being prepared. The topic is examined in the following chapters. In general, the problem with such structures is their lack of effective capacity to fully assume the task with which they are entrusted.

9. The international context

Domestic biosafety policy, law and administration in Latin America and the Caribbean operate in an international context that should be taken into account, because many times what is established at the world, regional and subregional levels has a decisive influence on what is done within each of our countries.

In that regard, it should be recalled that there are international legal policies and regulations at the world level that have been dealing with biosafety for some time, and that our countries, as part of the world community of nations, have assumed a commitment to them.

The main source of these policies is in the Declaration issued by the United Nations Conference on Environment and Development and the world action plan approved at that Conference, which is known as Agenda 21 (Rio de Janeiro, 1992).

But, there is also international law that deals with the regulation of biosafety from different standpoints, beginning with the Convention on Biological Diversity, signed at the same Conference, and other texts prior to the Convention, such as the International Plant Protection Convention, the International Convention for the Protection of New Plant Varieties, the Convention Concerning the Protection of the World Cultural and Natural Heritage and the Convention on International Trade in Endangered Species of Wild Fauna and Flora, among others. No less important to biosafety are other international agreements such as GATT 1994 and its complementary instruments, particularly the Agreement on Health and Plant Health Measures, that regulate world trade.

Together with these international agreements, there are other instruments that express world consensus on biosafety, such as the International Code of Conduct for the Distribution and Use of Pesticides (FAO), the Technical Guidelines on

Biotechnological Safety (UNEP), the Voluntary Code of Conduct for Releasing Genetically Modified Organisms into the Environment (UNIDO), the Code of Conduct regarding Plant Biotechnology (FAO), the Codex Alimentarius (FAO), etc.

Special attention should, however, be given to the Protocol on Biosafety, which has recently been under negotiation and was not signed last February, as was programmed, owing to the lack of the necessary consensus, especially on the part of the United States, which, although it is not a Contracting Party to the Convention on Biological Diversity, has led the opposition of the five other countries that oppose the consensus reached by the rest of the international community.

The Protocol does not regulate all aspects of biosafety. In fact, the Protocol only regulates the transboundary movements of LMOs produced by modern biotechnology that can have harmful effects on the conservation and sustainable use of biological diversity. Consequently, the Protocol is not, in and of itself, a solution to the gaps that may occur in the domestic legislation of the countries of the world in this field, which should, with or without the Protocol, comprehensively regulate biosafety. However, the mechanisms established by the Protocol call for significant legislation on biosafety in the countries that have not developed it and, to a certain degree, determine the content of national legislation.

All these instruments, which together form the world context related to the question of biosafety, are examined in the following chapters. Additionally, there are other developments of biosafety policy, law and administration at the regional and subregional levels, especially developments that involve the countries in which the biotechnological industry has developed most, such as the countries that form the European Union. It should be recalled, for example, that in 1990, the European Council adopted two directives: the first referred to the contained use of genetically modified microorganisms (Directive 90/219/EEC) and the second to the intentional release into the environment of genetically modified organisms (Directive 90/220/EEC).**(13)**

These and other referents are important in providing a basis for the reflection made further on regarding guidelines for a biosafety policy in Latin America and the Caribbean.

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(13) In this framework, measures such as the wide moratorium on LMOs recently agreed to in Luxembourg by the Environment Ministers of the European Union have been adopted to operate until new rules that restore consumer confidence are approved.

Chapter II

Biosafety Policy, Law and Administration in the countries of Latin America and the Caribbean

1. Introduction

As stated in the previous chapter, biosafety is an element that has been present for many years in the policy, law and administration in the countries of Latin America and the Caribbean as a means of addressing the problem associated with the risks posed by the invasion of exotic species and traditional biotechnology developments. Today the risks from modern biotechnology are changing the biosafety system into something much more complex, as required by the magnitude of these risks.

It is a process that is under way with progress which, in general terms, could be described as modest, but that reflects the will to confront these risks. As noted in the previous chapter, in most cases these advances are responses to external causes, such as specific requests formulated by transnational companies to release modified organisms for field tests or for transgenic crops themselves. This incipient development contrasts with the rapid growth of land area covered by transgenic crops (such as soybeans, maize and canola), growth that is taking place at a more rapid pace than in other parts of the world.

The negotiations of the Protocol on Biosafety have made this process more dynamic. In fact, the debate that has arisen around the Protocol, which has not yet been concluded, has placed the governments of the region in a position where they need to define a set of policies to face the problems caused by transboundary movements of genetically modified organisms, in addition to a clear, appropriate and consistent policy on biological safety as a whole and, particularly modern biotechnological safety.

This chapter examines these advances in the context of biosafety policy, law and administration in general, but underscores advances related to the problems of modern biotechnological safety. To that end, this second version of the document offers an overview of the state of the art in some countries of Latin America and the Caribbean through the presentation of eight case studies that refer to the following countries: Argentina, Brazil, Chile, Colombia, Costa Rica, Cuba, Mexico and Peru.

An examination of each of these cases is organized around the topics of biosafety policy and law, on the one hand, and biosafety administration, on the other. The topics of biosafety policy and law are examined together because, to date, the policies in this field have generally been included in the same legislation that implements them.

Biosafety law is itself scattered and does not occupy an important place in environmental legislation. In fact, its texts are generally found in provisions that are incorporated in numerous and diverse bodies of law that usually deal with public health and plant and animal health, as well as agricultural production: they are the codes or laws on public health and food, laws on plant and animal health, agrochemicals and even trade, especially international trade, and other laws, which are the principal sources of the policy and law that regulates biosafety. In contrast to what occurs with

other environmental topics, biosafety is not regulated by the general laws on environment that our countries have been adopting since 1974, nor by sectoral legislation for the protection of certain natural resources.

This chapter pays special attention to specific legislation on modern biotechnological safety, in the understanding that it should be considered in the context of biosafety legislation in general. But, as may be seen throughout this chapter, such specific legislation is relatively scarce.

A similar warning should be made in reference to the administration that deals with biosafety. It is usually found in the administrative structures that deal with agricultural production and public health, and environmental authorities play a minimum role in such administration.

In recent years there have been some changes resulting from the concern that has arisen with regard to the effects of LMOs, but these changes have usually been made within each sector, based on the existing structures in the field of agricultural production and public health. The situation is, however, very fluid and changes from one moment to the next. But these changes are not usually accompanied by the measures necessary to provide the new bodies with effective capacity to perform the task entrusted to them, since they do not allocate related resources or include them in a system that enables them to fulfil their duties.

2. The case of Argentina

The case of Argentina is of special importance from the standpoint of protecting its biological diversity, which has high rates of endemism, if it is borne in mind that there have been important modern biotechnological applications in the country, especially in the field of agriculture. Argentina is the world's third largest producer of transgenic soybeans and has also developed some biotechnologies of its own. In 1998, Argentina had 5.5 million hectares of transgenic crops, ranking second in the world.**(14)**

Biosafety policy and law

In Argentina, preservation of the natural heritage and biological diversity is a constitutional duty of authorities, as established in the 1994 Constitution (article 41). This preservation includes safeguarding the natural environment from the biological risks to which it is exposed. In accordance with the Constitution, it is the duty of the Nation to issue regulations that contain minimum budgets for protection, and the duty of the provinces to issue any necessary regulations to supplement them, without the national regulations altering local jurisdictions. No national regulations on biological safety have been issued since the 1994 Constitution entered into force. The provisions now in force were issued prior to the current Constitution (although they are amended periodically)and have antecedents that date back to 1905.**(15)**

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(14) *Cf.* Carmen Vicién, "Bioseguridad agropecuaria en Argentina: algunos factores a tener en cuenta", a paper presented at the joint UNEP-ECLAC meeting on "Biosafety policy, law and administration in the countries of Latin America and the Caribbean" (Santiago, Chile, 29 and 30 November 1999).

(15) At that time, Law no. 4.863 was issued. It regulates the defence of agricultural production throughout the territory of the Republic against the invasion of parasitic or harmful animals and plants. This defence is entrusted to the Executive Branch through the means indicated in this Law, as long as the animals or plants are or may become a pest, owing to their extensive, invasive or calamitous nature, or when they may affect other animals or plants when they appear in a province or territory (article 1).

Today, the new provisions have preferentially been aimed at establishing a framework for modern biotechnological safety, revolving around laws that have arisen in response to the requests of companies for authorization to experiment with and/or release living modified organisms (LMOs) into the environment. These provisions fall within the framework of different laws.[(16)]

One of these laws is Law no. 20.247 of 1973 on seed and plant-breeding creations.[(17)] The Law creates the National Seed Commission in the sphere of what was then the Ministry of Agriculture and Livestock, which is the body than enforces the Law, with the advisory assistance of the Commission. In addition to regulating seeds, the Law establishes a National Registry for Seed Commerce and Monitoring and a National Registry for Cultivated Varieties and the Ownership of Cultivated Varieties. The Law is regulated by Decree no. 2.183 of 1991, which establishes that the Secretariat, as the authority that will enforce the Law, shall, through the National Seed Service (SENASE), exercise the authority indicated in article 6 of this Decree. SENASE was transformed into the National Seed Institute (INASE) by Decree no. 2.917 of 1991, which declares that obtaining, producing, distributing and internally and externally marketing seeds and phytogenetic and biotechnological creations lie in the nation's best interest.[(18)]

Another of the laws that should be taken into account is Law no. 13.636 of 1949 on the control of veterinarian products, which stipulates that the import, export, preparation, holding, distribution and/or sale of products for the diagnosis, prevention and treatment of animal diseases shall be subject throughout the territory of the Republic to the control of the Executive Branch through what was then the Ministry of Agriculture and Livestock (article 1). The Law states that these activities shall be subject to provisional or final permits granted subsequent to the completion of investigations, tests, experiences and fulfilment of any other requirements by the authority (article 2). The Law prohibits these activities from being carried out with products made with secret formulas or with undefined components (article 5) and requires the products to be canned and labelled, with the official authorization, formula and chemical or biological composition written in Spanish and displayed in an easily viewed place, among other requirements (article 7).

In this legal framework, regulations have been issued to govern biotechnological safety. In view of the importance of biotechnological applications to agriculture, in Argentina many of the regulations refer to agricultural matters. In 1991, the National Advisory Commission on Agricultural Biotechnology (CONABIA) was established in the Secretariat of Agriculture, Livestock, Fisheries and Food (SAGPyA), as a consultative and technical support body to provide it with advisory assistance in the formulation and enforcement of the regulations on introducing and releasing into the environment plant and animal material obtained through genetic engineering.[(19)] CONABIA began to formulate the regulations now being applied in this field.

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(16) All these laws are associated with agriculture and linked to plant protection (Decree-Law no. 6.704/66 on defending the health of agricultural products and its amendments), seeds and plant-breeding creations (Law no. 20.247/73 on seeds and plant-breeding creations and its Decree on regulations) and animal health (Law no. 13.636/49 on Veterinarian Products, Supervision of their creation and marketing).

(17) The purpose of this Law is defined in article 1 as: "to promote efficient seed production and marketing, ensure agricultural producers of the identity and quality of the seeds they acquire and protect the property rights to plant-breeding creations".

(18) Among other powers, the Decree grants INASE jurisdiction "to be in charge of national and international certification, observing agreements signed or to be signed on the physiological, physical and genetic quality of all plant organisms to be used for sowing, planting or propagation" (article 4).

(19) *Cf.* Carmen Vicién, "Bioseguridad agropecuaria en Argentina: algunos factores a tener en cuenta", a paper presented at the joint UNEP/ECLAC meeting on "Biosafety policy, law and administration in the countries of Latin America and the Caribbean" (Santiago, Chile, 29 and 30 November 1999).

Among the provisions that refer to agricultural biotechnological safety is Resolution no. 656 of the SAGPyA of 30 July 1992, amended by Resolution no. 837 of 9 September 1993 (which replaces Annexes I and II of the previous Resolution with another Annex I) and by Resolution no. 289 of 1997 (which replaces this Annex I with another Annex I), which establishes the technical and biosafety requirements that should be met for experimentation and/or release into the environment of genetically modified organisms and genetically modified microorganisms and/or their products, as well as Resolution no. 226 of 1997, which establishes isolation measures.**(20)**

The supervision carried out is aimed at products on the basis of the proposed use, which, as one author says, includes aspects of the procedures used to obtain them, which could signify a risk to the environment, agricultural production or human health.**(21)**

The criteria used to evaluate requests take into account: 1) the agroecosystem where the experiment will be conducted, which involves consideration of national experience with the crop, the species and related germ plasm, the persistence potential of the material released and the possible harmful consequences on other organisms present in the environment; 2) the biological characteristics of the organism, which means that an evaluation should be made of the possibility of discharges, genetic leaks, pathogen movements, dispersion of pollen and genetic stability of the material to be tested; 3) the possible effects on human health related to the safety of the staff in charge of the test; and 4) the actual feasibility of implementing the necessary biosafety measures, such as infrastructure, technical capacity of the institution making the request, inspections, etc.

Between 1991/1992 and 1997/1998 the requests to release LMOs into the environment increased significantly (from three in the first of these periods to 72 in the second period). In these years, 286 permits to release LMOs into the environment were granted for the following crops: maize, soybeans, cotton, sunflowers, wheat, tomatoes, rape, sugar beets and potatoes. The main characteristics introduced are herbicide tolerance and insect resistance (including Roundup Ready and Liberty Link).**(22)**

Once a release request has been granted, a "flexibility" permit may be requested.**(23)** This means that in the case of future releases, the only requirement is to present information on the area planted, the planting date, the release location and the

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(20) In Argentina, a genetically modified organism is considered to be an organism in which any of its genes or other genetic material have been modified through the following techniques: 1) the insertion by any method of a virus, bacterial plasma or other vector system of a nucleic acid molecule, which has been produced by any method outside this virus, bacterial plasma or other vector system, in order to produce a new combination of genetic material which is capable of being inserted in an organism in which this combination does not occur naturally and within which it will be inheritable genetic material; 2) the insertion in an organism, by microinjection, macroinjection, microencapsulation or other direct means, of inheritable genetic material prepared outside this organism; 3) use of recombinant DNA molecules in *in vitro* fertilization that involves the genetic transformation of a eukaryotic cell.

(21) *Cf.* All that follows by Esteban Hopp, "Supervisión de organismos transgénicos en Argentina: reglamentaciones y estado actual de la situación", a paper presented at the First Brazilian Congress on Biosafety and the First Latin American Symposium on Transgenic Products (Rio de Janeiro, 26-29 September 1999).

(22) *Cf. op. cit*. in the previous footnote.

(23) Resolution no. 131 of 6 October 1998 approved the request and registration forms for flexibility in the conditions for permits to experiment and/or release genetically modified organisms into the environment.

harvesting date. In these cases, CONABIO participation is limited to conducting inspections of the crop and of the final disposal of the material.[(24)]

Authorization is granted on the condition that a certain number of precautionary measures are taken. It is the responsibility of CONABIO, in plenary and by unanimous agreement of all its members, to determine the safety conditions that will guarantee protection against even the smallest potential risks. For its part, SAGPyA is responsible for granting the authorization requested.[(25)]

Marketing authorization requires an administrative procedure that is carried out in three stages: 1) assessment of the risks to the agrosystems posed by mass cultivation on a commercial scale of the transgenic material under consideration; 2) evaluation of the transgenic material as food; and 3) a ruling on the advisability of marketing the transgenic material in terms of its impact on the markets.[(26)]

Monitoring subsequent to the tests is the responsibility of the National Seed Institute and the National Agricultural Food Health and Quality Service. The monitoring involves an *in situ* assessment of compliance and, if necessary, the determination of measures that should be applied to prevent adverse effects on the environment.

Finally, it should be noted that some efforts have been made to harmonize biosafety policies in the agricultural matters in the countries of the Southern Cone, as well as in the sphere of Mercosur.[(27)]

The risks of biotechnology also have an influence on human health and environment. Consequently, in 1993, the National Commission on Biotechnology and Health (CONByS) was established in the Directorate of the National Food and Medical Technology Administration (Secretariat of Health and Social Action). The essential purpose of CONByS consists of analysing and studying the regulations in force that govern the development, preparation and approval of biotechnological products for human health and consumption.

Biosafety administration

Measures to control and manage organisms genetically modified through genetic engineering for food and agriculture are entrusted to the Secretariat of Agriculture, Livestock, Fisheries and Food (SAGPyA), specifically through the Undersecretariat of Agricultural and Forestry Production, which is assisted by the National Advisory Commission on Agricultural Biotechnology (CONABIA).

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(24) The following materials, whose characteristics are specified, have flexibility permits for the conditions required for experimentation: soybeans (tolerance to glyphosate), maize (resistance to lepidoptera in three types of different events), maize (tolerance to glufosinate-ammonium), cotton (resistance to lepidoptera), and maize (resistance to glyphosate).

(25) Releases are determined by the characteristics of the organism and the agro-ecological characteristics of the release site, as well as by the use of appropriate experimental conditions, including suitability of the party responsible for the release into the environment. *Cf.* Carmen Vicién, "Bioseguridad agropecuaria en Argentina: algunos factores a tener en cuenta, a paper presented at the joint UNEP-ECLAC meeting on "Biosafety policy, law and administration in the countries of Latin America and the Caribbean" (Santiago, Chile, 29 and 30 November 1999).

(26) *Cf. op. cit*. in the previous footnote.

(27) In 1992, a workshop on "Harmonization of biosafety in the Southern Cone", organized by the Inter-American Institute for Cooperation on Agriculture (IICA) and the International Service for the Acquisition of Appropriate Agrobiotechnologies (ISAAA), was held in Buenos Aires. There have also been Latin American Meetings on Agricultural Biotechnology, where note has been made of the need for regulations and mechanisms for the national supervision of field and marketing tests of the genetic materials. In the sphere of Mercosur a meeting on biosafety and marketing of genetically modified organisms was held in Buenos Aires in 1995.

CONABIA was established by Resolution no. 124 of 24 October 1991 adopted by what was then the Secretariat of Agriculture, Livestock and Fisheries (now the SAGPyA). Its functions are to provide the Secretariat with advisory assistance on technical and biosafety requirements that genetic materials obtained through biotechnological procedures should meet prior to being released into the environment by any procedure or method, regardless of their nature, as well as to propose regulations and issue opinions on topics within its sphere of competence.[(28)]

With regard to the effects of biotechnology on health, in 1993, as previously noted, the National Commission on Biotechnology and Health (CONByS) was established in the Directorate of the National Food and Medical Technology Administration (Secretariat of Health and Social Action) to analyse and study the regulations in force that govern the development, preparation and approval of biotechnological products for human health and consumption. This Commission has two Sub-commissions formed by professionals in the public and private sectors: the first deals with *in vitro* diagnoses and biological drugs, and the second with *in vivo* diagnoses and plants for industry.

3. The case of Brazil

Brazil, a country of continental dimensions, is endowed with significant biological diversity that makes it one of the world's principal countries with diversity of mega proportions. Protecting its biodiversity is, consequently, a matter of great priority.

Just as in the case of Argentina, important applications of modern biotechnology have taken place, especially in agriculture: Brazil is the world's second largest producer of soybeans (30.5 million tons in the 1998-1999 period), preceded by the United States (75.5 million tons) and followed by Argentina (18.0 million tons). Important development of this crop has taken place particularly in the states of Rio Grande do Sul, Paraná, San Pablo and Mato Grosso do Sul.[(29)] Brazil is also a country that has developed some biotechnologies of its own.

Policy and law

The main source of national policy on biosafety is the legal framework that regulates it. However, a provision states that it is the responsibility of the National Technical Commission on Biosafety (CTNBio) to propose policy of this type.[(30)] This legal framework is found basically in the 1988 Constitution and in Law no. 8.974 of 1995 (Law on Biosafety), which provides regulations for items II and V in article 225, paragraph 1, of the Federal Constitution; establishes regulations for the use of genetic

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(28) The composition of CONABIA is regulated by Resolution no. 669 of 23 August 1993, amended by Resolution no. 328 of 20 May 1997, which calls for a mixed composition of representatives of public and private sector institutions. The public institutions include the National Seed Institute (INASE), the National Agricultural Health and Quality Service (SENASA), the National Agricultural Technology Institute (INTA), the National Council on Scientific and Technical Research (CONICET), the Universidad de Buenos Aires, the Secretariat of Natural Resources and Sustainable Development and the Secretariat of Public Health. Participants from the private sector include representatives of the Argentine Seed Association (ASA), the Argentine Forum on Biotechnology, the Argentine Ecology Association, the Argentine Chamber of Agricultural Health and Fertilizers and the Argentine Chamber of Veterinarian Products.

(29) *Cf.* Leila Macedo Oda et al., "Genetically modified foods: economic aspects and public acceptance in Brazil", a paper presented at the First Brazilian Congress on Biosafety and the First Latin American Symposium on Transgenic Products (Rio de Janeiro, 26-29 September 1999.

(30) In accordance with Decree no. 1.752, article 2, of 1995 it is the responsibility of the CTNBio to "propose national policy on biosafety, including guidelines, programmes and goals for scientific progress related to biotechnology and environmental conservation, always bearing in mind the defence of human life and public health".

engineering techniques and the release of genetically modified organisms into the environment; authorizes the Executive Branch to establish the National Technical Commission on Biosafety under the Presidency of the Republic; and calls for other measures.

In fact, article 225, paragraph 1, of the Constitution states that it is the duty of public authorities to "preserve the diversity and integrity o the genetic heritage of the country and to monitor the entities dedicated to research and manipulation of genetic material", as well as to "control the production, marketing and use of techniques, methods and substances that may pose risk to life, to the quality of life and to the environment" (items II and V, respectively). On the basis of these constitutional provisions, Law no. 8.974 of 1995 was enacted. Its specific purpose is to regulate the use of genetic engineering techniques and the release into the environment of genetically modified organisms.**(31)**

The legal framework for biosafety in Brazil is, however, much more complex. Just as occurs in practically all the countries in the region, this topic should be considered from the standpoint of other laws which, in different ways and to different degrees, work together to regulate it, as is the case, first of all, with Law no. 6.938 of 1981 on national environmental policy, which is the country's most important legal instrument in the field of environment and establishes the principles of that policy and its objectives, as well as the mechanisms for its application, including environmental impact assessments.**(32)**

Together with this last Law, consideration should also be given to other legal instruments such as, for example, Decree no. 24.114 of 1934 (Regulations to Defend Plant Health) and Law no. 8.171 of 1991 (Law on Agricultural Policy), which include environmental protection among their objectives and as one of their instruments. In the same manner, many of the legal instruments**(33)** that make up the complex web of Brazilian environmental legislation should be taken into account as part of the legal framework on biosafety.**(34)**

These legal provisions are supplemented by others that regulate the introduction into the environment of alien organisms, whether they be exotic or GMOs, and some of these provisions have been in force since 1934. They come from different ministries, such as the Ministries of Agriculture and Supply; Science and Technology; Health; and Environment, Water Resources and the Legal Amazon. Furthermore, the CTNBio, in fulfilling its duties, issues regulatory instructions in its sphere of competence that regulate important matters.**(35)**

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(31) A genetically modified organism is defined by the Law as an "organism whose genetic material (DNA/RNA) has been modified by any genetic engineering technique" (article 3-IV). Genetic engineering, in turn, is defined as the manipulation of recombinant DNA/RNA molecules.

(32) Articles 2, 4, 9 and the following articles in Law no. 6.938.

(33) As is the case, for example, with Law no. 5.197 of 1967, on wild fauna, which prohibits the introduction of imported exotic species; Law no. 4.771 of 1965 on forests; Law no. 7.802 of 1989 on agricultural toxins; Law no. 6.9902 of 1981 on environmental protection areas; Law no. 6.803 of 1980 on industrial zones of critical polluted areas; etc. Together with them, consideration should be given to other more general instruments such as Law no. 7.347 of 1985 on public civil action, as well as Law no. 9.605 of 1998 on environmental crimes.

(34) An initiative to consolidate the most important branches of Brazilian environmental legislation is being developed in the Chamber of Deputies in Brazil, where a working group has been formed for that purpose.

(35) To date, 18 instructions have been issued. They include topics such as the biosafety quality certificate, the operation of the Internal Biosafety Commissions, genetically modified plant imports for research, the planned release into the environment of GMOs, the transport of GMOs, the classification of experiments with genetically modified plants, work with GMOs in confinement, genetic manipulation and cloning of human

Since it began operating in June 1996, the National Technical Commission on Biosafety has authorized 626 field tests with GMOs, of which 585 dealt with genetic modification of maize (432 for demonstration purposes and 153 for experimental tests) and 28 with genetic modification of soybeans. Other authorizations for field tests have dealt with sugarcane (5), cotton (3), eucalyptus (2), rice (1) and potatoes (1). The CTNBio has also called for monitoring of the crops, which should be carried out by the applicants under the supervision of the Commission.**(36)**

Brazil tends to introduce species that have already been applied commercially in other countries.**(37)** The first genetically modified product that the CTNBio authorized for marketing in Brazil was for soybeans and is known as Roundup Ready (28 September 1998).**(38)**

Just as has occurred in Europe, modern biotechnology application in agriculture has given rise to the mobilization of public opinion which, in the case of Brazil, has been headed by consumer protection bodies and non-governmental organizations.

An important result of this mobilization has been the decision handed down on 18 June 1999 by Judge Antonio Souza Prudente of the Sixth Circuit Court of the Brazilian Federal Justice system, who, in a case file by the Brazilian Consumer Defence Institute, ruled that the companies sued, Monsanto de Brasil Ltda. And Monsay Ltda. should have submitted a prior assessment of the environmental impact of planting and marketing transgenic soybeans, in spite of the authorization granted by the CTNBio. This decision was appealed by the companies and Judge Plauto Ribeiro, Head of the Federal Regional Court of the First Region, has already ruled against suspending the sentence appealed, as was requested.**(39)** There has also been a particularly strong reaction in the state of Rio Grande do Sul, which is the largest transgenic soybean producer in Brazil, and its authorities have finally decided to transform it into a state "free from transgenic products".**(40)**

The debate is of great importance in a country such as Brazil, where intensive modern biotechnological activities are being conducted**(41)** and where the development of

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beings, genetic intervention in human beings, imports of genetically modified microorganisms for use in work in confinement, etc.

(36) *Cf.* Leila Machado Oda *et al*., "Risk Assessment and Risk Management of Genetically Modified Organisms in Brazil", a paper presented at the joint UNEP-ECLAC meeting on "Biosafety Policy, Law and Administration in the countries of Latin America and the Caribbean" (Santiago, Chile, 29 and 30 November 1999).

(37) *Cf.* Leila Machado Oda *et al*., "Risk Assessment and Risk Management of Genetically Modified Organisms in Brazil", a paper presented at the joint UNEP-ECLAC meeting on "Biosafety Policy, Law and Administration in the countries of Latin America and the Caribbean" (Santiago, Chile, 29 and 30 November 1999).

(38) *Ibidem.*

(39) For its part, on 30 June 1999, the National Environment Council of Brazil issued a resolution in which it reaffirmed the need for an environmental license and the application of an environmental impact study for releasing transgenics into the environment, in accordance with resolution 237/97 of the Council itself.

(40) Various non-governmental organizations meeting on 20 August 1999 in Porto Alegre, the state capital of Rio Grande do Sul, demanded, among other matters, that the federal, state and municipal governments, based on precautionary criteria, immediately suspend each and every action to legalize the production and marketing of national and imported transgenic foods.

(41) As of July 1999, 112 institutions had received an environmental quality certificate to conduct research on GMOs, which is being preferentially aimed at maize, soybeans and sugarcane. *Cf.* Leila Macedo Oda et al., "Risk assessment and risk management of genetically modified organisms in Brazil", a paper presented at the First Brazilian Congress on Biosafety and the First Latin American Symposium on Transgenic Products (Rio de Janeiro, 26-29 September 1999).

agriculture oriented towards genetic products is a priority in the economic policy of the government.[(42)]

The Law on Biosafety

In most of the countries of Latin America and the Caribbean, biosafety regulations have been developed around the rules established some time ago. In Brazil, it was decided to enact a specific law on biosafety. However the 1995 Law does not regulate all biosafety topics, but only the genetic engineering techniques and the release of GMOs into the environment.[(43)] The Law does not deal, for example, with the importing of domesticated or wild organisms or the movement of these organisms from one region to another in Brazil, which, in fact, can have environmental impacts equal to or even more serious than those of certain GMOs. These topics are regulated by other provisions, specifically by legislation on plant and animal health, which is perhaps insufficient to cover them appropriately. The Law on Biosafety is supplemented by Decree no. 1.752 of 1995, which provides regulations for Law no. 8.974 of 5 January 1995, establishes provisions on the linkage, sphere of competence and composition of the National Technical Commission on Biosafety, and calls for other measures. Article 3 of this Decree was amended by Decree no. 2.577 of 1998.

Eight activities related to GMOs are dealt with in this Law: construction, cultivation, handling, transport, marketing, consumption, release and disposal. The interests protected are the life and health of human beings, animals and plants, as well as the environment. The Law also establishes mechanisms to monitor the activities that use genetic engineering techniques, including scientific research, which can only be conducted by juridical persons.

The competent bodies in the federal sphere are the Ministries of Health; of Agriculture and Supply; and of Environment, Water Resources and the Legal Amazon. These Ministries must take into account the final technical rulings of the CTNBio, which means that they must consider them, but not necessarily obey them. These functions also involve the participation of the Ministry of Science and Technology, through its control over the CTNBio. Control is carried out through three specific administrative requirements: registration of the products that contain GMOs or products derived from them; authorization for the operation of entities that conduct GMO-related activities; and authorization to bring into the country any product that contains GMOs or products derived from them. The existing authorization system includes the release of GMOs into the environment.[(44)]

The previous environmental impact assessment provided for in the Constitution and in the Law on National Environmental Policy fulfil an important function in this case. The CTNBio functions in Regulations of the Law include demanding the environmental impact assessment (EIA) as an additional document if considered necessary, and the environmental impact report (RIMA) on the products and the application included in the release of a GMO into the environment, in addition to specific demands related to

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(42) *Cf.* Leila Macedo Oda et al., "Risk Assessment and Risk Management of Genetically Modified Organisms in Brazil", a paper presented at the joint UNEP-ECLAC meeting on "Biosafety Policy, Law and Administration in the countries of Latin America and the Caribbean" (Santiago, Chile, 29 and 30 November 1999).

(43) In accordance with the sole paragraph of article 3 in the Law, the results of techniques that do not involve the direct introduction of hereditary material into an organism are not considered GMOs as long as they do not include recombinant DNA/RNA molecules or GMOs (such as *in vitro* insemination). Furthermore, the Law does not apply to genetic modifications that are obtained through certain techniques that do not involve the use of a GMO as a receptor or donor (article 4).

(44) For all the above, *Cf.* Paulo Affonso Leme Machado, *Direito ambiental brasileiro*, Malheiros, Sao Paulo, 1999, 7th ed., second printing, pp. 785 and following pages.

the applicable degree of risk (article 2.XIV). As stated before, the demand for this requirement is in litigation in the case of transgenic soybeans.

The Law establishes provisions for an environmental quality certificate (CQB is its acronym in Portuguese), which the CTNBio is responsible for issuing. This certificate should be required by the interested company, which should certify its constitution as a corporation, its location and its financial suitability, and should provide a detailed description of its facilities and its staff. As noted previously, in July 1999, this certificate had been granted to 112 institutions.

It should be underscored that all the activities aimed at releasing GMOs into the environment must be authorized, case by case, by the competent ministry, bearing in mind the final technical ruling of the CTNBio. The procedure for this purpose includes a proposal by the chief researcher, an analysis of the proposal by the respective internal biosafety commission, the request submitted to the CNTBio, publication in the Official Gazette of the Union of an abstract of the project for comments by the public in general and local authorities, an analysis by the Specific Sectoral Committee and, finally the final technical ruling by the CTNBio and the final decision on the request, as well as publication in the Official Gazette of the Union and its notification to the internal biosafety commission.**(45)**

It should also be noted that CTNBio involvement continues after it has issued the technical ruling, since it assesses the manner in which the experiments are conducted and indicates measures that may be required for them to be carried out effectively.**(46)**

Finally, in the field of liability, the Law on Biosafety states that the actor responsible for any damage caused to the environment and to third parties affected by its activities shall provide indemnification or redress for them, whether or not there is unintentional lack of due diligence.**(47)** This civil liability exists without prejudice to any administrative or criminal liability for the same acts.**(48)** The Law also provides for a system of joint liability of the organizations that finance or sponsor GMO-linked activities or projects.**(49)** The Public Prosecutor's Offices of the Union and of the States are empowered to file related civil and criminal charges.**(50)**

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(45) *Cf.* Leila Macedo Oda et al., "Genetically modified foods: economic aspects and public acceptance in Brazil", a paper presented at the First Brazilian Congress on Biosafety and the First Latin American Symposium on Transgenic Products (Rio de Janeiro, 26-29 September 1999).

(46) *Cf.* Leila Macedo Oda *et al*. "Risk Assessment and Risk Management of Genetically Modified Organisms in Brazil", a paper presented at the joint UNEP-ECLAC meeting on "Biosafety Policy, Law and Administration in the countries of Latin America and the Caribbean" (Santiago, Chile, 29 and 30 November 1999).

(47) In this case, the principle of objective civil liability is followed, as was the case with the Law on National Environmental Policy of 1981.

(48) The Law of Biosafety defines five offences: the genetic manipulation of human germinal cells; *in vivo* intervention in human genetic material (except for the treatment of genetic defects); the production, storage or manipulation of human embryos to be used as biological material; *in vivo* intervention in genetic material of animals; the release or disposal of GMOs into the environment in violation of CTNBio regulations and the regulations of the Law.

(49) In the terms established in article 2, paragraph 3, of the Law.

(50) The topic had already been dealt with in the Law on Public Civil Action of 1995, where it was established that the main action and precautionary action provided for in this Law could be exercised by the Union, the States and the Municipalities, as well as by autarkies, public enterprises, foundations, mixed economy associations, and associations that fulfil certain requirements.

Plant and animal health[51]

The Regulations to Defend Plant Health date back to 1934 (Decree no. 24.114 of 12 April 1934). The Ministry of Agriculture and Supply is responsible for any plant material that enters the country for commercial or research purposes.[52]

The introduction of germ plasm is governed by the above-mentioned Regulations. If living organisms (useful insects and microorganisms) are being imported, authorization should not be granted without consulting the National Agricultural Defence Council. Quarantine regulations and procedures for the exchange of living organisms for research on biological control of pests, diseases, weeds and other scientific purposes are found in Internal Administrative Rule no. 74 of 7 March 1994, issued by the Ministry of Agriculture and Supply.

Animal imports for agricultural purposes are the responsibility of the Animal Health Defence Service, based on Decree no. 24.548 of 3 July 1934. As is the case with plants, a permit to import animals takes into account the origin (exporting country) and the potential health risk of the imports to domestic livestock. The interested parties should observe the specific procedures in this Decree.

These activities also involve the Ministry of Environment, Water Resources and the Legal Amazon, through the Brazilian Environment Institute (IBAMA). In fact, the IBAMA Wildlife Department is in charge of authorizing wild organism imports, based on the provisions in Internal Administrative Rule no. 29 of 24 March 1994. For its part, the IBAMA Department of Fisheries and Aquaculture is in charge of authorizing the introduction of aquatic species into the country, based on Decree no. 221 of 28 February 1967. The Ministry itself also has its own regulations for releasing living organisms (Internal Administrative Rule no. 29, 74 and 142, all of 1994).

Industrialized animal and plant products are the responsibility of the Ministry of Health. This Ministry has three specialized centres for analyzing medicines, cosmetics and industrialized foods, respectively.

Administration

Federal administration of the Brazilian biosafety system involves the participation of various ministries, such as the Ministry of Agriculture and Supply, the Ministry of Health and the Ministry of Environment, Water Resources and the Legal Amazon, in the terms indicated above.

A unique aspect of the Brazilian case is the inclusion of the National Technical Commission on Biosafety under the Ministry of Science and Technology, which differs from the case in many countries of Latin America, where the topic of biosafety is basically the responsibility of the Ministries of Agriculture.[53]

The National Technical Commission on Biosafety (CTNBio) is provided for in the Law on Biosafety and it was established almost a year later by Decree no. 1.752 of 1995, which provided regulations on its composition, powers and procedures.

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(51) For all that follows, *Cf.* Eliana M. G. Fontes *et al.*, "Sistema de información sobre biodiversidad/biotechnología para el desarrollo sustentable", April 1998, a paper that may be found at http:/www.bdt.org.br/sci?sci.legi.bio.

(52) Since 1977, plant materials for research have been dealt with by the Brazilian Agricultural Research Company (EMBRAPA is its acronym in Portuguese), a responsibility delegated to it by the Ministry.

(53) In Europe, in contrast, biosafety is the responsibility of the environment ministries, while in the United State it falls to the triad formed by the United States Department of Agriculture – USDA, the Environmental Protection Agency – EPA, and the Food and Drug Administration – FDA, according to the matter in question.

The Commission operates under the Executive Secretariat of the Ministry of Science and Technology and is responsible for biosafety in matters related to research on genetically modified organisms and the proposal for national biosafety policy. The CTNBio is formed by 18 members, of which seven are government representatives and 11 are from civil society.**(54)** The acts of the Commission are made public.**(55)**

The CNTBio functions, which it began performing on 16 June 1996, are mentioned in article 2 of Decree no. 1.752. They include: 1) to establish regulations regarding activities and projects related to GMOs;**(56)** 2) to classify GMOs according to their degree of risk; 3) to establish operating mechanisms for the Internal Biosafety Commissions (CIBIO) 4) to issue a final technical ruling on projects related to GMOs that belong to risk group II, and send that ruling to the competent bodies;**(57)** 5) to issue a final technical ruling prior to any release of a GMO into the environment, and send it to the competent bodies; 6) to issue a prior final technical ruling on the registration, use and marketing of products that contain GMOs or their derivatives, and send it to the competent bodies; 7) to issue a Biosafety Quality Certificate (CQB is its acronym in Portuguese);**(58)** 8) to require an environmental impact study and risk analysis, with specific requirements according to the degree of risk.**(59)** On the basis of these functions, the CTNBio has been proposing national policy on biosafety and representing the country at various forums.**(60)**

The CTNBio has Specific Sectoral Commissions (CSE), which operate as an extension of its activities, together with the Ministries of Health; of Agriculture and Supply; and of Environment, Water Resources and the Legal Amazon. The function of these commissions is to provide the supervisory bodies of these ministries with technical support. The commissions are formed by a representative of the respective Ministry in the CNTBio, who serves as the chair, and by members of the CNTBio in areas linked to this sector.**(61)**

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(54) One representative from each of the following ministries: Environment, Water Resources and the Legal Amazon; Science and Technology; Health; Education and Sports; and Foreign Affairs; two representatives of the Ministry of Agriculture and Supply (one from the plant area and another from the animal area); one representatives of the biotechnological business sector; one representative of the legally constituted body for the health protection of workers; one representative of the legally constituted body for consumer defence; and eight outstanding specialists in biotechnology (of which two should be in the human area, two in the animal area, two in the plant area and two in the environmental area).

(55) The principle of publishing governmental acts, established in the Constitution (where acts may be kept secret only in exceptional cases), is applied here, which is of special importance in this field, owing to the repercussions that these acts could have on citizens' lives.

(56) The function of establishing regulations takes place through the previously mentioned Regulatory Instructions.

(57) The Law on Biosafety establishes a classification of genetically modified organisms, in accordance with their degree of risk. Group II includes all of these organisms that present a major degree of risk and, therefore, are not included in group I.

(58) The CQB is granted for facilities to be used for any activities or projects that include GMOs prior to their operation or when the established safety conditions are to be modified.

(59) This is the result of article 2-XIV of Decree 1.752 of 1995, which authorizes the Commission to require this study as an additional document, if it deems it necessary, as well as the specific requirements for the applicable degree of risk.

(60) *Cf.* Leila Machado Oda *et al*. Risk Assessment and Risk Management of Genetically Modified Organisms in Brazil, a paper presented at the joint UNEP-ECLAC meeting on "Biosafety Policy, Law and Administration in the countries of Latin America and the Caribbean" (Santiago, Chile, 29 and 30 November 1999).

(61) The manner in which the functions of these Commissions were established is criticized by Paulo Affonso Leme Machado (*Cf. op. cit. supra*, pp.896 and 897).

Furthermore, in every institution that conducts genetic engineering activities, there is an Internal Biosafety Commission (CIBIO),[(62)] formed by at least three specialists in the field of biotechnology. In each institution there is also a chief researcher or chief technician responsible for each specific project.[(63)]

4. The case of Chile

Biological diversity in Chile is outstanding for its high degree of endemism, which makes its protection particularly important.[(64)] It is also a country where there have been some applications of modern biotechnology in agriculture.

Policy and law

Chile has an environmental policy officially established by the Board of Ministers on the National Environment Commission.[(65)] In this officially established environmental policy there is no explicit reference to biological safety as part of environmental protection.

However, it should be noted that the third specific objective in the policy consists of "promoting the protection of the environmental heritage and the sustainable use of natural resources" and that in the lines of action regarding the definition and establishment of standards and measures to conserve biodiversity, it states that: "Progress is being made in implementing the Convention on Biological Diversity through the preparation of a national strategy for the conservation, management and sustainable use of biodiversity and the design of a plan of action…". This indicates that the policy on biological safety, from the standpoint of environmental protection, will probably be defined in this strategy.[(66)]

What exists in Chile is a National Programme on Agricultural and Forestry Biotechnology, prepared by the Ministry of Agriculture to maintain and increase the competitiveness of this important sector of the national economy. The Programme grew out of a diagnosis of the situation regarding agricultural and forestry biotechnology in Chile, which demonstrated that both human and physical resources

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(62) In accordance with article 10 of the Law on Biosafety, these Commissions perform functions such as the creation and implementation of preventive programmes and periodic inspections, the delivery to the CTNBio of all the documents required for analysis and the issuing of authorizations to conduct research, when it is necessary; the preparation of registries of all the GMO-related activities or projects being conducted; delivery of notification to the CTNBio, to the health authorities and to the workers of the results of the risk assessments, as well as of any accident or incident that could cause the dissemination of a biological agent; the investigation of accidents and defects possibly related to GMOs, and delivery of notification of the conclusions and measures taken to the CTNBio; and preparation of annual reports on the matters established in the Law, including a list of the research projects under way or to be initiated, with all the contents required.

(63) Their duties are indicated in Annex II of Regulatory Instruction no. 1.

(64) In Chile there are more than 5,215 plant species, of which approximately 2,700 are endemic. There 142 species of native mammals, 96 of which are land mammals and 46 sea mammals, in the country. Of the land species, 16 are strictly endemic. Of the 439 recognized bird species. 15 are considered endemic; 31 of the 69 reptile species are considered endemic, and 25 of the 39 amphibian species are considered endemic (*Cf.* "La diversidad biológica y su conservación en América del Sur" UICN-Sur, Quito, 1998).

(65) It is set forth in a document entitled "An environmental policy for sustainable development", approved on 9 January 1998 by this Board. Through this document, "the Government declares the basis and principles of the environmental policy, lays down the lines of action to achieve them, and establishes its environmental agenda up to the year 2000". There it is stated that since the arrival of democracy (1990), sustainable development has been the general objective of governmental policy and, consistent with what has been done since that time, its environmental policy is made explicit in this document.

(66) Chile is a Party to the Convention on Biological Diversity, which was enacted in that country by Executive Decree no. 1.963 of 28 December 1994 and published in the Official Gazette on 6 May 1995.

were deficient, that there were no links between the generators of technology and its users and that there were no clear mechanisms in the country to encourage, coordinate and establish priorities for the activities to be developed in biotechnology in order to achieve the production of goods and services that could be used by the agricultural and forestry production sector or directly by consumers.**(67)**

In general terms, just as in most of the countries in the region, the policy on biological safety in Chile has been established preferentially through legislation and is expressed in various aspects, principally in relation to the protection of agricultural production, but also in relation to the protection of human health and the environment.

In Chile, the legal system for environmental protection is provided for in the Constitution and is developed, first of all, by Law no. 19.300 of 1994, the Law on General Bases for the Environment, whose provisions, although they do not specifically regulate biological security, can be applied, since, as indicated in article 1, they deal with "the right to live in a pollution-free environment, environmental protection, the preservation of nature and the conservation of the environmental heritage", without prejudice to any other legal regulations that may be established on these matters.

The legal regulations are included, for the most part, in agricultural legislation and, basically, in Decree Law no. 3557 of 1980, which has been amended several times (most recently through Law 19.558 of 1989), which establishes provisions on agricultural protection.**(68)** These regulations on agricultural protection provide for measures to prevent, control and fight pests,**(69)** which include the import, export and shipping in the national territory of goods hazardous to plants,**(70)** as well as fertilizers and pesticides.**(71)**

In matters regarding the introduction of these goods into the country, article 18 of this Decree-Law stipulates that, through a well-founded resolution, published in the Official Gazette, the Agricultural and Livestock Service may issue regulations for that purpose and "be able to reject or prohibit it". In any case, the entry of goods hazardous to plants, when permitted by the law, should be allowed only at ports of entry that the Service itself has authorized for that purpose (article 19). These goods should be accompanied by a health certificate that certifies they are free of the pests specified by the Service and, when deemed necessary, by a certificate of origin (article 20). The Service is responsible for inspecting any plant product to be introduced into the country (article 21). Customs, postal services and any other State organisms are

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(67) *Cf.* Carlos Muñoz, "Situación de la biotecnología en el sector agropecuario y forestal chileno: regulaciones y programa nacional", en *Gestión en biotecnología: propuesta de bases para Iberoamérica*, which is a publication prepared by CYDET (Buenos Aires, 1996).

(68) Consideration should also be given to the provisions in Decree Law no. 1.764 of 1977, which establishes regulations for seed research, production and marketing (published in the Official Gazette on 30 April 1977).

(69) Pest is defined as "any living or special organism which, owing to the degree and extension of its occurrence, poses a serious threat to the health of plants or their products" (article 3-b).

(70) Goods hazardous to plants is defined as "any items potentially capable of constituting or transporting pests" (article 3-a).

(71) The Penal Code, in turn, classifies offences related to plant and animal health, and severely sanctions any party which, intentionally and without a permit from the competent authority, propagates an animal disease or a plant pest with penalties that increase if the disease or pest propagated has been declared capable of causing serious damage to the national economy. The same is true if the propagation of the diseases referred to in this paragraph arise from the illicit introduction into the country of animals or plant species. Furthermore, the Code classifies as an offense the improper propagation of organisms, products, or chemical, viral, bacteriological, radioactive or any other type of elements or agents that could endanger plant or animal life, or their supply to the population.

prohibited from authorizing the entry of goods hazardous to plants without the Service having granted the related authorization (article 22).[(72)]

These provisions, which are common in all plant health systems, protect the plant health of the country and prevent the effects of phenomena such as the introduction of exotic plant species, but they have also served as a basis for regulating modern biotechnological safety, at least, from the standpoint of introducing transgenic products. In fact, on the basis of these provisions, the Agricultural and Livestock Service issued Resolution no. 1.927 of 5 October 1993 on the introduction of transgenic plant material for reproduction (amended by Resolution no. 4.144 of 1998), through which, considering the risks to agriculture posed by this introduction, it was stipulated that it could only be carried out after prior authorization by the Department of Agricultural Protection of the Agricultural and Livestock Service.[(73)]

It should be noted that, in accordance with this resolution, each entry of goods should previously be authorized by the National Director of the Agricultural and Livestock Service and that the authorization can only be granted for "material to be in reproduction for export purposes"; that is, for transgenic seeds that will be used to produce seeds for export. The request for authorization should be submitted together with a favourable report granted by the official agency of the country of origin, where it is indicated that the material was tested in the field and proved to be innocuous to agriculture and the environment (which, in fact, does not guarantee that it is equally innocuous to the environment where it is applied), as well as detailed technical information on the material, similar to that delivered in the country of origin to conduct the first field tests. The analysis methodology used to certify the transgenic material and the quarantine certificate granted by the office of the Service regarding the location of the proposed site should also be submitted. The authorization granted should include the conditions that must be met by the post-entry crop quarantine.[(74)]

Other important provisions in the field of biological safety are found in Law no. 19.473, published in the Official Gazette on 27 September 1996 (which replaced the former Law on Hunting), as well as in its regulations, enacted by Executive Decree no. 5 of 9 January 1998, which was published in the Official Gazette on 7 December 1998. The same may be said of Law no. 18.892, the General Law on Fisheries and Aquaculture, published in the Official Gazette on 21 January 1992, as well as its complementary regulations.

Biological safety is also regulated from the standpoint of public health, but modern biotechnological safety is not dealt with explicitly in the health legislation. The main body of regulations is the Health Code, which dates back to 1931, but was extensively amended in 1967 through Decree-Law no. 725, published in the Official Gazette on 31 January 1968 (subsequently amended by Law no. 18.826 of 1989). One of the important topics is the installation, expansion or transfer of biotechnological activities, which are subject to the Code's general provisions on the authorization that the

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(72) In the field of transporting goods hazardous to plants through national territory, it should be carried out in vehicles whose conditions, in the judgment of the Service, will prevent the pollution or propagation of pests (article 28), and such transport may even be prohibited through general resolutions when the risk of pollution makes it necessary (article 31).

(73) Apart from the previous regulations, through Resolution no. 1.165 of 10 August 1990, the import of cereals for consumption and industrialization will be authorized in each specific case by resolution of the Agricultural Protection Division, which will specify the quarantine requirements that must be fulfilled, indicating any additional declarations that should appear in the official plant health certificate of the country of origin to cover the shipment.

(74) On the basis of these provisions, the entry of transgenic seeds for subsequent export of tomato, canola, maize, soybeans, cabbage, tobacco and wheat have been authorized.

municipalities should be responsible for granting to industries for that purpose, following the health authority's report on the effects they could have on the environment.[(75)] In contrast, the Code contains specific regulations on radioactive installations, since article 86 specifies that the Health Service, in the territory under its jurisdiction, shall be responsible for granting prior authorization for radioactive facilities to operate there, in the understanding that such facilities are where radioactive materials or equipment that generates ionizing radiations are produced, treated, handled, stored or used.[(76)]

A particular concern is transgenic foods. In Chile, they are governed by the Health Code (recently amended for that purpose), as well as by a specific set of regulations dealing with them. In accordance with the provisions in force, the Health Ministry should evaluate this type of foods on a case-by-case basis, since they require special health authorization. These same provisions contain regulations on labelling transgenic foods.[(77)]

Administration

The main environmental organism in Chile is the National Environment Commission (CONAMA), established by Law no. 19.300 as an operationally decentralized public service, subject to the supervision of the President of the Republic through the Ministry-Secretariat General of the Republic. The main organs of CONAMA are the Board of Directors, the Executive Directorate, the Consultative Council and the Regional Environment Commissions. The Board of Directors is the maximum governing body of CONAMA and is formed by the Minister-Secretary General of the Presidency, who presides over it, and by the Ministers of Economics, Development and Reconstruction, Public Works, Agriculture, National Assets, Health, Mining, Housing and City Planning, Transport and Telecommunications, and Planning and Cooperation. Basically, CONAMA performs coordination functions within an environmental management system that consists of all the ministries, sectoral bodies of the central administration and the decentralized bodies to which the legal system in force in Chile assigns powers linked to environmental protection.

An important role in the field of biological safety is played by the Ministry of Agriculture and, particularly by the Agricultural and Livestock Service (SAG), which is an operationally decentralized service, subject to the supervision of the President of the

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(75) The same legal precept adds that, to issue such a report, the health authority shall take into account the community or inter-community regulatory plans and the risks that the industry's operations could pose to their workers, to the neighbourhood and to the community, but that the health authority shall issue a favourable report for a specific industrial or commercial activity, as long as the environmental health assessment carried out to prepare the report indicates that all the risks associated with its operation have been technically controlled. For its part, article 84 of the same Code states that the National Health Service shall be authorized to rule on the transfer of industries or deposits of materials which, in its judgement, may be hazardous to the health, safety and well-being of the population.

(76) The same legal provision states that the production, manufacture, acquisition, possession, use, handling, storage, import, export, distribution, sale, transport, abandonment or disposal of radioactive substances that are used or kept in radioactive installations or in equipment that generates ionizing radiations should be authorized by Health Services. Furthermore, it adds that these Services shall be responsible for controlling radioactive facilities and equipment that generate ionizing radiations; and for preventing the risks associated with the use and application of radioactive substances and ionizing radiations in relation to the people exposed, the element that generates them and the environment. And it concludes by indicating that the personnel who work in the radioactive facilities, using or handling radioactive substances or operating equipment or apparatuses that generate ionizing radiations, should have authorization from the pertinent Health Service. The Regulations on Authorizations for Radioactive Facilities and other similar activities was approved by Executive Decree no. 133 of 1984.

(77) *Cf.* Marcelo Urrutia, paper presented at the joint UNEP-ECLAC meeting on "Biosafety Policy, Law and Administration in Latin America and the Caribbean" (Santiago, Chile, 29 and 30 November 1999).

Republic through the Ministry of Agriculture. Its purpose is to contribute to the agricultural development of the country through the protection, maintenance and improvement of plant and animal health, the protection and conservation of renewable natural resources involved in the country's agricultural production and the control of agricultural inputs and products subject to regulation in the legal and regulatory norms.[(78)]

The powers and functions of the SAG cover a wide spectrum that includes all matters concerning the prevention, control and eradication of plant pests and communicable animal diseases, maintenance of a system for monitoring and diagnosing any forestry and agricultural diseases in the country that could have an important effect on national production, measures to prevent the entry into the country of any pests and diseases that might affect plant and animal health, the determination of measures that interested parties should adopt to prevent, control, combat and eradicate diseases or pests whose control is compulsory, and the direct or indirect implementation (although in a subsidiary manner) of activities to fulfil these measures when such pests and diseases could seriously affect national production, etc.[(79)]

In exercising these functions, the SAG issued the previously mentioned Resolution no. 1.927 of 1993 on the introduction of transgenic plant reproduction material. In parallel, the Ministry of Agriculture, through Resolution no. 269 of 1999, established a standing committee known as the Advisory Committee on the Release of Transgenic Organisms (CALT) and a Technical Secretariat. The Committee, whose responsibility is to advise the National Director of SAG on risk analysis, is formed by the Director of the Seed Department, the Head of the Agricultural Protection Department, the Head of the Agricultural and Livestock Protection Department, the Head of the Renewable Natural Resources Protection Department and in-house SAG and external specialists invited to serve on the Committee by the General Secretary of SAG. The CALT Technical Secretariat, in turn, is coordinated by the General Secretary of SAG and is formed by one professional from each of the different SAG departments mentioned in this Resolution.[(80)]

It should be noted that concerns about the development of biotechnology date back to the 1980s. In fact, the National Biotechnology Committee (CNB), unofficially attached to the National Commission on Scientific and Technological Research (CONICYT), was established in 1983. In 1987, CONICYT officially requested CNB to advise it on matters related to biotechnology and, on the basis of that mandate, CNB defined a set of interest areas and created a subcommittee for each of them. But, it was not until 1992, when biosafety, understood as biotechnological safety, was officially recognized through partial modification and regrouping into four major topic areas, with area III becoming the "human genome, diagnosis and biosafety area". Furthermore, on the

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(78) The SAG, which was formerly under the Chilean public administration, is now regulated by Law. no. 18.755 of 1989, amended by Law no. 19.283 of 1994.

(79) In addition to these powers and functions established in article 3 of the Law, there are others established in the same legal provision, such as enforcing and monitoring compliance with legal and regulatory norms on production and commerce in seeds, pesticides, fertilizers, animal feed, etc., as well as conducting bacteriological, food science and any other pertinent analyses and certifying fitness for human consumption of primary agricultural products for export; carrying out inspection and health control of pharmaceutical products that are exclusively for veterinarian use; restricting, in accordance with the law that regulates the field through substantiated resolutions of the National Director, the use or application of agrochemicals in specific areas in agricultural zones of the country when it could harm plant or animal health, or the conservation of renewable natural resources.

(80) *Cf.* Carmen Cabrera, "Análisis de riesgo", a paper presented at the joint UNEP-ECLAC meeting on "Biosafety Policy, Law and Administration in Latin America and the Caribbean" (Santiago, Chile, 29 and 30 November 1999).

basis of the results of a meeting of experts convened to define guidelines related to biosafety, CNB produced a document that included general biosafety principles, classification of risks and contention barriers, regulations for the release of microorganisms, bases for a biosafety plan and biosafety regulations for the management of microorganism pathogens in plants and animals and for the management of viruses, among other matters in the field.

The National Health Service has a Department of Environment Programmes, which is responsible for collaborating in the Service's programming by preparing specific environment programmes and supervising, coordinating and assessing the activities that the Service should conduct to protect the population from risks caused by the environment and to cooperate in the conservation, improvement and recovery of quality in its basic elements.

The activities of this Department are regulated by the Organic Regulations of the Health Service, approved by Executive Decree no. 4 of 1986, but did not include any functions specifically linked to biological safety and, in particular, to biotechnological safety, as may be seen in article 44.[(81)] The Department staff consists of professionals, technicians and other officials needed to perform the advisory and operational tasks it should fulfil in the areas of basic health, occupational health, food control, zoonosis and other environmental matters.

In at least one Health Service in each region, there is an environment laboratory that conducts the examinations and analyses required in the different areas of the specialty by the Departments of Environment Programmes in all the Health Services in the region, although, in accordance with the extension of the geographical area, communications and complexity, other Services may also have their own environment laboratories.

5. The case of Colombia

Colombia is another of the world's countries endowed with what is considered "mega-biodiversity", which makes the protection of its biological diversity from the standpoint of biosafety a matter of utmost importance.[(82)] In the case of Colombia, just as that of Peru, supranational decisions in the field must be taken into consideration, since it is a member country of the Cartagena Agreement.

Policy and law

The basic guidelines of Colombian environmental policy are established in its Constitution, which distinguishes itself among others by the number of provisions

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(81) These functions include, however, the preparation of programmes that should be conducted in accordance with the policies, general plans and technical regulations determined by the Ministry and the periodic assessment of the fulfilment of these programmes, so this article leaves open the possibility of preparing programmes on biological safety.

(82) This mega-diversity is based on the existence of approximately 50,000 higher plant species, of which more than 5,000 are endemic. The Chocó region is particularly important because of its endemism. Colombia also has the world's greatest diversity in bird species – 1,754 species, of which 73 are endemic – and it is also one of the countries with the greatest number of mammals – 359 known species. It has one of the largest numbers of reptiles with 386 known species, of which 104 are considered endemic, and it ranks second in the number of amphibians with 585 known species, of which 141 are endemic. (*Cf.* La diversidad Biológica en América de Su, UICN Sur, Quito, 1998). Of the total area of Colombia – 114,178,800 hectares of continental area – 53.2 million are covered by natural forests, 21.6 million by other types of vegetation in savannah areas, arid zones and wetlands, and at least 38.4 million are being used for agricultural purposes or for establishing settlements.

dedicated to environmental matters. There is, however, no provision that refers specifically to policy on biological safety. The topic is covered by broader provisions such as article 8 ("It is the obligation of the State and of persons to protect the cultural and natural wealth of the Nation"), 79 ("it is the duty of the State to protect the diversity and integrity of the environment, conserve areas of special ecological importance and promote education for achieving these goals") and 95 (which, among the duties of persons and citizens, includes the duty "to protect the cultural and natural resources of the country and safeguard the conservation of a healthy environment").

Subregional level

In the sphere of the Andean community, Decision 345/93 of the Cartagena Agreement applies to Colombia. Consequently, a common system to protect the breeders of new plant species is established, and the third transitory provision of the system stipulates that "The Member Countries shall, prior to 31 December 1994, approve a common system on access to biogenetic resources and guarantee the biosafety of the subregion, in accordance with the provisions in the Convention on Biological Diversity…".

This Decision was not adopted until 1996 and did not include the so-called "biosafety guarantee", probably because negotiations on the Protocol on Biosafety were under way at the world level. In fact, Decision 391/96, which established the above-mentioned "common system on access to genetic resources", states in its seventh transitory provision that: "The Member Countries shall adopt a common system on biosafety, in the framework of the Convention on Biological Diversity. To that end, the Member Countries, in coordination with the Board, shall initiate respective studies, particularly in relation to the transboundary movement of living modified organisms produced through biotechnology…"

The traditional topics of biological safety, however, occupy an important place at the subregional level, specifically in the regulations that make up the Andean System of Agricultural and Livestock Sanitation,[(83)] which were updated by Decision 328/92 to bring them into line with the rules of the World Trade Organization (WTO), especially the Agreement on Sanitation and Phytosanitation Measures.[(84)] This Decision has been supplemented by a set of Andean regulations that incorporate the principles contained in the Cartagena Agreement.[(85)]

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(83) The objectives contained in Article 2 of Decision 328 include: "d) Prevent the dissemination and transmission of any pests and diseases that may now exist in their territory, without that constituting a disguised restriction on intrasubregional trade and f) Standardize plant and animal health legislation in order to adopt subregional regulations and harmonize sanitation records".

(84) The information that follows was provided by Dr. Jorge Caillaux for preparing a document by the Latin American Association on Environmental Law, which is entitled "Medio ambiente y libre comercio en América Latina: los desafíos del libre comercio desde la perspectiva del Área de Libre Comercio de la Américas (ALCA)"", version of 31 March 1999.

(85) Decision 328 is supplemented by a number of Andean regulations that incorporate the principles contained in the WTO Agreement on Sanitation and Phytosanitation Measures, approved through Resolutions 347 (Andean sanitation regulation on intrasubregional trade in animals and products and by-products of livestock origin), 431 (Andean regulation on phytosanitation requirements applied to trade in agricultural products), 499 (Andean sanitation regulation for importing animals and livestock products and by-products from third countries) and 451 (which amends Annex 1 of Resolution 431) which harmonized animal health and plant health requirements for intrasubgregional trade and with third countries, and Resolutions 403 and 419, which update the Subregional Inventory of Pests and Animal Diseases of Economic Importance in the Andean Region and the Subregional Inventory of Pests and Plant Diseases of Economic Importance in the Andean Region, respectively. The Basic List of Pest and Diseases Exotic to the Andean Subregion was updated through Resolution 428.

In accordance with the existing System, the importing of agricultural and livestock products from the subregion by a Member Country is governed only by the sanitation regulations in the Registry of Subregional Sanitation Regulations of the Andean Community, for which a procedure is established. In preparing the Andean regulations, consideration was given to the national legislation of the Member Countries and the international sanitation regulations of the WTO governing bodies: the FAO International Convention on Phytosanitation Protection (CIPF), the International Epizootic Office (IEO) and the FAO/WHO Codex Alimentarius Commission.

Andean regulations that supplement Decision 328 include Decision 436 of 1998, which refers to the registration and control of chemical pesticides used for agriculture. The purpose of this Decision is to establish standardized requirements and procedures for the registration and control of chemical pesticides used for agriculture, to provide orientation for their proper use and management to prevent and minimize damage to health and the environment under authorized conditions and to facilitate their trade and distribution in the subregion. To that end, it is established that, if a Member Country decides to prohibit or severely limit the use of a pesticide because of the risks it poses to human health or the environment, it is obligated to notify the other Member Countries and the General Secretariat of that decision within 30 days at the most, and it may not export that product without the prior consent of the importing country. When chemical pesticides are manufactured or formulated in a Member Country exclusively for export, the competent national authority of that country shall provide the importing country with information on the reasons the product is not registered in the national sphere of the exporting country.

National level

The basic provisions for policy on biological safety are found in bodies of law of a general nature, which go beyond the topic of biological safety, such as the National Code on Renewable Natural Resources and Environmental Protection,**(86)** which was supplemented by Law no. 99 of 1993, as well as an important document called "National Policy on Biodiversity in Colombia".**(87)**

Among factors that deteriorate the environment, the Code includes the extinction or qualitative or quantitative reduction of animal or plant species or of genetic resources, the introduction of diseases or pests and the introduction, use and transport of harmful animal or plant species or products with hazardous substances (Article 8).

The Code also stipulates that the import of any plant specimen or product must have documents officially certifying that it meets all the regulations of the country of origin regarding plant health and the protection of species (article 198), and the Code's functions related to the management, use, exploitation and marketing of wild flora include provisions regarding the introduction or transplanting of plant specimens in national territory (article 201).

In the field of wild fauna, provisions of a similar nature have been established: article 258, item e), establishes that it is the responsibility of the Public Administration to prohibit or restrict the introduction, transplanting, cultivation and propagation of wild species harmful to the conservation and development of resources. This regulation is practically identical to that provided for in article 274 regarding hydrobiological resources, which, according to the Code, include the set of animal and plant organisms

(86) This Code entered into force through Decree no. 2811 of 18 December 1974 (Official Gazette of 18 December 1974).

(87) *Cf.* http://www.miniambiente.gov.co/miniamb/politicas/biodiversidad.htm

whose life cycle takes place completely within the aquatic environment and its products.

It should also be noted that, by regulating the sanitary protection of flora and fauna, article 290 stipulates that the introduction or import into the country of animal or plant species can only be carried out after having obtained prior authorization by the National Government, which shall take into account, among other factors, the protection of natural species, the need to develop or improve national agricultural and livestock production, the reactions of new species in the environment in which they are going to be introduced, the reactions of the receiving environment and of the native species to the species to be imported and the reaction to potentially hazardous races or biotypes.

Special mention should be made of article 291, which requires special authorization for the import, production, sale or distribution of hybrids or new species obtained through the use of genetic resources, as well as article 301, which stipulates that the Government shall establish the requirements and conditions for using genetic fertilization and modification methods.

The document on "National Policy on Biodiversity in Colombia", deals extensively with the topic of biological safety in chapter IV on "Strategy Guidelines".

In fact, Section A on "Conservation", number 2., refers to "Reducing processes and activities that cause biodiversity deterioration", which contains item b) on the "Introduction of invasive species and the transplanting of species form on ecosystem to amother". There it states that the introduction of invasive species and genetically modified organisms into the ecosystems of the country and the transplanting of species from one ecosystem to another is controlled through joint measures of the Regional Autonomous Corporations, the Ministries of Agriculture and Environment and the National Customs Office, whose entities shall define the bases for adopting codes of conduct against the effects of transferring, introducing and transplanting species. These codes shall be defined on the basis of studies on the introduction of exotic species, including genetically manipulated species and organisms used for biological control.

It also establishes that encouragement shall be given to the preparation of a protocol on biosafety in the framework of the Convention on Biological Diversity and the Andean Pact, that the necessary regulations shall be developed in the national sphere, and that it shall be the responsibility of the Ministries of Agriculture, of Health and of Environment and the respective research institutes linked to and under these ministries to design research programmes to assess the environmental impact of introducing species, taking into account the impacts on human populations and national biodiversity, and distinguishing between the impacts on land and water ecosystems. This assessment would be the basis for establishing measures to control invasive species according to the sphere of competence of the previously mentioned entities.

In relation to what this document on policy refers to as the transplanting of species from one ecosystem to another, it is stipulated that the institutions in charge of development, such as the National Institute of Fisheries and Aquaculture (INPA), shall evaluate the impacts of this activity on ecosystems and, in particular, its effects on previously established species and shall develop environmental criteria for the transplanting of species from one ecosystem to another.

Section C. "Usage", number 2, which refers to "strengthening and promoting the establishment of genetic banks and biotechnology programmes", states that the Humboldt Institute, the Colombian Agricultural Research Institute (CORPOICA), the

National Health Institute (INS) and the "Francisco José de Caldas" Colombian Institute for the Development of Science and Technology (COLCIENCIAS) shall promote the development of public, private and mixed biochemical and biotechnological research centres, facilitating the acquisition of equipment and the training of personnel, emphasizing, above all, the development of biotechnologies based on the use and improvement of native species, with cooperation between the private sector and research centres, as well as with national and foreign entities. Additionally, the Environment Ministry and COLCIENCIAS shall promote negotiations for a biosafety protocol and the regulations necessary to control the impact of releasing genetically modified species or varieties into the environment.

Finally, Section D. "Instruments", number 3. "Legislative development", indicates that the Environment Ministry and other competent entities shall make an analysis of legislation in the field of biodiversity to clarify the powers of the entities involved in its conservation and sustainable management and to identify the effectiveness of and gaps in legislation regarding the different aspects that deal with biodiversity. It also indicates that biosafety is a possible topic of the list of priorities for regulations.

In the field of modern biotechnological safety, the main legal regulations are found in Resolution no. 3.492 of the Colombian Agriculture Institute (ICA), issued on 22 December 1998, which regulates and establishes the procedure for introducing, producing, releasing and marketing genetically modified organisms (GMOs), and issues other provisions in this sphere.

The Resolution in question applies to plant GMOs that have been deliberately altered through the introduction of genetic material or through the manipulation of its genome and, consequently, does not apply to plants obtained through traditional improvement techniques and methods.

The Resolution also establishes an obligatory registry in the ICA in which the natural or juridical persons who dedicate their efforts to GMO introduction, production, content management, confined use, release and marketing must be registered.

Any GMO-related request must be examined on a case-by-case basis, and each of them must be subjected to the risk assessment necessary to determine the effect on agricultural production and agro-ecosystems caused by the GMO manipulation and use. For that purpose, the person submitting a request should fill out the application form which appears in an attachment to the Resolution.

In the field of GMO marketing, the Resolution also requires the related biosafety assessment, and it stipulates that the seeds, plants and other reproduction material intended for planting should have a clearly visible label with the words "GENETICALLY MODIFIED ORGANISM" printed on it.

The parties responsible for the GMOs authorized for marketing should follow up on them for at least three years after they are released and, consequently, they must submit the follow-up procedures to ICA for approval, although ICA may, in any case, decide to exercise any direct control it may deem advisable.

In general, those responsible for the GMOs must allow ICA to carry out verification, supervision and control of the tests, the taking of samples and the compilation of any information necessary to carry out its duties. Furthermore, in exercise of the precautionary principle or for reasons of biosafety, ICA can withdraw materials from the market whenever its deems it necessary, even though the materials have already been released into the environment, and it is not obliged to pay any indemnification.

The following acts are considered violations of this set of laws and can be sanctioned by ICA:

- Hindering ICA's measures to carry out, in a timely and appropriate manner, inspection and monitoring of greenhouse and field tests, storage sites, packing facilities and means of transport.
- Hiding or altering data, or refusing to provide the information requested by ICA.
- Failing to inform ICA, in a timely manner, of any biosafety risk or actual or imminent damage of which it is aware.
- Neglecting application, on a timely basis, of the mitigation measures provided for in case of emergency.
- Other acts that involve partial or total failure to comply with the provisions established in the aforementioned Regulations.

Administration

From an institutional point of view, the principal authority in environmental matters is the Environment Ministry, created in 1993 and divided into five Directorates and one Special Administrative Unit for the National Natural Parks System. The Ministry forms part of the National Environment System (SINA) in which 18 Regional Autonomous Corporations (CARs) also participate.

The functions of the Ministry, in accordance with Law no. 99 of 1993, which created it, include "to regulate, in accordance with the law, the acquisition, use, management, investigation, import and export, as well as the distribution of and trade in wild plant and animal species and genetic strains; to regulate the import, export and trade in such genetic material, establish control and monitoring mechanisms and procedures…", as well as "to issue environmental regulations for the distribution and use of chemical or biological substances for agricultural and livestock activities".

The same Law also stipulates that when the activities regulated by the Environment Ministry may affect human health this function shall be carried out in consultation with the Health Ministry, and with the Agriculture Ministry when it can affect plant or animal health. In actual practice, as will be seen further on, the Environment Ministry is not the principal regulator in the field of biotechnological safety.

Article 52 of the same Law states that environmental licenses are to be granted exclusively by the Environment Ministry for the "production and import of pesticides and substances, materials or products subject to control as a result of international agreements, conventions and protocols".

Although a number of institutions and regulations applicable to the field of biosafety in a broad sense have so far been listed here, in the field of living modified organisms (LVOs), the existing institutional and legal framework is concentrated basically in the agriculture sector.

The predominant role is played by the Colombian Agriculture Institute (ICA), which is attached to the Agriculture Ministry and has powers stemming from Law no. 101 of 23 December 1993, the "General Law on Agricultural and Fisheries Development".

ICA carries out activities for agricultural sanitation and technical control of the import, export, manufacturing, marketing, management and use of agricultural inputs and seeds used to protect national agricultural production and to minimize the food and environmental risks they involve. Its functions include adoption of the measures required for effective control of animal and plant health, and of biological and chemical risks, as well as technical control of the production and marketing of agricultural inputs and seeds that pose a risk to agricultural production and sanitation. This includes the

establishment of quality, effectiveness and safety requirements, as well as the methodology and reference procedures to determine whether they are met by agricultural inputs, in order to minimize risks that may result from their use.

Based on these powers and on Agreement no. 13 of 22 December 1998, ICA established the National Technical Council (CTN) for the introduction, production, release and marketing of genetically modified organisms (GMOs) used in agriculture. The Council serves as an advisory body to ICA in the field of agricultural biosafety and is formed by the following members:

- Head of the IDA Seed Division.
- Head of the ICA Plant Health Division.
- Coordinator of the ICA Genetic Resources and Biosafety Unit.
- A representative of the Environment Ministry.
- A representative of the Agriculture and Rural Development Ministry.
- A representative of the Health Ministry.
- A representative of the National University of Colombia.
- A representative of the Colombian Association of Seed Producers (ACOSEMILLAS), which conducts activities with GMOs.
- A representative of the National Association of Industrialists (ANDI), which conducts activities with GMOs.
- A representative of the National Campesino Association of Users (ANUC).
- A representative of the Colombian Farmers Association (SAC).

CTN functions are:

- To analyse the information provided by ICA and issue a written recommendation for each request examined.
- To advise ICA on measures and regulations aimed at plans for the use, management, production, release and marketing of GMOs in the short, medium and long term, indicating the activities required for that purpose.
- To advise ICA on the rules and regulations for activities and projects concerning the use, management, production, release and marketing of GMOs.
- To issue a judgement when a conflict in authority between State entities arises in the field of biosafety for GMO agricultural use.
- To propose national policies on biosafety for GMO agricultural use.
- To promote integrated work with other national and international entities in matters concerning biosafety of GMO agricultural use.
- Other functions entrusted to it through laws or regulations.

6. The case of Costa Rica

Costa Rica is a country endowed with a great wealth of biological diversity. Estimates indicate that it has five per cent of the world’s biodiversity, even though its area is not

large – 51,100 km^2. A system of protected areas that cover almost 23 per cent of the nation's territory has been established to conserve its resources.[(88)]

Recognition of the problems of biotechnological safety in Costa Rica has been more recent and is associated, as usual, with the development of biotechnology uses in agriculture, livestock breeding, industry and health. The first experiences in the field date back to 1991, when a meeting on biosafety was held in this country, sponsored by the Inter-American Institute for Cooperation on Agriculture (IICA). That meeting dealt with the first advances in the development of transgenic plants, criteria for releasing them in the field, and the shipping and importing of modified genetic materials.

The first applications for authorization to import transgenic seeds also date back to that same year, when a private company conducting seed reproduction projects for North American companies, requested and obtained authorization to conduct activities with transgenic soybean seeds resistant to the herbicide glyphosate made by Monsanto.[(89)]

Policy and law

The general guidelines of Costa Rican environmental policy are found in the Constitution and in the 1995 Organic Law on Environment. The specific guidelines on biological safety are found in a set of laws, including particularly the Law on Biodiversity, no 7.778 of 1998, as well as the Law on Wildlife Conservation, no. 7.317 of 1992, plus other laws that come from the agricultural sector: the Law on Plant Health Protection, no. 7.664 of 1997 (which was preceded by the General Law on Plant Health, no. 6.248 of 1978), and the Law on Animal Health. This list should also include the Law to Promote Scientific Development, no. 7.169 of 1990, which deals with the topic of biological safety in two of its provisions.

The Law on Wildlife Conservation[(90)] defines exotic species as organisms introduced into a specific country to which they are not native, in opposition, it adds, to what is autochthonous, endemic and indigenous (article 2). Article 3, when it establishes the sphere of public domain, includes species and varieties that have been introduced into the country and that have been genetically modified in the process of adaptation to the various ecosystems. The production, management, extraction, marketing, industrialization and use of the genetic material of wild flora and fauna, their parts, products and by-products, are declared to be of public interest and part of the national heritage.

Article 26 of the Law empowers the General Directorate of Wildlife in the Ministry of Natural Resources, Energy and Mines – now, the Ministry of Environment and Energy (MINAE) – to grant import permits for wildlife species. The permit application should be submitted to the Directorate together with an environmental impact assessment that includes, among other requisites, the objectives of importing the species, the actual

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(88) More than 8,500 species of plants, 220 species of reptiles, 160 species of amphibians, 205 species of mammals and 850 species of birds have been described in Costa Rica. *Cf.* the "Informe de Costa Rica" by Vivienne Solís Rivera and Patricia Madrigal Cordero, in "Un encuentro necesario: el manejo de la vida silvestre y sus regulaciones jurídicas. Análisis Centroamericano", ORCA-UICN, San José, 1994.

(89) Part of the information is found in the Country Report of Costa Rica (http://www.inbio.ac.cr/aoabio/Inf_país, and the paper "La regulación y control de los Productos Transgénicos en Costa Rica", by Walter Quiroz Ortega of the National Seed Office, presented at the Seminar "Impacto del Ingreso de Organismos Transgénicos y sus Subproductos a Costa Rica", was also used as a source.

(90) With regulations issued in Executive Decree no.2.2545-MIRENEM, published on 13 October 1993.

demand for the resources in the country, its life cycle in the original environment, its behaviour, movement and activity patterns, its potential as a predator, pest, competitor with native resources and species, control methods, potential hybridization, and experiences in introducing it in other countries. Violation of these provisions is punished by criminal and administrative sanctions provided for in the Law itself.

Article 50 of the Law adds that "all research and development activities carried out to obtain new varieties, hybrids, drugs or any other product obtained from wild species, their parts, products or by-products, should by approved by the General Directorate of Wildlife".

In turn, the Law on Biodiversity, in article 44, regulates the establishment of mechanisms and procedures for biosafety and, to that end, states that: "To avoid and prevent present or future damage or harm to human, animal or plant health or to the integrity of ecosystems, the regulations of this Law shall establish mechanisms and procedures for access to the elements of biodiversity for purposes of research on or the development, production, application, release or introduction of genetically modified organisms or exotic organisms".

Subsequently, the Law deals with liability in the field of environmental safety (article 45) and establishes that the State has the obligation to avoid any risk or hazard that threatens the permanency of ecosystems, as well as to prevent, mitigate or restore environmental damage that threatens life or deteriorates the quality of life. It adds that: "Those directing or responsible for the management of genetically modified organisms shall be civilly liable for any damage and harm caused, as established in the Organic Law on Environment, the civil code and other pertinent laws. Criminal liability is established in the existing legal regulations."

The Law also deals with the registry of and permits for genetically modified organisms (Article 46). It establishes that any individual or corporation that intends to import, export, experiment with, mobilize, release into the environment, reproduce, market or use genetically modified organisms for research purposes in the agricultural field, regardless of whether they have been created in or outside of the country, must obtain a prior permit from the plant health protection service, which will submit a report to CONAGEBIO, and CONAGEBIO will keep a quarterly record of all national and foreign individuals and corporations that carry out activities in genetic manipulation. The National Technical Commission on Biosafety must also be requested to issue a judgement, which shall be binding and shall establish the necessary measures for risk assessment and management.

The Technical Office of CONAGEBIO has the authority to reject any clearly unsubstantiated request (the period and procedure will be provided for in the regulations). The Technical Office of CONAGEBIO can also modify or revoke any permit granted in accordance with the previous articles, if it bases its action on technical, scientific and safety criteria. If it suspects imminent danger, unforeseeable situations or the lack of compliance with official provisions, it can hold, seize, destroy or reissue genetically modified organisms, as well as other types of organisms, and can prohibit the transfer, experimentation, release into the environment, reproduction and marketing of such organisms to protect human health and the environment.

Law no. 6.248 of 2 May 1978, the General Law on Plant Health, was, at its time, the legal basis on which the Ministry of Agriculture and Livestock (MAG), through the General Directorate of Plant Health, considered the first applications submitted and established the technical requirements for importing transgenic seeds and releasing them into the environment.

This Law prohibits the import or transfer by any means of transport of agents that could cause, or any material that could propagate, pests or diseases in plants, and provides that the import of plants or plant products must meet a number of requirements, including a prior import permit, a plant health certificate and other documents demonstrating that they have not been contaminated by propagation agents or other means.

Nevertheless, and even though the purpose of this Law is to protect plants of economic value and their production against harm produced by pests and diseases and to prevent environmental pollution and contribute to safeguarding human and animal health, biotechnological safety was not explicitly dealt with in this regulation. Consequently, the General Directorate of Plant Health called for the establishment of a Committee of Experts with advisory capacities in this area. This is the way the National Technical Advisory Committee on Biosafety CTANB), attached to the Ministry of Agriculture and Livestock (MAG), was created and formally established in 1996 through Decree no. 2.5919 of MAG-MICIT, with basically advisory functions. In 1997, as a result of the Law on Phytosanitary Protection, it became a Commission and was defined as a advisory body to the State Phytosanitary Service, and it was indicated that its composition, powers and functions would be established in the related regulations.

Chapter IV, Section Two, of the Law on Phytosanitary Protection is dedicated to the physanitary regulations of biotechnological organisms or products. Article 41 of the Law states that: "Individuals or corporations that import, investigate, export, experiment with, mobilize, release into the environment, reproduce and market transgenic plants, genetically modified organisms or their products, agents of biological control and other types of organisms for agricultural use produced within or outside the country must obtain prior authorization from the State Phytosanitary Service".

When the Directorate of Phytosanitary Protection receives an application, it must convene the CTANB, which analyses the proposal and delivers a technical judgement to the official institutions. It should be noted that, for purposes of the applications and the import and/or release of transgenic plants in the environment, the requirements requested are as follows:

1. *Exact addresses of the exporters, importers and applicants.*
2. *Exact addresses of the natural or juridical persons who are developing the material.*
3. *Description of the genetically modified materials, indicating the morphological characteristics, physiological activities, etc.*
4. *Detailed description of the molecular biology.*
5. *Detailed description of the uses and purposes of the genetically altered material.*
6. *Description of the safety processes and procedures used to prevent pollution, release and dissemination of the modified product.*
7. *A detailed description of the final destination of the modified material.*
8. *A detailed description of the methods proposed for the management, treatment and final disposal of the product remnants.*

In the application is approved, the Directorate of Phytosanitary Protection Services issues the related permits and certificates, which it may subsequently modify or revoke (article 42), based on technical, scientific and safety criteria. It is also the

responsibility of this Directorate to supervise the material at the time it is imported, as well as the laboratory and field tests. These tests are also subject to supervision by the ONS and CTANB.

More specific regulations were introduced through Decree no. 26.921-MAG, the "Regulations of the Law on Phytosanitary Protection", through which phytosanitary regulations for plant biotechnology organisms and products were established and more precise specifications were set down for the composition of the CTANB and its operational mechanisms, as well as guidelines for the preparation, implementation and observation of phytosanitary measures.

The regulatory framework for biological safety is supplemented by Executive Decree no. 21189-MAG of 10 March 1992, which establishes the Council for Phytosanitary Protection in Integrated Pest Management, as well as by Executive Decree no. 2491-MAG of 14 November 1995, which creates the National Agricultural and Technology Transfer System(SNITTA) and the National Commission for Agricultural Research and Technology Transfer (CONITTA), entrusted with advising the Ministry of Agriculture and Livestock in this field, as well as with preparing and following up on the National Plan for Agricultural Research and Technology Transfer.

Administration

The institutions with key responsibilities in the field of biological safety (in the broadest sense of this concept) are the Ministry of Environment and Energy and the Ministry of Agriculture and Livestock.

In the case of the Ministry of Environment and Energy, its should be recalled that Decree no. 24.692-MIRENEM of 20 September 1995 established the General Regulations for the Ministry of Natural Resources, Energy and Mines, the institutional predecessor of the Ministry of Environment and Energy, and the provisions in the Regulations are therefore applicable to the Ministry of Environment and Energy. In the terms of these Regulations, it is the responsibility of the current Ministry of Environment and Energy to serve as the governing body for policies, regulations and administration regarding environmental laws and to guarantee the protection, conservation and sustainable use of the country's natural resources.

The most important functions of the MAG in this field are those that take place through the previously mentioned Technical Commission on Biosafety, an advisory body to the State Phytosanitary Service, whose powers include recommending to entities of the State Phystosanitary Service, when there is any suspicion or evidence of hazards, unforeseeable situations or failure to fulfil official provisions, that transgenic plants, living modified organisms or their products, biological control agents and other types of organisms for agricultural use should be withheld, seized, destroyed or reissued; and to prohibit the transfer, investigation, experimentation, release into the environment, reproduction and marketing of these organisms, with a view to protecting agriculture, the environment and human, plant and animal health. As is evident in the second of these two powers, the capacity of the Commission goes beyond advisory functions, since it makes decisions at a certain level.

This Commission, in accordance with the Regulations of the Law on Phytosanitary Protection, is formed by one representative of the Ministry of Science and Technology, two representatives of the Ministry of Agriculture and Livestock, one representative of the Ministry of Environment and Energy, one representative of the National Seed Office and four representatives designated by the National Academy of Sciences.

The following institutions form the institutional framework, not only for matters regarding biotechnological safety, but also biosafety in general:

a) The General Directorate of Plant Health is responsible for the entry and movements, in general, of plants, whether they are transgenic or not.

b) The National Seed Office (ONS) was established in 1978 as a semi-autonomous body attached to the MAG. Its activities are legally based on Law no. 6.289 of 4 December 1978, the General Law on Seeds, on the basis of which it is responsible for promoting and regulating seed production and marketing; it controls seed production in the country, and, at the same time, seeks to ensure sufficient supply. In carrying out its functions, the National Seed Office has monitored all the transgenic seed reproduction projects to date.[(91)] The ONS is responsible for coordination between public and private companies and with programmes for genetic improvement in the supply of varieties for seed certification programmes, and serves as a certifying entity.

c) The National Phytogenetic Resources Commission (CONAREFI), attached to the ONS, is in charge of promoting the gathering, use and exchange of germ plasm for its direct use in plant production and improvement programmes.

d) The Biodiversity Advisory Commission (COABIO), established through Executive Decree no. 24.555, serves as a technical consultative commission to provide advisory services and recommend measures to carry out commitments and new activities in the framework of the Convention on Biological Diversity and Agenda 21, promoting the dissemination and organization of discussions on the activities in the country in the field of conservation, sustainable use and equitable distribution in the uses of biodiversity.

e) The National Biotechnology Commission (CONABIOTEC), attached to the Ministry of Science and Technology, was established by Executive Decree no. 21.065 of 15 February 1993 and is in charge of recommending policies, technical and administrative guidelines, work areas and priorities in the field of biotechnology for all the entities in the public sector and in the National Science and Technology System, as well as promoting agreement plans with the private sector.

7. The case of Cuba

Biodiversity in Cuba is high – it is considered the greatest in the Caribbean Islands, with approximately 6,700 plant species divided into 1,300 genera and 181 families. Although there is less knowledge of the fauna than the flora, there is outstanding diversity in groups such as mollusks (2,947 known species), arachnids (1,300 species) and insects (7,493 species), in which estimates indicate that there are considerable numbers of species yet to be known. Endemism in Cuba is also considered the highest in the Antilles – 51 per cent in vascular plants and more than 90 per cent of the principal groups of land invertebrates. It is especially concentrated in the mountainous areas and particularly in the Sagua-Baracoa system where it is estimated that more than 80 per cent of the flora is endemic.

(91) As of 1996, according to the data of the National Seed Office (1997), 41 transgenic projects had been conducted in Costa Rica. All these projects have been contracted with United States companies to increase seeds for export.

Policy and law

Development of biotechnology and the chemical pharmaceutical industry has been part of Cuban State policy. In the 1980, the State put into operation an Economic and Social Development Programme for that purpose and established the so-called "Biological Front", formed by a set of research institutions that incorporated biotechnology into their lines of work. Concern regarding the safety of some aspects of biotechnology emerged in that development and was first specifically expressed in the establishment of a Biosafety Commission in the Academy of Sciences in 1984.**(92)**

In 1993, under the coordination of the Commission for Environmental Protection and the Sound Use of Natural Resources (COMARNA), the National Environment and Development Programme was prepared,**(93)** as a Cuban adaptation of Agenda 21. Chapter 12 of the Programme is dedicated to the "Sound Management of Biotechnology" and begins by recognizing the potential positive impact that the use of biotechnology and genetic engineering results can offer the developing countries.

In reference to national efforts, the Chapter notes that important results have already been obtained in the form of vaccines and medicines, decontamination of highly charged organic wastes, production of livestock feed, new varieties of plants and the production and use of biofertilizers and biological preparations for agriculture. The Chapter also states that means for establishing and controlling safety and cooperation measures were being improved. It cannot be said, however, that the topics related to biotechnological safety are emphasized in this Chapter,

In 1996, when efforts to prepare a new Environment Law were already under way, the Ministry of Science, Technology and Environment perceived the urgency of regulating some topics regarding biological diversity, including matters related to biosafety. This is the origin of Resolution 111 of 14 October 1996.

Resolution 111, which is still in force, does not apply to all biological resources. In fact, an exception in the enforcement of its provisions is made for biological resources related to agricultural, livestock and fisheries production of the Ministry of Agriculture, the sugar industry, the fisheries industry and other state producers, cooperatives and private producers duly authorized by the competent authorities, to be used for human food and animal feed, and that are traditionally used in the country for those purposes. However, the Resolution indicates that the introduction of species, subspecies, varieties and races, both of animals and plants, with a view to their extensive cultivation in the country or for use in genetic improvement programmes or other activities, shall not be included in the above-mentioned exception.

Chapter III of the Resolution is dedicated to the introduction of species, and stipulates that it shall be subject to approval by the Environmental Management and Inspection Centre,**(94)** together with the National Biological Safety Centre, which shall hear the opinion of as many institutions as necessary. It also establishes the criteria and requirements to be taken into account for approving such introductions. For its part, Chapter IV deals with the introduction of genetically modified organisms into the

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(92) Decree-Law no. 147 of 21 April 1994 stipulated that the Academy of Sciences of Cuba, which until then had assumed state management functions as a central administrative body of the State, would be called the Ministry of Science, Technology and Environment (CITMA). Subsequently, through Decree-Law no. 163 of 3 April 1996, the Academy of Sciences was reinstalled as an independent institution attached to CTIMA.

(93) Approved by the Government in 1993 and published in 1995 by the Ministry of Science, Technology and Environment.

(94) The Environmental Management and Inspection Centre has become the Environmental Inspection and Control Centre, also subordinate to the Environment Agency, and, in both position and rank, replaces the powers and functions of the former Centre.

environment and establishes that the National Biological Safety Centre, together with the Environmental Management and Inspection Centre and any other necessary centres and institutions, shall guarantee the implementation of measures aimed at appropriately controlling the introduction of genetically modified organisms into the environment and, for that purpose, shall take into account the factors that the Resolution lists specifically.

When the Environment Law was approved in 1997, it reaffirmed the powers of the Ministry of Science, Technology and Environment. In fact, in article 12, item h), in stipulates that it is the responsibility of the Ministry, "in coordination with other competent bodies and agencies, to put environmental policy into operation in the field of biological safety and to supervise its implementation." Thus, the authority for the Ministry to perform this governing function is established in a regulation of the highest rank.

The same Law contains other pertinent provisions, among which note should be made of article 28, which lists the activities subject to environmental impact assessment and includes, among others, "activities that involve the introduction of exotic species" and "efforts related to biotechnology, and biotechnological products and processes".

Article 86 of the Law stipulates that it is the responsibility of the Ministry of Science, Technology and Environment to issue provisions regarding the import and introduction into the environment of species that are new or are subject to special regulations, and, for that purpose, it should take into account the following considerations: a) possible reactions of species in the environment in which they are going to be introduced; b) possible reactions of the recipient environment and native species to the species to be introduced; c) the risk that potentially hazardous genotypes may be produced; d) the possible introduction of exotic and epizootic diseases that may affect plants and animals; e) the risk to human health; and f) other factors of special interest to environmental protection.

Finally, article 88, item l, of the Law establishes that it is the responsibility of CITMA to "regulate and control risks stemming from the use and release of living organisms modified by biotechnology or other substances or products that may affect the conservation and sustainable use of biological diversity or produce risks to human, animal or plant health".

As may be seen, the treatment given to the topic of biosafety in the Law is based on a broad concept, in which, although there are specifications regarding the risks resulting from biotechnology, it is dealt with in a more general context that covers the introduction into the environment of exotic species, whether they are genetically modified or not.

This is also the approach in the main regulation in the field of biosafety, Decree-Law no. 190 of 28 January 1999, "Biological Safety", which establishes general provisions that regulate the following activities in national territory:

a) *The use, investigation, testing, production, import and export of biological agents and their products, organisms or parts of such organisms with genetic information; and*

b) *The release into the environment of biological agents, organisms and parts of such organisms with genetic information, activities aimed at ensuring fulfilment of international commitments assumed by the Cuban State in the field of biological safety or related to it, the prevention of accidents that could occur and the adoption of measures to protect the environment and particularly the population, workers, animals and*

plants from any adverse effects that could be caused by activities related to organisms and parts of organisms with genetic information.

Decree-Law 190 defines biological safety as "the set of scientific and organizational measures, including human, technical engineering and physical measures, to protect workers in the facilities, the community and the environment from the risks involved in work with biological agents or the release of organisms into the environment, whether they are genetically modified or exotic; in order to reduce to the minimum any effects that may arise and rapidly eliminate their possible effects in case of pollution, adverse effects, leaks or losses".

In accordance with this broad definition, Decree-Law 190 regulates the topics of facilities and the release of organisms into the environment, as well as monitoring and inspection activities, the authorization system, hazardous biological wastes and biological emergencies.

Decree-Law 190 also establishes the bases for a set of regulations on biosafety, several of which are now being drafted, and the first Resolution (no. 42 of 5 April 1999, of the Ministry of Science, Technology and Environment) has already been adopted. It approves and puts into force the official list of biological agents that may affect man, animals and plants, which is attached as an annex to the Resolution.

Finally, Decree-Law 190 announces the issuing of regulations for the accounting and control of biological materials, equipment and technologies; of biological safety in the facilities that handle biological agents, organisms and parts of these organisms with genetic information; of facilities that handle biological and toxinic agents on different scales; of state environmental inspection of biological safety; and of biological safety certification.**(95)**

As occurs in other cases, there are legal frameworks supplementary to the regulations directly linked to biological safety, as in the case of veterinarian medicine and plant health (phytosanitary protection). The first of these fields is governed by Decree-Law no. 137 of 16 April 1993, "Veterinarian Medicine", which defines veterinarian medical service, establishes the functions of the Ministry of Agriculture, the veterinarian-sanitary quarantine system, the export, import and internal circulation of animals, products and raw materials of animal origin, and regulations on reproduction, breeding and slaughtering. This Decree-Law is supplemented by Decree 181 of 17 April 1993, which defines violations of its regulations.

In the field of plant health, Decree-Law no. 153, "Plant Health Regulations", of 31 August 1994, states that its objectives are to protect the national territory from the introduction and spreading of pests that may damage plants or by-products of plant origin that are subject to quarantine, as well as agents that facilitate their propagation accidentally or intentionally; to achieve satisfactory plant health conditions through the prevention, localization, control and eradication of plant pests; to establish basic regulations on plant health that include, among other matters, the import of plants, as well as of products and raw materials of plant origin; to determine the field of application for measures by the State Plant Protection Service; and to regulate the establishment or lifting of plant quarantines and of states of phytosanitary warning and emergency. A previous Decree, no. 169 of 17 April 1992, had defined violations in this field and established the authorities empowered to enforce measures.

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(95) *Cf.* Rodríguez Dueña, José "Gestión de la Bioseguridad en Cuba", a paper presented by Mr. Juan Carlos Menéndez de San Pedro, at the joint UNEP-ECLAC meeting on "Biosafety Policy, Law and Administration in the countries of Latin America and the Caribbean" (Santiago, Chile, 29 and 30 November 1999).

In contrast to the regulations already referred to, where the action of two decrees are combined in the same sphere, Decree 175 of 22 October 1993 contains the sole body of regulations on seed quality and violations, establishing the basic regulations and measures on the production, conservation, use, storage, transport, benefit, distribution, supply and sale of seeds, which includes the creation of the State Seed Fund, the establishment of the seed inspection and certification service, the control and registration of varieties and the regulations on import and export activities, all of which are also under the jurisdiction of the Ministry of Agriculture.

In relation to health legislation, Decree 104 of 26 April 1982, establishes the norms that apply throughout the territory of the Republic of Cuba for international health control and the procedure for controlling and collecting the related administrative fines.

For its part, the Public Health Law, Law 41 of 13 July 1983, establishes basic principles for the regulation of social relations in the field of public health, in order to contribute to guaranteeing health promotion, disease prevention, reestablishment of health, social rehabilitation of patients and social welfare. This Law makes the Public Health Ministry the governing body in the field, including scientific, technical and methodological regulations in all matters concerning the fight against epidemics, state health inspection, hygiene-epidemiological prophylaxis and health education. In accordance with the provisions in this Law, it is also the responsibility of the Public Health Ministry to issue measures related to environmental health control.

Decree-Law 54 of 23 April 1982, "Basic Health Provisions", establishes general regulations to orient sanitary hygiene control activities entrusted to the Public Health Ministry and indicates its functions to prevent and control diseases that may affect the health of the population, as well as to provide for measures that will contribute to a healthier environment and, in coordination with the Agriculture Ministry, specific health norms to regulate matters concerning the possession, transport and introduction into the country of farmyard animals, domestic animals and others, and measures to prevent communicable diseases, epidemics and the proliferation of vectors.

In another field, Decree-Law 186 of 17 June 1998, "Physical Safety and Protection System", regulates the operation of the System and establishes the powers of the Interior Ministry in this sphere, while Law 75 of 21 December 1994, on National Defence, establishes general mobilization in case of natural disasters. This Law provides for measures to reduce to the minimum the impact on flora and fauna in case nuclear, chemical, biological or incendiary weapons are used. It also confirms Civil Defence as a vital agency in the country's defence system, whose purpose is to protect the population and the national economy against destructive means of the enemy and in case of natural disasters or other types of catastrophes, as well as from the consequences of environmental deterioration.

Decree no. 205 of 25 March 1996, "Preparation of the Economy for Defence", in turn, includes, among the basic principles carried out to prepare the economy for defence, the following statement: "Natural resources and environment are protected, and strict control is maintained over environmental pollution in relation to military aggression, natural disasters or other types of catastrophes and, in necessary, steps are taken for rehabilitation. Protection is also provided for biodiversity, biological safety, hazardous and radioactive wastes, flora, fauna, land and inland waters".

Cuba has been giving special attention to the institutional development under way and, in that regard, it has also received support from the United Nations Environment Programme and the Global Environment Facility. The Science, Technology and Environment Ministry, through its National Biological Safety Centre, has been selected, together with 18 other countries (Bolivia is the other participating country from this

region), to implement its National Biosafety System, through the implementation of a Biosafety Pilot Project. Other projects are also being prepared for continuation of the first project, including the establishment of a Regional Centre for Training and Information Exchange and the designing of a National Biosafety Strategy.[(96)]

Some of the lines of action towards which the National Biological Safety strategy could foreseeably be directed are identified in the Action Plan of the National Biological Diversity Strategy.[(97)] The seventh section of the Plan is called "Environmentally safe use and development of biotechnology" and includes the following activities: implement the UNEP guidelines in the field of biological safety; prepare and implement training programmes and exchange of knowledge in the field of biological safety; conduct a national inventory of facilities, biological agents handled, and releases of organisms into the environment; identify species susceptible to being affected by the transfer of genes, taking the conservation of native species as a premise; establish a methodology for biological risk assessment and management for releasing biological agents and genetically modified and exotic organisms into the environment; prepare manuals and technical standards in the field of biological safety; prepare guidelines for using safe biotechnological methods for the conservation of species that require it, whether they be wild or domesticated and/or endangered; and implement a code of ethics for the use of biotechnology.

Lines of work that have so far been identified and are being conducted by the National Biological Safety Centre are biosafety in facilities, biosafety in releasing organisms into the environment, and safeguarding and safety in relation to international agreements. Particular emphasis is being placed on the development of a "biosafety culture", which includes diverse training activities.[(98)]

Administration

In 1993, the Commission for Environmental Protection and the Sound Use of Natural Resources (COMARNA)[(99)] was entrusted with aspects of biosafety and, through Resolution 1/94 of 25 March 1994, adopted by COMARNA itself, work in this sphere was regulated. Resolution 1/94, after listing the specific functions of the Commission in relation to biological safety, established two working groups: the Technical Advisory Working Group and the State Inspection Working Group,[(100)] formed by representatives of the institutions that make up the National System for Environmental Protection and the Sound Use of Natural Resources, to provide COMARNA with advisory services and to be in charge of performing functions related to biosafety in their respective institutions.

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(96) In the framework of this Project, four national workshops and one regional workshop were held to assess biosafety in the country, establish priorities, assess the national biological safety system and assess biological risk.

(97) The National Biological Diversity Strategy (1998) has been developed as an activity to adapt the Convention on Biological Diversity, under the auspices of GEF and followed a national country study on biological diversity, conducted in the same manner.

(98) *Cf.* Rodríguez Dueña, José "Gestión de la Bioseguridad en Cuba", a paper presented by Mr. Juan Carlos Menéndez de San Pedro, at the joint UNEP-ECLAC meeting on "Biosafety Policy, Law and Administration in the countries of Latin America and the Caribbean" (Santiago, Chile, 29 and 30 November 1999).

(99) COMARNA became part of CITMA through Decree-Law 147, as previously mentioned.

(100) The Technical Advisory Working Group was formed by the Cuban Academy of Sciences, the Public Health Ministry, the Agriculture Ministry the Higher Education Ministry, the Sugar Ministry, the Food Industry Ministry, the Revolutionary Armed Forces Ministry and the National Staff of Civil Defence, which, in the Environmental Inspection Group, were joined by the State Committee on Labour and Social Security and the Civil Aeronautic Institute, with the General Public Prosecutor's Office of the Republic as a guest participant.

In April 1994, COMARNA was eliminated, giving way to the current institutional system, whose essential component is the Ministry of Science, Technology and Environment, established through Decree-Law no. 147 of 21 April 1994. A subsequent agreement, of 25 November 1994, of the Executive Committee of the Cabinet Council, provisionally approved, until the new legislation on the organization of the Central State Administration is adopted, the objective, functions and powers of the Ministry of Science, Technology and Environment and established, among those functions and powers, that of directing and controlling the implementation of policy to guarantee environmental protection and the sound use of natural resources as part of the sustainable development of the country and proposing and establishing the national strategies necessary to protect specific natural resources and biodiversity, without any explicit reference to biological safety.

In exercising these powers and through Resolution 67 of 15 July 1996, the Ministry of Science, Technology and Environment established the Biological Safety Centre, attached to the Ministry, in order to organize, direct, execute, supervise and control the national biological safety system. For that purpose, the Centre was entrusted with the following institutional responsibilities:

a) *Organize, direct, execute, supervise and control, as necessary, the National Biological Safety System.*

b) *Participate, together with the competent bodies, agencies and institutions, in regulating and supervising activities related to the physical protection from biological and toxinic agents, as well as from organisms released into the environment.*

c) *Prepare and propose a comprehensive development programme and lines of research for biological safety, in coordination with specialized and competent bodies, agencies and institutions.*

d) *Conduct, together with the related bodies, agencies and institutions, assessments of risks to human health and the environment in relation to investment projects and other activities related to work with potential biological risks and propose pertinent measures in each case.*

e) *Organize and direct inspections of biomedical and biotechnological facilities, as well as any facility that operates with biological agents and areas in which organisms are released into the environment, so as to verify compliance with the provisions and standards established in the field of biological safety.*

f) *Propose juridical instruments and technical standards to allow biological safety measures to be established and supplemented.*

g) *Prepare recommendations regarding the incorporation of these topics in the study plans of middle- and high-level specialists, according to their needs, and promote the technical-professional specialization and improvement of personnel dedicated to biological safety.*

h) *Verify biological safety technical systems and equipment and primary containment barriers.*

i) *Establish procedures for the accounting and control of biological and toxinic agents and of organisms that are released into the environment, in coordination with the pertinent bodies, agencies and entities.*

j) *Organize and implement procedures for granting licenses to facilities that handle biological agents, as well as authorization or other types of permits for activities related to the siting, design and acquisition of facilities and the*

reception or shipment of biological and toxinic agents, as well as their destruction and disuse, important transfers, research or field testing and the release of organisms into the environment, and other activities related to fulfilment of the commitments assumed by the Republic of Cuba in international legal instruments in these matters.

k) *Establish a classification by risk groups of biological and toxinic agents that may affect humans, animals and plants, in coordination with the pertinent bodies, agencies and institutions.*

Even though CITMA is the governing body, many other agencies and institutions are involved in one way or another in activities related to biosafety and, in fact, they have been involved for decades, without explicit reference to the term, but dealing with related matters, such as the import and export of exotic species, veterinarian medicine and plant health, whose legal frameworks have already been referred to. The most important example in this regard is that of the Agriculture Ministry, the entity in charge of directing, executing and controlling application of the State and Government policy regarding forestry, wild flora and fauna, veterinarian and other activities.

Naturally, as we have already seen, the health sector is also involved, since the Public Health Ministry directs, executes and controls State and Government policy on matters regarding health problems of the population.

Other agencies closely linked to the topic are those linked to the internal safety and protection of facilities. That is the case with the Interior Ministry, which directs, executes and controls the organization, maintenance and defence of the safety and internal order of the country, and its principal powers and functions include directing the Physical Safety and Protection System, a set of organizational and control measures with safety and protection staff and activities to guarantee the integrity and care of persons, assets and resources related to possible dangers of different types.

Additionally, there is a National Civil Defence Staff, which is an entity in charge of safeguarding fulfilment of civil defence measures, which are understood as the set of State defense measures carried out in times of peace and during exceptional circumstances to protect the population and the national economy against an enemy's means of destruction and in cases of natural disasters and other types of catastrophes, as well as the consequences of environmental deterioration. The President of the State Council directs Civil Defence through the Ministry of Revolutionary Armed Forces, which, for that purpose, has the National Civil Defense Staff, the principal entity for directing the system.

Finally, note should be made of the Labour and Social Security Ministry, which directs, regulates and controls state and government policy regarding aspects of labour protection in the facilities and related safety measures, as well as the General Customs Office of the Republic, a system of agencies directly under the Cabinet Council, which is in charge of the customs system and, in that regard, controls factors in the provisions regarding the import and export of biological agents and genetically modified organisms.

8. The case of Mexico

Mexico is one of the countries with the highest levels of biodiversity in the world, just as other Latin American countries.[(101)] Furthermore, the country has been developing a certain biotechnological capacity, which is most evident in the field of transgenic plant production.[(102)]

Protection of this biological diversity is a priority matter in the country and has given rise to a set of measures, which, among other topics, deal with biological safety and particularly with the safety of modern biotechnology, whose development is overwhelming.

To date, specifically in reference to Mexican agriculture, more than 100 applications have been authorized to release living modified organisms (LVOs) in the field, in greenhouses, planted pots or laboratories; but, in most cases, it has been the incorporation of a characteristic into a species and the authorizations have been of one single type.[(103)] However, this situation is becoming more complex each day.

Policy and law

The federal government's biosafety policy has gradually been structured in certain key sectors of federal public administration, principally in the environment and natural resources sector, the agriculture sector and the health sector. This policy is reflected in the plans and programmes that have been produced by the national six-year planning system, but it is more frequently expressed in legislation that has been issued in recent years. However, there is no clear, sufficient and consistent policy that covers all the components of biosafety, and particularly the safety of modern biotechnology.

In the environment and natural resources sector, the 1995-2000 Environment Programme draws attention to the importance of the country's ecological assets and the importance of conserving them. The 1997-2000 Programme for Wildlife Conservation and Productive Diversification in Rural Areas, in turn, underscores the importance of the genetic information possessed by wildlife in Latin America, and indicates that it is the property of countries that hold only 11 per cent of all the existing patents in biotechnology that have been developed on the basis of Latin American wild products and resources that are also the property of these Latin American countries. The remaining 89 per cent belong to Japan, the United States and

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(101) In Mexico, there are at least 23,702 known plant species, 5,167 vertebrate species (of which at least 1,054 are birds, 704 are reptiles and 491 are mammals), 6,000 species of mushrooms, 2,625 arachnids, 2,780 Homoptera (cicadas, plant lice), 2,344 curculios (weevils), 1,805 bees and 1,816 butterflies. Mexico ranks fourth in the world in plant and amphibian species, second in mammals and first in reptiles. These species have a high degree of endemism. In fact, endemic species in Mexico include 9,670 plants (mostly Phanerograma), 1,760 arachnids, more than 265 Homoptera, 951 curculios, 200 butterflies, 174 amphibians, 368 reptiles, 11 birds and 142 mammals (*Cf.* Secretariat of Environment, Natural Resources and Fisheries and the National Institute of Statistics, Geography and Informatics, *Estadísticas del Medio Ambiente*, Mexico, 1997, p.71.

(102) Since 1983, theses types of activities have been carried out in the Plant Genetic Engineering Department of the Irapuato Unit of the Research and Advanced Studies Centre (National Polytechnic Institute), which was subsequently joined by the Biotechnology Institute and the Nitrogen Fixation Centre of the Universidad Nacional Autónoma de México, the Scientific Research Centre of Yucatan, the National Institute of Forestry, Agricultural and Livestock Research, the Colegio de Postgraduados, the Universidad de Aguascalientes and the Technological Institute of Celaya. In Mexico there is also an agriculture biotechnology group that belongs to the International Centre for the Improvement of Maize and Wheat.

(103) *Cf.* The document entitled "Organismos vivos modificados en la agricultura mexicana: desarrollo biotecnológico y conservación de la diversidad biológica", prepared through the Presidency of the Republic by researchers from ten institutions, under the coordination of the National Science and Technology Commission and the National Commission for Knowledge on the Use of Biodiversity (April 1999),p. 20.

member countries of the European Union. Finally the 1995-2000 Forestry and Land Programme emphasizes the importance of modern biotechnology in the reclamation of productive land that has been lost through the use of unsound agricultural practices or polluting industrial activity.

The 1995-2000 Agricultural and Rural Development Programme, in turn, underscores the importance that the present administration gives to modern biotechnology in this field, when it indicates that what may turn out to be the second "green revolution" is developing in this discipline: "genetic engineering" – says the Programme – "is very close to offering spectacular results for increased productivity and environmental protection". Consequently it proposes the preparation of a national agricultural biotechnology programme, which has not yet taken place.

An important part of the Programme is dedicated to planning for the strengthening of plant and animal health measures and activities to protect the country from the introduction of pests and diseases that could affect plant and animals, as well as to prevent the spreading of those that already exist. In the field of agricultural health, the Programme proposes to face the challenge of preventing the entry into the country of exotic pests and diseases that could affect national agriculture and livestock, as well as to control and eradicate diseases and pests that exist in Mexico. The Programme also proposes to promote the commercial trade of products from the agricultural sector with other countries in the framework of international agreements and conventions on plant and animal health that are in force or that could be established bilaterally or as part of multilateral agreements.**(104)**

Finally, the 1995-2000 Programme to Reform the Health Sector proposes a set of measures that involve strengthening the Research, Ethics and Biosafety Commissions in the institutions where health research is conducted, as well as furthering the establishment of units that provide support for several institutions, including biotechnology units.

All these references demonstrate the existence of a national policy in the field of biosafety, which is expressed in the various sectors of the federal public administration that are somehow linked to the field, but it does not reach the comprehensive scope required, at least within the national planning system. However, as has been stated, the most important elements of this policy are found in the legislation that regulates the matter, as will be seen below.

In any case, the need for a clear, adequate and consistent biosafety policy has already led to the preparation of a specific proposal to establish an entity that would formulate national policy on biosafety and would have wide credibility and independence, which would guarantee that the State governs this field of such great public importance, and that the adoption of decisions to prevent possible damage to biological diversity and human health would have broad backing by society and the scientific community.**(105)** This initiative was carried out several days ago through a Presidential Agreement to

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(104) This strategy includes ongoing communication with health services in other countries in order to exchange technical information and specialists, as well as with international organizations such as the International Office on Epizooic Diseases, the International Regional Agricultural Health Organization, the Inter-American Institute for Cooperation on Agriculture, the Pan American Health Organization, the Plant Protection Organization, WHO, FAO, and the Codex Alimentarius, as well as with States Parties to the International Plant Protection Convention.

(105) *Cf.* The document entitled "Organismos vivos modificados en la agricultura mexicana: desarrollo biotecnológico y conservación de la diversidad biológica", prepared through the Presidency of the Republic by researchers from ten institutions, under the coordination of the National Science and Technology Commission and the National Commission for Knowledge on the Use of Biodiversity (April 1999),p. 20.

establish the Inter-Secretarial Commission on Biosafety and Genetically Modified Organisms, which is examined further on.[(106)]

Legislation in the field is governed by the 1988 General Law on Ecological Balance and Environmental Protection (LGEEPA), which is a "framework" law on environmental protection and the promotion of sustainable development. This Law was extensively amended in 1996. The LGEEPA does not regulate biosafety in a systematic manner, but it contains some provisions that refer particularly to modern biotechnological safety, as is the case with articles 87 and 87 bis.[(107)]

In fact, article 87 stipulates that the gathering of wild flora and fauna species, as well as other biological resources for purposes of scientific research requires authorization by the Secretariat and should be subject to the terms and formal procedures established in any official Mexican regulations that may be issued, as well as in any other applicable regulations. But it explicitly states that these authorizations shall not cover their use for biotechnological purposes.

In turn, article 87 *bis* stipulates that the use of wild flora and fauna species, as well as other biological resources, for biotechnology purposes also requires authorization by the Secretariat, which may only be granted with the prior, explicit and informed consent of the owner or legitimate holder of the property on which the biological resource is located.

But article 87 *bis* adds two important rules: first, the owners or legitimate holders of the property shall have the right to an equitable share of the benefits that result or may result from the uses referred to in this article, in accordance with the applicable legal provisions; and, second, the Secretariat of Environment, Natural Resources and Fisheries (SEMARNAP) and other competent agencies of the federal public administration should establish the mechanisms necessary for the exchange of information on authorizations or decisions regarding the use of biological resources for biotechnological purposes.

In this field, and perhaps more than in any other, the conservation of biodiversity may be endangered by external factors. Thus, article 85 of the LGEEPA stipulates that, when required for the protection of species, SEMARNAP shall urge the Secretariat of Commerce and Industrial Development to establish regulatory or restrictive measures, either partial or total, on the export or import of wild plant and animal specimens and to impose the necessary restrictions on the circulation or transit through national territory of wild plant and animal species from and towards foreign destinations. This provision, which dates back to 1988, does not explicitly refer to living modified organisms (LMOs).

There is, however, another broader provision in the field, which is included in the regulations on hazardous materials and wastes and could be applied to LMOs if they can be considered hazardous materials, in accordance with their legal definition.[(108)]

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(106) The Agreement referred to was published in the Official Gazette of the Federation on 5 November 1993, and established the Commission in order to coordinate Federal Public Administration policies regarding biosafety and the production, import, export, mobilization, propagation, release, consumption and, in general, use and exploitation of genetically modified organisms, their products and by-products.

(107) Article 3 of the Law defines biotechnology as "any technological application that uses biological resources, living organisms or their by-products to create or modify products or processes for specific uses". The same precept defines biological resources as "genetic resources, organisms or parts of them, population or any other biotic component of ecosystems with actual or potential value or usefulness to the human being" and, in turn, genetic resources as "genetic material of actual or potential value".

(108) Hazardous materials are defined in article 3 of the LGEEPA as "elements, substances, compounds, wastes or a mixture of them which, apart from their physical state, pose a risk to the environment, health or natural resources because of their corrosive, reactive, explosive or biological-infectious characteristics.

This provision is article 153, through which the import or export of hazardous materials or wastes should be subject to any restrictions established by the Federal Executive, in accordance with the provisions in the Law on Foreign Trade. In any case, SEMARNAP is responsible for the ecological control and monitoring of hazardous materials or wastes that are imported or will be exported, applying the related safety measures, without prejudice to any pertinent provision in the Customs Law. Furthermore, the authorizations granted for the import or export of hazardous materials may be revoked when, among other cases, supervening causes prove that the authorized hazardous materials pose a greater risk to ecological balance than that taken into account for granting the related authorization and when the import or export operations fail to meet the requirements established in the ecological guide issued by SEMARNAP.

Another provision that should be taken into account in the field of biosafety, conservation and sustainable use of biodiversity is article 143 of the LGEEPA, through which pesticides, fertilizers and other hazardous materials are subject to any official Mexican standards issued in their respective spheres of competence by SEMARNAP and the Secretariats of Agriculture, Livestock and Rural Development; Health; and Commerce and Industrial Development.

However, basic mechanisms of the LGEEPA, such as environmental impact assessment and the regulation of high risk activities, give no consideration to the risk of modern biotechnology in their stipulations. The most important instruments for that purpose are the official Mexican standards established in accordance with the provisions in the 1993 Law on Metrology and Standardization and the legislation in force. And for such purposes, the most important legislation is found in the Federal Law on Plant Health and the Federal Law on Animal Health.

The Law on Metrology and Standardization states that the purpose of official Mexican standards shall be to establish the following factors, among others: 1) the characteristics and/or specifications that should be met by products and processes when they may pose a threat to the safety of persons; when they may damage human, animal or plant health, the general environment or the work environment; or when there is a need to preserve natural resources; 2) the characteristics and/or specifications, criteria and procedures to protect and promote improvement of the environment and ecosystems, as well as to conserve natural resources; 3) the characteristics and/or specifications, criteria and procedures to protect and promote the health of persons, animals or plants; 4) determination of the commercial, health, ecological, quality, safety and hygiene information and requirements that should be met by labels, cans, packaging and advertising of products and services to provide the consumer or user with information; 5) the characteristics and/or specifications that should be met by equipment, materials, devices and industrial, commercial, service and household facilities for health, aquaculture, agricultural, livestock, ecological, communications, safety or quality purposes, particularly when they are hazardous.

The purpose of the 1994 Federal Law on Plant Health is to regulate and promote plant health. In turn, the purpose of plant health is to promote and monitor compliance with plant health provisions; to diagnose and prevent the spreading and introduction of pests that affect plants, their products or their by-products; to establish plant health measures; and to regulate biological effectiveness, application, use and management of inputs, as well as the development and delivery of phytosanitary activities and services. This Law contains some provisions on transgenic materials that define how the "artificially modified genotypes which, owing to their traits of reproduction and permanence in the environment, have the capacity to transfer to another organism recombinant genes with the potential of presenting foreseeable or unexpected effects".

The authority for enforcing the Law is the Secretariat of Agriculture, Livestock and Rural Development (SAGAR).

On the basis of these two laws, the most important text on biosafety was issued; it is Official Mexican Standard NOM-056-FITO-1995, which establishes the phytosanitary requirements for national mobilization, import and establishment of field testing of organisms manipulated through the application of genetic engineering. In enforcing this standard, an important role is played by the National Committee on Agricultural Biosafety, which was established as an auxiliary consultative body of the General Directorate for Plant Health, formed by a collegiate body of specialists in related matters.**(109)**

NOM-056 regulates certification for releasing a transgenic product into the environment and establishes the requirements that should be met by the interested party to obtain it and the procedures that should be following regarding the application submitted for that purpose, which consists of its being reviewed by the National Committee on Agricultural Biosafety and, once a favourable judgement has been handed down by the Committee, of the certificate being issued by the General Directorate for Plant Health (DGVS).

In accordance with this NOM standard, the applicant should prepare a letter of commitment in which he assumes responsibility for the handling or destruction of the product in a way that will prevent it from entering the environment, once the tests have been concluded, as well as a statement when the procedure is carried out. The transgenic product released, mobilized and/or imported should be kept within the areas and locations specified in the application and should be identified with a label that contains the information required by the NOM standard.

The person authorized by SAGAR to carry out the inspections and follow-up on the transgenic product released should periodically report to the Secretariat on the behaviour of the product, based on the requirements that should be met, in accordance with the related certification. In turn, the individual or corporation that has been granted the phytosanitary release certification should send the DGVS periodic reports and a final report on the characteristics of the behaviour of the transgenic product, in accordance with the specifications in the related certificate.

There is also an obligation to inform the DGSV of any accidental release of the transgenic product, which should take place within 24 hours following the accident. If the manipulated product or the associated host organism present characteristics substantially different from those listed in the request, or if it presents signs of disease or presents mortality or any unforeseen effect on the organisms at which it was not targeted, a written report should be submitted within five working days following the incident.

The staff authorized by the Secretariat may inspect the place where the manipulated products will be released into the environment, the enclosed areas before and after the mobilization and records of the products as many times as considered necessary.

The NOM-056 standard also regulates phytosanitary certification for the import of transgenic products and notification of mobilization. It is the responsibility of the General Directorate for Plant and Animal Health Inspection at Ports, Airports and Borders to issue this certificate, which requires, among other requisites, an international phytosanitary certificate from the country of origin. For the interstate

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(109) The functions of this Committee have now been transferred to the Biosafety Consultative Council, in the terms of the Presidential Agreement that established the Inter-Secretarial Commission on Biosafety and Genetically Modified Organisms, published in the Official Gazette of the Federation on 5 November 1999.

movement of a transgenic product, the interested party should notify the DGSV, which should officially reply to the interested party, in the same time and following the same procedures required for import, noting whether such mobilization can be carried out. The individual or corporation that has been granted an import certificate for a transgenic product should notify the DGSV of the product's date of arrival at its final destination or failure to carry out the product's importation for any reason.

The DGSV may cancel the certificate for the release into the environment if it does not fulfil one or more of the conditions established in the certificate, and shall provide notification of the reasons for the cancellation within ten days.

To conclude with this topic, it should be noted that the success of shat is known as organic agriculture, which is a reaction to transgenic agriculture, led to the regulation of this activity through official Mexican standard NOM-037-FITO-1995, which establishes specifications in the production and processing of organic agricultural products. This NOM standard establishes the bases for certification of the production and processing of organic agricultural products, which makes it applicable to agricultural plant products that bear indications referring to organic production.

The purpose of the1993 Federal Law on Animal Health is to establish bases for the diagnosis, prevention, control and eradication of animal diseases and pests, with the exception of those whose habitat is aquatic. The Law regulates, among other matters, animal health measures and risk analyses, which consist of an assessment of the probability of the entry, establishment and propagation of animal diseases and pests in the national territory or an area in the country, in accordance with any animal health measures could be applied, as well as any possible biological, economic and environmental consequences. The Law also regulates biological products, that is, biological reagents, sera and vaccines that can be used to diagnose, treat and prevent animal diseases, as well as hormones and genetic material of animal origin that are useful for reproductive purposes. The authority for enforcing the Law is SAGAR. A set of NOM standards linked to the topic of biosafety is also derived from this Law.

Another Law that should be mentioned in this account of legal regulations that have a bearing on the topic of biosafety in Mexico is the 1996 Federal Law on Plant Varieties, which stems from the so-called "UPOV Convention" or "Plant Breeders' Convention" (the 1961 International Convention for the Protection of New Varieties of Plants, amended in 1978), to which Mexico is a Contracting Party. The purpose of this Law is to protect the rights of those who obtain new plant varieties, granting recognition to their rights as the breeder of a new plant variety, as well as their right to take advantage of and exploit, exclusively although temporarily, the new variety obtained and its propagation material (seeds).

The 1984 General Law on Health works together with previous laws to regulate certain components of biosafety, from the perspective of human health protection. A basic provision of the Law is article 98, which stipulates that in the health institutions, under the responsibility of the respective directors or head officials and in accordance with the applicable provisions, a biosafety commission should be formed to be in charge of regulating the use of ionizing radiations or genetic engineering techniques.

Another basic provision in the Law is article 232, which refers to medicines of biological origin for immunological action and stipulates that their label should include the specifications of the living organism used for their preparation and the name of the disease for which it is used, in accordance with accepted international nomenclature.

The General Law on Health also regulates pesticides, fertilizers and toxic substances from the standpoint of human health, stipulating, for example, that during the process, use or application of pesticides, fertilizers and toxic substances, efforts should be made

to avoid their contact or proximity to food and other objects which, once they have been contaminated, pose a risk to human health (article 280).

In the field of importing and exporting these products and raw materials, the Law entrusts the Secretariat of Health with their sanitary control (article 283). Sanitary authorization by the Secretariat of Health is required to import pesticides, fertilizers and toxic substances that pose a risk to health (article 298).

An important official Mexican standard (NOM-048-SSA1-1993) has resulted from the General Law on Health. It establish a standardized method for assessing health risks caused by environmental agents and fills the need for a useful instrument that enables the health authority to determine the degree of risk of a specific population, either that exposed to the agents or those who, for diverse reasons, remain in the area where the risk factors are generated for a long time and whose health may therefore be affected.

In the case of transgenic products, the consumer protection provisions referring to the information that should be provided take on special importance. In Mexico, the Federal Law on Consumer Protection states that all suppliers of goods or services must provide the consumer with clear, truthful and adequate information, whatever means is used, and it prohibits any information that directly or indirectly involves imprecision, vagueness, omission, ambiguity or exaggeration or that, through any other circumstances, may mislead the consumer or cause error or confusion regarding, among other factors, the components or ingredients that make up the product or their percentage in it, as well as the benefits or implications of its use (article 5).

Administration

Biosafety and, within it, biotechnological safety constitute a field that lies principally within the sphere of competence of the three Secretariats of State that have been mentioned: the Secretariat of Environment, Natural Resources and Fisheries (SEMARNAP); the Secretariat of Agriculture, Livestock and Rural Development SAGAR); and the Secretariat of Health. Each of them has different agencies that make up the basic core of biosafety management at the federal level.

SEMARNAP plays a leading role in the conservation and sustainable use of biodiversity. In accordance with article 32 *bis* of the Organic Law on Federal Public Administration (LOAPF), amended in 1994, it is responsible for promoting the protection, restoration and conservation of ecosystems and natural resources, as well as formulating and directing national policy in the field of natural resources, as long as these functions have not been explicitly entrusted to another agency, and to manage and regulate the exploitation and promote the sustainable use of natural resources that are the responsibility of the Federation, with the exception of petroleum and all liquid, solid and gaseous hydrocarbons, as well as radioactive minerals.

SEMARNAP has a decentralized body, the National Ecology Institute (INE), which, in the terms of article 54 of the By-Laws of the Secretariat, is responsible for formulating, directing and evaluating national policy in the field of ecology and environmental protection to ensure the conservation and restoration of ecosystems, as well as their sustainable use and development. One of INE's specific functions is to assess, examine and rule on environmental impact declarations of development projects, as well as to assess, examine and rule on environmental risk studies presented by those responsible for conducting high risk activities in operating establishments. To perform these duties, INE has various administrative units, including a General Directorate on Hazardous Materials, Wastes and Activities; a General Directorate for Ecological Management and Environmental Impact; and a General Directorate on Environmental Regulation.

The Secretariat of Agriculture, Livestock and Rural Development (SAGAR) is the federal agency which, in accordance with article 35 of the LOAPF, is in charge of these topics. The specific powers of SAGAR include promoting programmes and preparing official standards on animal and plant health, as well as planning, coordinating, supervising and evaluating health campaigns; organizing and promoting agricultural, livestock, poultry-breeding, bee-raising and forestry research; establishing experimental institutes, laboratories, breeding stations, seedbeds and nurseries; establishing links with institutions of higher education in the related localities in coordination, when pertinent, with SEMARNAP. SAGAR is also responsible for participating, together with SEMARNAP, in the conservation of farmland, pastures and forests, and for applying pertinent techniques and procedures for that purpose.

SAGAR has various decentralized agencies, as can been seen in its By-Laws, including the National Institute of Forestry, Agricultural and Livestock Research (INIFAP), which conducts biotechnology development activities[(110)] and the National Seed Inspection and Certification Service.[(111)]

In this field, however, the most important decentralized agency of SAGAR is the National Agricultural Health Commission, which was recently established to bring together the plant and animal health services in one single agency. The Commission members include the General Directorates for Plant Health, Animal Health, and Plant and Animal Health Inspection at Ports, Airports and Borders; as well as the parallel structures of the National Centre for Animal Health Verification Services, the National Centre for Animal Health Diagnostic Services, the Mediterranean Fly Unit, the National Reference Centre and the Mexico-United States Commission to Prevent Foot-and-Mouth Disease and other Exotic Animal Diseases.[(112)]

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(110) In fact, in accordance with article 37 of these By-Laws, it is the responsibility of INIFAP, among other functions, to generate and adapt agricultural, livestock and forestry knowledge and technologies, as well as to conduct research and promote the use of technology needed to conserve, protect, develop, restore and use, in a sound and sustainable manner, agricultural, livestock, farm forestry, poultry-breeding, bee-keeping and forestry production.

(111) In accordance with article 52 of the SAGAR By-Laws, it is the responsibility of this Service, among other functions, to further, promote, organize and coordinate, if pertinent, activities related to the protection of plant breeder rights, technology transfer in the field of phytogenetic resources and plant varieties; to establish, together with other pertinent agencies and institutions, international policies, activities and agreements on the conservation, access, use and comprehensive management of phytogenetic resources, rights to protect breeders and seed quality analysis; and to prepare draft official Mexican standards and Mexican regulations for the protection, evaluation and description of variety traits, as well as for seed certification, and to monitor their application, once they have been approved.

(112) In accordance with article 47 of the SAGAR By-Laws, it is the responsibility of the Commission, among many other functions, to establish and issue permits, licenses, certificates, opinions and any other regulatory instrument in the field of plant and animal health; to carry out plant and animal health inspections at ports, airports, borders and any checkpoints established; to regulate, in coordination with the competent agencies, the issuing of documents for the registration and import of agricultural pesticides and the machinery and equipment necessary to apply them, as well as to issue any related technical reports; to regulate and supervise the use of pesticides and of the machinery and equipment for their application, as well as to assess their effectiveness and quality in pest and disease control, in accordance with the official standards; to establish standards and regulate, in terms of plant and animal health, the import and mobilization of agricultural products and by-products, as well as the import of biological, chemical, pharmaceutical and feed products of agricultural origin , including feed for animal consumption, and, if pertinent, the equipment for their shipping, packing and storage; to regulate, in terms of plant and animal health, the national manufacture of biological, chemical, pharmaceutical products and feeds for use in animals or animal consumption, when they may pose a risk to plant and animal health, including services linked to the production process and, if pertinent, to control their destination and application; to withhold or denounce goods that pose plant and animal health risks to the country or fail to meet the applicable legal provisions, etc. As has been stated, the functions of the Commission have been assumed by the Biosafety Consultative Council, established through the Presidential Agreement that created the Inter-Secretarial Commission on Biosafety and Genetically Modified Organisms.

The National Committee on Agricultural Biosafety (CNBA), which was established as an consultative body to the General Directorate for Plant Health and has already been mentioned several times, had, until now, been carrying out its functions in the sphere of this Commission.[(113)]

Finally, the Health Secretariat is the federal agency which, in the terms of article 39 of the LOAPF, is in charge of establishing and directing national policy in the field of general health, with the exception of matters related to environmental health. Its many functions include planning, regulating, coordinating and assessing the National Health System and promoting appropriate participation of the public agencies and entities that provide health services, so as to ensure fulfilment of the right to health protection; planning, regulating and controlling health regulation services that are the responsibility of the National Health System; organizing and administering general health services throughout the Republic; directing general health policy in the Republic with the exception of agricultural health unless it involves maintaining human health; directing special health policy in ports, coasts and border areas, with the exception of agricultural health unless it affects or may affect human health; controlling hygiene and inspecting the preparation, possession, use, supply, import, export and circulation of food and beverages; controlling the preparation, application, import and export of biological products, with the exception of products for veterinarian use; regulating veterinarian hygiene exclusively in relation to food that may affect human health; and serving as the health authority, exercising powers in the field of general health that the laws confer on the Federal Executive, monitoring fulfilment of the General Law on Health, its regulations and other applicable provisions and exercising special action in the field of general health.

The Secretariat of Health has various general directorates that deal with matters linked to biosafety, including the General Directorate for Health Quality in Goods and Services and the General Directorate for Environmental Health.[(114)]

In this account of administrative components for biosafety and, more specifically, modern biotechnological safety, in Mexico, it should be noted that there is a National Commission for Biodiversity Knowledge and Use (CANABIO), which was established in 1992 by Presidential Decision, and amended in 1994. CONABIO is a inter-secretarial commission established in accordance with article 21 of the Organic Law on Federal Public Administration (LOAPF), which grants the President of the Republic the power to "establish inter-secretarial commissions to deal with matters in which several Secretariats of State or Administrative Departments should participate" (first paragraph), which "may be transitory or permanent and shall be presided over by whomever the President designates" (paragraph 3).

CONABIO plays a basic role in national environmental policy on the conservation of biodiversity and the sustainable use of its components and, at the same time, in response to the commitment that all countries assumed in 1992 in the Convention on

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(113) The Federal Law on Plant Health established the National Plant Health Consultative Council, which is the national consultative body in the field of plant health and provides the Secretariat with support in formulating, developing and evaluating phytosanitary measures (article 16).

(114) In accordance with article 22 of the By-Laws of the Secretariat, it is the responsibility of the latter Directorate, among many other functions, to conduct studies and determine the maximum allowable concentrations for the human being of environmental pollutants; to exercise health control and monitoring of establishments which conduct activities which, because they handle toxic or hazardous agents, pose a risk to health; as well as establishments, products and services indicated by a decision of the Secretary; and to exercise health control and monitoring and issue or revoke, if pertinent, health authorizations for processing, importing, exporting and final disposal of pesticides, plant nutrients and substances that are toxic or hazardous to health.

Biological Diversity in the field of "identification and follow-up" of biodiversity. The LGEEPA makes reference to the Commission when it stipulates that the criteria for the conservation and sustainable use of wild flora and fauna shall be taken into account in "the establishment of a national information system on biodiversity and certification of the sustainable use of its components being developed by the National Commission for Biodiversity Knowledge and Use" (article 80, paragraph V).

Finally, as indicated at the beginning, note should be made of the recently established Inter-Secretarial Commission on Biosafety and Genetically Modified Organisms, whose purpose is "to coordinate the policies of the Federal Public Administration regarding biosafety and the production, import, export, mobilization, propagation, release, consumption and, in general, use and exploitation of genetically modified organisms, their products and by-products (article 1). The Commission is formed by the heads of the Secretariats of Agriculture, Livestock and Rural Development; Environment, Natural Resources and Fisheries; Health; Finance and Public Credit; Commerce and Industrial Development; and Public Education; as well as the National Council of Science and Technology. The presidency of the Commission will be exercised on a rotational basis by the heads of the first three agencies referred to (article 3).

Together with the Commission, the Decision established a Biosafety Consultative Council, as a consultative body that the Commission must consult on technical and scientific aspects. It is formed by a minimum of ten researchers of recognized prestige and experience in these matters, and it assumes the functions that had been performed by the National Committee on Agricultural Biosafety (article 7 and the second transitory article).

The functions of the Commission are indicated, one by one, in article 2 of the Presidential Decision. They include, in particular, the preparation and presentation to the President of the Republic of national policies in the field, the incorporation of these policies in the sectoral programmes and the presentation of periodic reports to the President on the progress made in the activities entrusted to it. Another important function of the Commission consists of proposing the updating and improvement of the legal framework in matters that fall within its sphere of competence, and submitting to the National Standardization Commission proposals for official Mexican standards regarding experiments, production, marketing, importing, exporting, mobilization, propagation, commercial and semi-commercial experimental release into the environment, and human and animal consumption of organisms that are considered genetically modified, their products and by-products. It is also the responsibility of the Commission to determine, in accordance with the applicable legal provisions, criteria to standardize the processing of the granting of authorizations, licenses and permits that the agencies issue to conduct these activities and simplify the administration, as well as to recommend the criteria that should be observed in the related regulations, in order to make public the benefits and probable risks in the use and consumption of genetically modified organisms that are released in commercial and semi-commercial spheres, in accordance with the technical and scientific information available.[(115)]

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(115) Furthermore, it is the responsibility of the Commission, among other functions that should be mentioned in particular, to promote the establishment and continuous updating of a registry of genetically modified organisms, the establishment of a databank on the existence and distribution of wild species related to genetically modified organisms that may be released, as well as mechanisms for monitoring and assessing environmental impact on human and animal health resulting from the release, production and consumption of such organisms, their products and by-products; and to promote the systematization of national and international information pertinent to the functions of the Commission, as well as the establishment of a system for information, orientation, care and complaints related to genetically modified organisms.

9. The case of Peru

Peru is a country with mega-diversity.[(116)] The importance assigned to protecting biological diversity in the country is reflected in the 1993 Constitution, where it is established that "the State is obligated to promote the conservation of biological diversity" (article 68).

Priority areas for the development of biotechnology in Peru are plant biology, microorganism and industrial biology, human health and animal reproduction. It should be noted that, of these areas, the only one that has any guidelines for its development is plant biology. Those guidelines were prepared by the National Council on Science and Technology (CONCYTEC).

Policy and law

In accordance with the Constitution, "the State decides on national environmental policy" (article 67). Guidelines for this policy are established in the 1990 Code on Environment and Natural Resources. There, biological (genetic) diversity is included among the basic elements for guaranteeing and upgrading the population's quality of life (article 1, 4). Biological safety is regulated in chapter IX of this Code, from the standpoint of "genetic diversity and ecosystems".[(117)]

There is no specific policy on biotechnological safety, perhaps because it has only been developed to a small degree in the country. That is indicated in the National Strategy on Biological Diversity of Peru, when it states that "the report on the current situation of biotechnology in Peru estimates very little development of biotechnology, in view of its low impact on the productive sectors. The causes that lead to this situation are the lack of identifying this activity as a priority for the country's development, a limited critical mass of researchers, poorly equipped laboratories with limited logistic and information support, and few lines of research aimed at solving national priority problems in the medium and long term.[(118)]

What could be considered national biological safety policy in Peru is expressed in legislation at the subregional and national level.

The subregional level

Peru forms part of the Cartagena Agreement or the Andean Community of Nations, in the framework of which Decision 345/93 was adopted. This Decision establishes a Common System for Protecting the Breeders of Plant Varieties, and its Third Transitory

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(116) Estimates indicate that Peruvian flora consist of some 25,000 species – ten per cent of the world's total – and that 30 per cent of them are endemic. At the world level, Peru is the country that ranks fifth in number of species, first in number of plant species with properties known and used by the population – 4,400 species – and first in native domesticated species – 128. In fauna, it ranks first in fish – 2,000 species equivalent to ten per cent of the world total – second in birds – 1,730 species, third in amphibians – 330 species and third in mammals – 462 species. There are 70 million hectares of topical forest in the country. Peru is also one of the world centres of origin and domestication of potatoes, tomatoes, tobacco, beans, quinine and quinoa, among other species. Peru ranks first in varieties of potatoes, chile peppers, maize (36), Andean cereals, and Andean tubers and roots; it has 128 species of domesticated native plants which, in turn, have up to thousands of varieties and diverse wild forms (150 wild species of potatoes and 15 of tomatoes).

(117) The Code establishes that the population of *all* species shall be maintained at level sufficient to, at least, guarantee their survival and that the environments necessary for that purpose shall be safeguarded, with the State in charge of ensuring the conservation of species and the maintenance of their diversity (article 38).

(118) *Cf.* The National Strategy on Biological Diversity in Peru.

Provision stipulates that: "The Member Countries shall approve, prior to 31 December 1994, a Common System on Access to Biogenetic Resources and a Guarantee for Biosafety in the Subregion., in accordance with the provisions in the Convention on Biological Diversity…".

This Decision was not adopted until 1996 and did not include the so-called "biosafety guarantee", probably because negotiations on the Protocol on biosafety were under way at the world level. In fact, Decision 391/96, which established the above-mentioned "common system on access to genetic resources", states in its seventh transitory provision that: "The Member Countries shall adopt a common system on biosafety, in the framework of the Convention on Biological Diversity. To that end, the Member Countries, in coordination with the Board, shall initiate respective studies, particularly in relation to the transboundary movement of living modified organisms produced through biotechnology…"

The traditional topics of biological safety, however, occupy an important place at the subregional level, specifically in the regulations that make up the Andean System of Agricultural and Livestock Sanitation,[(119)] which were updated by Decision 328/92 to bring them into line with the rules of the World Trade Organization (WTO), especially the Agreement on Sanitation and Phytosanitation Measures.[(120)] This Decision has been supplemented by a set of Andean regulations that incorporate the principles contained in the Cartagena Agreement.[(121)]

In accordance with the existing System, the importing of agricultural and livestock products from the subregion by a Member Country is governed only by the sanitation regulations in the Registry of Subregional Sanitation Regulations of the Andean Community, for which a procedure is established. In preparing the Andean regulations, consideration was given to the national legislation of the Member Countries and the international sanitation regulations of the WTO governing bodies: the FAO International Convention on Phytosanitation Protection (CIPF), the International Epizootic Office (IEO) and the FAO/WHO Codex Alimentarius Commission.

Andean regulations that supplement Decision 328 include Decision 436 of 1998, which refers to the registration and control of chemical pesticides used for agriculture. The purpose of this Decision is to establish standardized requirements and procedures for the registration and control of chemical pesticides used for agriculture, to provide orientation for their proper use and management to prevent and minimize damage to health and the environment under authorized conditions and to facilitate their trade

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(119) The objectives contained in Article 2 of Decision 328 include: "d) Prevent the dissemination and transmission of any pests and diseases that may now exist in their territory, without that constituting a disguised restriction on intrasubregional trade and f) Standardize plant and animal health legislation in order to adopt subregional regulations and harmonize sanitation records".

(120) The information that follows was provided by Dr. Jorge Caillaux for preparing a document by the Latin American Association on Environmental Law, which is entitled "Medio ambiente y libre comercio en América Latina: los desafíos del libre comercio desde la perspectiva del Área de libre Comercio de la Américas (ALCA)"", version of 31 March 1999.

(121) Decision 328 is supplemented by a number of Andean regulations that incorporate the principles contained in the WTO Agreement on Sanitation and Phytosanitation Measures, approved through Resolutions 347 (Andean sanitation regulation on intrasubregional trade in animals and products and by-products of livestock origin), 431 (Andean regulation on phytosanitation requirements applied to trade in agricultural products), 499 (Andean sanitation regulation for importing animals and livestock products and by-products from third countries) and 451 (which amends Annex 1 of Resolution 431) which harmonized animal health and plant health requirements for intrasubgregional trade and with third countries, and Resolutions 403 and 419, which update the Subregional Inventory of Pests and Animal Diseases of Economic Importance in the Andean Region and the Subregional Inventory of Pests and Plant Diseases of Economic Importance in the Andean Region, respectively. The Basic List of Pest and Diseases Exotic to the Andean Subregion was updated through Resolution 428.

and distribution in the subregion. To that end, it is established that, if a Member country decides to prohibit or severely limit the use of a pesticide because of the risks it poses to human health or the environment, it is obligated to notify the other Member Countries and the General Secretariat of that decision within 30 days, at the most, and it may not export that product without the prior consent of the importing country. When chemical pesticides are manufactured or formulated in a Member country exclusively for export, the competent national authority of that country shall provide the importing country with information on the reasons the product is not registered in the national sphere of the exporting country.

The national level. The Code on Environment and Natural Resources and other laws

This Code is the basic legal text in the field of environment and natural resources in Peru. As noted previously, the Code establishes the guidelines for environmental policy in the country and regulates the topic of biological safety from the standpoint of "genetic diversity and ecosystems", which is the title of chapter IX.

In 1990, the Code was inserted into a legal system that included diverse laws on natural resources, such as the Forestry and Wild Fauna Law (Decree-Law no. 21.147 of 1975), which establishes the framework for the conservation of the resources its title indicates and, according to the second transitory provision of the Code, should have been updated within 60 calendar days after the Code was issued, but has not yet been amended. However, this system has been renovated in other topics, as is evident in the General Law on Fisheries (Decree-Law no. 25.977of 1992), which establishes the legal framework for activities related to the conservation, management and use of hydrobiological resources.

However, the most outstanding laws pertinent to the question at hand is the legislation that has been enacted in the past three years and culminated with a law that refers specifically to the topic of biotechnological safety. This legislation includes Law no. 26.744, the Law to Promote Integrated Pest Management; Law no. 26.821 of 1997, the Organic Law on the Sustainable Use of Natural Resources; Law no. 26.839 of 1997, the Law on the Conservation and Sustainable Use of Biological Diversity; and Law no. 27.104 of 1999, the Law to Prevent Risks Derived from the Use of Biotechnology.

Going back to the Code on Environment and Natural Resources, it should be noted that the provisions in chapter IX deal, first of all, with the introduction of exotic species, stipulating that authorization is required to introduce exotic species that may alter the diversity of species in an ecosystem and, in more general terms, requires such authorization for any introduction of plant and animal species into the country.**(122)** The Code also deals with plant and animal diseases.**(123)**

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(122) Article 40 stipulates that "the introduction of exotic species that may alter the diversity of species in an ecosystem should be previously authorized by the competent authority" and that "authorization shall not be granted to introduce any exotic species whose harmful effect has been duly proven". In turn, article 41 states that "the introduction into the country of animal or plant species may only be carried out following prior authorization by the competent authority", which must take into account, among other factors, the following criteria: "a) the reaction of new species to the environment in which they are to be introduced; b) the reactions of the receiving environment and of species native to the environment where they are going to be implanted; c) the risk of potentially hazardous races or biotypes".

(123) According to article 44 of the Code, the competent authority must issue the measures necessary to prevent the introduction or dissemination of animal or plant diseases, and the State should establish epidemiological prevention and control systems and promote the use of biological control systems. Article 55 adds that "the importing of any plant or animal specimen shall require official documents certifying that they have met the standards in the country of origin regarding plant or animal health and the protection of species".

The code gives special attention to the topic of genetic resources. In that regard, it states that "the genetic resources of the species that inhabit the national territory shall be conserved and used to the benefit of present and future generations", specifying that the State may prohibit the export of genetic resources whenever it considers it advisable (article 46). The State should promote and support research on genetic resources to determine their potential and possibilities for sustainable use, and should also promote the development and use of genetic resources in their place of origin as a means of conserving their existence to the benefit of the nation (article 47). Conservation of genetic resources in their place of origin should be carried out through the organization of genetic banks, herbaria, botanical gardens, zoos and other appropriate means (article 48).

Together with the Code, Law 26.744, the Law to Promote Integrated Pest Management, should also be considered part of this biosafety system. It promotes pest control in national agriculture through biological, cultural, genetic, mechanical and physical control and indicates that, in the case of genetic control, all the safety measures necessary to control possible genetic variation should be taken.

Similarly, the Organic Law on the Sustainable Use of Natural Resources (Law no. 26.821 of 1997), which deals with the establishment of a legal framework for the sustainable use of natural resources in the country, should also be considered part of the biosafety system, as well as Law no. 26.839 of 1997, the Law on the Conservation and Sustainable Use of Biodiversity, which regulates the conservation and sustainable use of ecosystems, species and genes.**(124)**

The Law on the Prevention of Risks Derived from the Use of Biotechnology(*125*)

The purpose of this Law is to regulate biotechnological safety in accordance with the Constitution and with the provisions in Article 8, letter g) and Article 19, numbers 3) and 4), of the Convention on Biological Diversity, approved by Legislative Resolution No. 26181, to protect human health, the environment and biological diversity; to promote safety in biotechnology research and development and its applications for production and the delivery of services; to regulate, administer and control risks derived from the confined use and release of LMOs; and to regulate the trade and marketing within the country and with the rest of the world of LMOs, facilitating international technology transfer, in accordance with the international agreements signed by and subscribed to by the nation.

This Law does not apply to activities related to the human genome, all the vaccinations applied to human beings and the organisms whose genetic modification is obtained through conventional techniques and traditional methods: *in vitro* fertilization, conjugation, transduction, transformation or any other natural process, as long as it does not involve the manipulation of recombinant DNA molecules or the use of LMOs as vector, receptor or parent organisms.**(126)**

The Law successively regulates the precautionary principle, risk assessment and management, information prior to the LMO introduction, general aspects of procedure

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(124) Article 25 of the Law declares research a national priority and refers explicitly to the knowledge, conservation, and industrial and medicinal application of genetic resources through traditional and modern biotechnology, while article stipulates that "research on and the development and production, release, introduction and transport of genetically modified organisms within the entire national system shall require safety mechanisms to prevent damage to the environment and human health".

(125) Published in the Official Gazette "El Peruano" on 12 May 1999, Year XVII-No. 6896. p. 173055.

(126) *Cf.* Jorge Caillaux, paper presented at the joint UNEP-ECLAC meeting on "Biosafety Policies, Law and Administration in Latin America and the Caribbean" (Santiago, Chile, 29 and 30 November 1999).

and confidentiality. The Law also stipulates that its regulations will be issued within 90 days following its enactment, but they have not yet been issued.

Within 60 calendar days following the date on which the Law enters into force, the public and private institutions conducting activities with LMOs in national territory should establish a Technical Standardization Committee to be in charge of preparing technical standards in the field of biotechnological safety, which will be approved by the INDECOPI Commission on Technical and Commercial Regulations.

Individuals and corporations that conduct activities involving LMO research, production, introduction, manipulation, transport, storage, conservation, commerce, marketing, confined use and release should register within 120 working days following the enactment of the Law in the registry implemented for that purpose by the related sectoral entities.

Some final provisions of the Law call for consultation with specific institutions. Thus, when activities with transgenic LMOs are conducted, it is stipulated that the National Programme on Genetic Resources and Biotechnology (PRONARGEB) of the National Agrarian Research Institute (INIA) should issue a technical opinion prior to proceeding with the fulfilment of registries, requisites and established procedures. If these activities take place in the Amazon region, a prior opinion should also be given by the Peruvian Amazon Research Institute (IIAP).

If LMOs of plant origin are to be imported, the National Agrarian Health Service (SENASA), prior to granting the related Plant or Animal Health Certificate, should require the importer to present the administrative decision in which the request to bring the OMO into national territory was approved.

Although rules for introducing LMOs from one ecosystem into another within the country have not been established, a Technical Standardization Committee has been established in IDECOPI with the direct participation of entities that work with LMOs, to establish domestic standards in the field of biotechnological safety. Registries have also been established for entities and for LMOs.[(127)]

Administration

The National Environment Council (CONAM) was established through Law no. 26.410 of 1994 and the "Law on the National Environment Council", and its organization and functions are established in Executive Decree no. 048-97-PCM of 1997, the "Regulations on the organization and Functions of the National Environment Council". CONAM is the coordinating body of State policies on all matters related to environment, including, of course, biological diversity and, consequently, factors regarding biosafety.

In accordance with the Law on the Prevention of Risks Derived from the Use of Biotechnology, the National Environment Council (CONAM) is responsible for inter-sectoral coordination in the field of conservation and sustainable use of biological diversity and, through the structural framework of environmental management, for coordination between the competent sectoral authorities in matters related to biotechnological safety.

CONAM presides over the National Commission on Biological Diversity (CONADIB), established through Executive Decision no. 227-993-RE, which is in charge of formulating the National Strategy on Biological Diversity, of coordinating the

(127) *Ibidem*.

environmental protection activities required with the other sectors and of serving as a consultative body in the field and as support for CONAM in proposing guidelines for LMOs.[(128)]

For its part, the Foreign Affairs Ministry has an Environment and Sustainable Development Department which, in turn, forms part of the Directorate for Special Affairs. One of the missions of the Directorate is to follow up on the country's fulfilment and participation in the international negotiations on the Convention on Biological Diversity and its Protocol on Biosafety.

The Agriculture Ministry (MINAG) includes various institutions related to the field, particularly the National Institute on Natural Resources (INRENA), which is in charge of regulating aspects related to renewable natural resources; the National Institute for Agrarian Research (INIA), which focuses its activities on aspects linked to genetic resources; the National Agrarian Health Service (SENASA), which is responsible for agrarian health and the import, export and internal transport of living specimens of flora, fauna and microorganisms; and the Regional Directorates of Agriculture, which, in all the regions of the country, deal with the national regulations on the use and management of protected natural areas and wild flora and fauna species.

This framework is completed by the Fisheries Ministry, in charge of managing biological water resources at the national level, and the Peruvian Amazon Research Institute (IIAP), which is an autonomous entity that has it headquarters in Iquitos, is responsible for research on and evaluation of resources in Amazonia, and includes agencies linked to water resources and biological diversity.

General functions of the competent sectoral bodies are: to fulfil and enforce legislation on biotechnological safety; to evaluate risk management programmes, to evaluate applications submitted to conduct activities covered by the Law, to issue administrative decisions to authorize or reject the applications; to keep records of the persons authorized to conduct activities; and to keep a registry of the LMOs and their by-products that have been authorized or rejected at the national level.

Conclusions

Many conclusions may be drawn from the case studies presented: these cases cover a significant number of countries in the region, as well as a significant geographical area and, thus, the most important components of biological diversity in the region. It should be noted, however, that the selection of these case studies does not exhaustively cover biosafety developments in the region, nor does it present all the possible political, law and administrative frameworks in the countries. Consequently it does not seek to be exhaustive, but rather to illustrate the trends and traits that distinguish biosafety development in the region and, on that basis, some conclusions and recommendations can be formulated.

The most important conclusions are listed below:

The first general conclusion that can be drawn is that the development of biosafety policy, law and administration differs in the countries examined. However, it presents a similar path, so the existing differences are, in fact, differences that have to do with the stage of development in each of these countries.

The second general conclusion is that development in the different countries has a common point of departure, which is the regulation of biological safety in reference to

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(128) For information on institutions in the field of biological diversity in Peru and other factors related to the National Strategy on Biological Diversity, see www.conam.gob.pe/endb/docs/Informe Nacional.

the introduction of exotic species and the effects that it could have on agricultural production and environment. At the same time, a biological safety system to protect human health has been established. The seriousness of these effects on agricultural and livestock production has resulted in the problems of biological safety being preferentially addressed in terms of plant and animal health, as well as health in general.

Important legislation in agrarian, health and environmental matters

Country	Agrarian and health legislation	Environmental legislation
Argentina	Law on the control of veterinarian products (1949) and Law on seed and phytogenetic creations (1973)	
Brazil	Regulations on Plant Health Protection (1934) and Law on Agricultural Policy (1991)	Law on National Environmental Policy (1981)
Chile	Health Code (1931), amended (1968 and 1989) and Decree-Law on Agricultural Protection (1980)	Lon on General Bases for Environment (1994)
Colombia	General Law on Agricultural and Fisheries Development (1993)	National Code on Renewable Natural Resources and Environmental Protection (1974)
Costa Rica	Law on Wildlife Conservation (1992) and Law on Plant Health Protection (1997)	Organic Law on Environment (1995) and Law on Biodiversity (1998)
Cuba	Decree on International Health Control (1982), Decree-Law on Veterinarian Medicine (1993), Decree on Seed Quality Regulations (1993), Decree-Law on Plant Health (1994)	Law on Environment (1997)
Mexico	General Law on Health (1984), Federal Law on Animal Health (1993) and Federal Law on Plant Health (1994)	General Law on Ecological Balance and Environmental Protection (1988) amended (1996)
Peru	Law on the Promotion of Integrated Pest Management (1997)	Code on Environment and Natural Resources (1990), Organic Law for the Sustainable Use of Natural Resources (1997) and Law on the Conservation and Sustainable Use of Biological Diversity (1997)

That is also the reason that the current administration of biosafety usually is the responsibility of agricultural and health authorities, with little participation on the part of environment authorities.

Incipient development to deal with modern biotechnological safety is evident, although it differs a great deal from country to country. This development is the result of biotechnology introduced from abroad, particularly in reference to agriculture, but also as a result of the first national developments in modern biotechnology. This situation is not limited to the largest countries in the region, which have begun to develop transgenic agriculture on a significant geographical scale.

Important institutions

Country	Entities
Argentina	Secretariat of Agriculture, Livestock, Fisheries and Food, Secretariat of Health and Social Action
Brazil	Ministry of Science and Technology, Ministry of Agriculture and Supply, Ministry of Health, and Ministry of Environment, Water Resources and the Legal Amazon

Chile	Ministry of Agriculture and Ministry of Health
Colombia	Ministry of Agriculture (Colombian Health Institute), Ministry of Environment and Ministry of Health
Costa Rica	Ministry of Agriculture and Livestock and Ministry of Environment and Energy
Cuba	Ministry of Science, Technology and Environment, Ministry of Agriculture and Ministry of Public Health
Mexico	Secretariat of Agriculture, Livestock and Rural Development, Secretariat of Environment, Natural Resources and Fisheries, and Secretariat of Health
Peru	National Environment Council, Ministry of Agriculture and Ministry of Fisheries

As a result of the causes that encourage it, a great deal of this development is concentrated on problems posed by the application of modern biotechnology in agriculture. The most widespread trend consists of extending the traditional system on biological safety to these new problems through the issuing of regulations and the establishment of institutions that deal specifically with such problems. But, this trend is being overcome in some countries that are seeking overall systems of biological safety that break with the existing inertia, surmount the sectoralization in which the problems have been addressed, and offer a comprehensive approach to dealing with such problems.

To a great degree, this comprehensiveness is now being attained through biosafety regulations and through the creation of commissions or committees whose functions are basically to advise specific administrative bodies in charge of decision-making.

Biosafety commissions and other similar entities

Country	Institution
Argentina	National Advisory Commission on Agricultural Biosafety (CONABIA) Commission on Biotechnology and Health (CONByS)
Brazil	National Technical Commission on Biosafety (CNTBio)
Chile	Advisory Committee on the Release of Transgenic Organisms
Colombia	National Technical Committee (CTN)
Costa Rica	National Technical Advisory Committee on Biosafety (CTANB)
Mexico	Inter-Secretariat Commission on Biosafety and Living Modified Organisms and the Biosafety Consultative Council
Peru	National Commission on Biological Diversity (CONADIB)

In any case, it is a process still being developed and depends on the specific problems in each country, but there are already some results that should be taken into account by those who wish to make innovations in their respective countries.

That being said, some more specific conclusions regarding biosafety policy, law and administration can be formulated, apart from the problems of sectoralization, as is the case with the conclusions presented below.

Since this document has special interest in the effects of modern biotechnology on biological diversity, perhaps an important conclusion to be formulated is the limited presence of the problems related to the effects of biotechnology on the environment in biosafety policy, law and administration, which can be explained by the way in which this process has developed.

In fact, there are few provisions from the agricultural sector that take into account the effects of biotechnology on biological diversity. These omissions also occur in environmental legislation itself, which has not yet assumed the problems of biosafety as a problem of major concern. The exception is to be found in the countries that have begun to construct a global system through biosafety laws and the establishment of entities that take into account all the possible effects of modern biotechnology.

Development of biosafety legislative

Country	Legislative development
Brazil	Law 8,974/95, "Law on Biosafety
Cuba	Decree-Law 190/99, "Law on Biological Safety"
Peru	Law 27,104/99, "Law to Prevent Risks Derived from the Use of Biotechnology"
Costa Rica	Law 7,778/98, "Law on Biodiversity (which dedicates a chapter to biosafety)

Even in the countries that have made the most important progress in this field, the topic of biological safety has not been completely incorporated. Generally, what draws attention to these cases are the problems of modern biotechnology from abroad. It is eminently a case of reaction to external pressures, which demand decision-making that involves increasingly complex processes.

In any case, endogenous biotechnology development, which is unquestionably increasing, does not match the rate or the magnitude of the steady increase in the areas planted with transgenic crops. Furthermore, progress in the plant field is much more evident than biosafety associated with transgenic animals.

It is also normal that biological safety policy is formulated through the same legislation that implements it. The legislative debate on the topic consequently becomes extremely important. However, the most significant regulations in the field of modern biotechnological safety are usually dealt with in administrative resolutions that are usually adopted apart from any public discussion of the issue. This fact is important because interests of all types involved in the decisions adopted can distort them.

The introduction of exotic species continues being considered on the basis of those imported from other countries, in circumstances in which the size of many of our countries involves important diversity of ecosystems and demands another approach to the problem.

At this stage of transition, there are two parallel systems of safety in many countries, which could be called the traditional system and the modern system, whose compatibility is not clear and, in any case, is perceived as complicated, particularly from a bureaucratic point of view.

It is possible that the new bodies established to address problems that must be faced lack the effective capacity to do so, that is, the human, technical and material resources needed to carry out the operations required. In this case, as in many others in Latin America and the Caribbean, the accelerated rate at which modern biotechnology is expanding forms part of a recurring economic crisis which, among

other factors, produces a fiscal crisis in the State and, therefore, a weakening of its control, not only in the traditional field of State activities, but also, and above all, in new matters that seem to be of priority to society, such as biological safety.

In synthesis, all that has been said regarding biosafety policy, law and administration arises from the specific unique features of each country that has been examined. There is a certain response capacity to face the traditional challenges posed by the problem of biosafety, but it is most probably insufficient at this time, and will be even more so in the future, given the overwhelming development of modern biotechnology and the risks that it may involve.

The lack of a comprehensive policy and legislation on biological safety to face the challenges posed not only by questions regarding the release of living modified organisms in national territory, but also biosafety problems in general, together with the lack of administration with effective capacity to apply the criteria established, clearly shows that the countries in the region need: 1) a clear, adequate and consistent policy on biosafety that takes into account the multiple factors involved in the development of modern biotechnology, including the transboundary movement of LMOs in the prevailing open world trade system; and 2) legislation and administration to enforce it; that is, legal instruments that establish the rules of the game and public entities that have the human, technical and material resources necessary to assess the risks of modern biotechnology.

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Chapter III
The international context

1. Introduction

This chapter examines the international context in which biosafety policy, law and administration in Latin America and the Caribbean have been expressed at the country level; that is, the international policies and legal regulations that deal with this topic at the world and regional level.

The purpose of this chapter is to show how the topic of biosafety and biotechnological safety in particular have been increasingly dealt with in the international context, which has been especially evident in the past two decades. In fact, in these past two decades a framework of international instruments – both binding and non-binding – has been established and these instruments are, to a great extent, comparable to national trends in the topic, since they show development that ranges from old instruments aimed principally at the protection of plant and animal health and the conservation of and trade in species, up to other more recent instruments where the problems of biosafety and biotechnological safety in particular are included more explicitly.

Consequently, this chapter examines, first of all, the Declaration issued by the United Nations Conference on Environment and Development and the world action plan approved at that Conference, known as Agenda 21 (Rio de Janeiro, 1992). It then examines international law that deals directly with the regulation of biosafety from different angles, as is the case with the Convention on Biological Diversity, signed at the same Conference and the International Plant Protection Convention.

Subsequently, note is made of other international agreements that refer, with different approaches (but preferentially with a view to protecting the natural environment), to the protection of biological diversity and which, for that reason, should be taken into account in the international context of biosafety. These include the International Convention for the Protection of New Varieties of Plants, the Convention Concerning the Protection of the World Cultural and Natural Heritage and the Convention on International Trade in Endangered Species of Wild Fauna and Flora, among others. Owing to its influence on the topic of biosafety, special attention is given to GATT 1994 and its supplementary instruments, especially the Agreement on Sanitary and Phytosanitary Measures, which regulate world trade.

Reference is also made to a set of other instruments that express world consensus on biosafety, such as the Technical Guidelines on Bosafety (UNEP), the International Commitment on Genetic Resources, the International Code of Conduct on the Distribution and Use of Pesticides (FAO), the Voluntary Code of Conduct on the Release into the Environment of Genetically Modified Organisms (UNIDO), the Codex Alimentarius (FAO), etc.

International law at the regional level is also recalled in this chapter, or at least mentioned. Finally, because of its importance to the topic being dealt with in this document, the Protocol on Biosafety, on which negotiations have recently been taking place, is examined separately in the following chapter. This Protocol would regulate the transboundary movement of LMOs that are produced using modern biotechnology and could have harmful effects on the conservation and sustainable use of biological diversity.

2. The Rio Declaration

The United Nations Conference on Environment and Development (Rio de Janeiro, 1992) approved the so-called "Rio Declaration". The Declaration reaffirms the Stockholm Declaration and "seeking to build upon it", proclaims 27 principles that seek to "establish a new and equitable global partnership through the creation of new levels of cooperation among States, key sectors of societies and people", as well as to work towards "international agreements which respect the interests of all and protect the integrity of the global environmental and developmental system".

The Rio Declaration does not refer directly to modern biotechnological safety, but it does establish Principle 15 known as the precautionary principle, which has a direct bearing on the topic being examined. Thus, what is called the "precautionary approach" appears in the first article of the Protocol on Biosafety as its governing principle.

Principle 15 of the Rio Declaration states that: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

The basis of the precautionary approach lies in recognizing that scientific proof that a given situation may affect the environment usually comes after the damage has already been done. Thus, the burden of proof is reversed, and a party who wishes to develop a given activity must demonstrate that it is beneficial or harmless to the environment or, otherwise, that its effects are under control. The adoption of a precautionary approach therefore assumes the adoption of scientifically-based criteria combined with an anticipatory and long-term approach.

In the topic being dealt with, the precautionary approach is also based on the idea that modern biotechnology is not a mere extension of traditional biotechnology, but rather involves an entire conceptual change of vast dimensions, that future impacts should be prevented to the extent allowed by existing information and that there should be early mitigation systems.[(129)]

3. Agenda 21

Agenda 21 is a detailed global plan of action by problem area, which contains cost estimates and attempts to assign responsibilities. Within these problem areas, Agenda 21 includes what is called "environmentally sound management of biotechnology", the area to which chapter 16 is dedicated.

Agenda 21 recognizes that the development of modern biotechnology is an emerging activity and a knowledge-intensive field, but that, by itself, it cannot resolve all the fundamental problems of environment and development. However, Agenda 21 expects biotechnology to make an important contribution by facilitating, for example, better health care, enhanced food security through sustainable agricultural practices, improved supplies of potable water, more efficient industrial development processes

(129) The Rio Declaration was quite prodigious in the field of principles on international cooperation. In view of its importance to the topic being examined, principle 9 should be recalled. It stipulates that: "States should cooperate to strengthen endogenous capacity-building for sustainable development by improving scientific and technological knowledge, and by enhancing the development, adaptation, diffusion and transfer of technologies, including new and innovative technologies.

for transforming raw materials, support for sustainable methods of afforestation and reforestation and detoxification of hazardous wastes.

Agenda 21 adds that biotechnology can also create new opportunities for global partnerships, especially between the countries rich in biological resources (including genetic resources) but lacking the expertise and investments needed to apply such resources through biotechnology and the countries that have developed the expertise to transform biological resources so that they serve the needs of sustainable development. Biotechnology can also assist in the conservation of those resources through, for example, *ex situ* techniques.

On the basis of these considerations, Agenda 21 formulates a set of programmes that refer to increasing the availability of food, feed and renewable raw materials; improving human health; enhancing protection of the environment; enhancing safety and developing international mechanisms for cooperation; and establishing enabling mechanisms for the development and the environmentally sound application of biotechnology.

It is interesting to examine, although superficially, the guidelines of the programme on increasing safety and the establishment of international cooperation mechanisms developed in Agenda 21, because they reflect global consensus on the topic being examined in this document.

It is recognized that there is a need for further development of internationally agreed principles on risk assessment and management of all aspects of biotechnology, which should build upon those developed at the national level. And it says that only when adequate and transparent safety and border-control procedures are in place will the community at large be able to derive maximum benefit from, and be in a much better position to accept the potential benefits and risks of, biotechnology.

The aim of the programme is to ensure safety in biotechnology development, application, exchange and transfer through international agreement on principles to be applied on risk assessment and management, with particular reference to health and environmental considerations, including the widest possible public participation and taking account of ethical considerations.

Thus, the proposed activities call for close international cooperation that should build upon planned or existing activities to accelerate the environmentally sound application of biotechnology, especially in developing countries.

Some management activities are included, such as making the existing safety procedures widely available by collecting the existing information and adapting it to the specific needs of different countries and regions; as well as continuing with the development of the existing safety procedures to promote scientific development and categorization in the areas of risk assessment and risk management (information requirements; databases; procedures for assessing risks and conditions of release; establishment of safety conditions; monitoring and inspections, taking account of ongoing national, regional and international initiatives and avoiding duplication wherever possible).

Other management activities included in Agenda 21 are compiling, updating and developing compatible safety procedures into a framework of internationally agreed principles as a basis for guidelines to be applied on safety in biotechnology, including consideration of the need for and feasibility of an international agreement, and promoting information exchanges as a basis for further development, drawing on the work already undertaken by international or other expert bodies.

Agenda 21 also includes among these activities the undertaking of training programmes at the national and regional levels on the application of the proposed technical guidelines and assistance in exchanging information about the procedures required for safe handling and risk management and about the conditions of release of the products of biotechnology, and cooperation in providing immediate assistance in cases of emergencies that may arise in conjunction with the use of biotechnology products.**(130)**

Finally, Agenda 21 underscores the importance of Governments at the appropriate level, with the support of international and regional organizations, raising awareness of the relative benefits and risks of biotechnology.

4. The Convention on Biological Diversity

The Convention on Biological Diversity, negotiated under the auspices of the United Nations Environment Programme (UNEP), was adopted in May 1992 and opened for signature during the Earth Summit on 5 June 1992. It entered into force on 29 December 1993.

The objectives of the Convention on Biological Diversity (CBD) are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding (Article 1).

The CBD does not directly regulate biosafety in relation to the conservation and sustainable use of biodiversity, but it establishes the bases for a protocol on biosafety, when in the third paragraph of article 19 it stipulates that "The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity".

The CBD makes numerous references to biosafety and, in particular, to biotechnology safety. Thus, in its preamble it recalls the precautionary criterion, by establishing that "where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat". The CBD defines "biotechnology" as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use", specifying that the term "technology" includes biotechnology.

In its provisions for *in-situ* conservation, the CBD stipulates that each Contracting party shall, as far as possible and as appropriate, "establish or maintain means to

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(130) Agenda 21 mentions something that is of utmost importance to the topic being examined in this document, when it points out that biotechnology research and development is undertaken both under highly sophisticated conditions and at the practical level in many countries. Efforts will be needed to ensure that the necessary infrastructure facilities for research, extension and technology activities are available on a decentralized basis. Global and regional collaboration for basic and applied research and development will also need to be further enhanced and every effort should be made to ensure that existing national and regional facilities are fully utilized. Such institutions already exist in some countries and it should be possible to make use of them for training purposes and joint research projects. Strengthening of universities, technical schools and local research institutions for the development of biotechnologies and extension services for their application will need to be developed, especially in developing countries.

regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health (Article 8, letter g), immediately adding that each Contracting Party shall "prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species (Article 8, letter h). These two provisions are pertinent to the field of biosafety.

In its provisions for access to and transfer of technology, the CBD stipulates that "Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment" (Article 16, paragraph 1).

The CBD also contains some specific provisions on the management of biotechnology and distribution of its benefits. These are found in Article 19, which establishes that "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties" (paragraph 1).

This provision is followed by another through which each Contracting Party assumes the commitment to take "all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms" (paragraph 2).

Finally, Article 19 also establishes that "Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced" (paragraph 4).

As previously stated, this provision creates an obligation for each Contracting Party to provide information on a living modified organism prior to supplying it to another Contracting Party, an obligation that exists apart from whether or not it is established in any other international agreement, or even in the Protocol being negotiated.**(131)**

5. The International Plant Protection Convention

The International Plant Protection Convention was adopted by the FAO Conference in 1951 and entered into force the following year. Subsequently, the FAO Conference approved a revised text of the Convention in 1979.

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(131) *Cf.* Leyla Glowka *et al*., *Guía del Convenio sobre la Diversidad Biológica*, World Conservation Union, Gland and Cambridge, 1996, p.114.

In the Preamble to the Convention, the contracting Governments explicitly recognize the usefulness of international cooperation to combat pests and diseases of plants and plant products and to prevent their introduction and extension across national borders.

Consequently, they establish that, in order to take effective and joint action to prevent the introduction and extension of plant and plant-product pests and diseases and to promote measures to combat them, they commitment themselves to adopt the legislative technical and administrative measures specified in the Convention itself or in supplementary agreements concluded. Furthermore, they assume the responsibility of enforcing all the requirements of this Convention in their territories.

Each of the contracting Governments is obligated to adopt the advisable provisions for issuing plant health certificates in accordance with the phytosanitary protection rules of the other contracting Governments and in accordance with the stipulations established in the Convention itself, which indicate who should issue such certificates and the way in which these should be prepared on the basis of a model established for that purpose (Article 5).

It is also stipulated that the parties may, in conjunction with the United Nations Food and Agriculture Organization (FAO), enter into regional agreements (Article 2).[(132)]

The Parties also (Article 4) commit themselves to establish an official plant protection organization to: i) inspect croplands and plant items that circulate in international traffic under conditions in which they may accidentally be carriers of pests or diseases; ii) to issue certificates on the health and origin of plant and plant-product items; and iii) to conduct research in the field of plant health protection. The Parties also commit themselves to strict regulation of plants and plant-product imports and exports through, when necessary, prohibitions, inspection and destruction of shipments.

International cooperation occupies an important place in the Convention (Article 7). In fact, all the Contracting Parties commit themselves to cooperate with FAO to establish world plant health information service, making full use of means and services of organizations that already exist for that purpose and, once it is established, to periodically provide the following information for distribution by FAO to the Contracting Parties. The Contracting Parties also commit themselves to participate, in so far as possible, in all special campaigns to combat specific destructive pests that may seriously threaten crops and require international measures to face emergencies.

Provisions such as those cited above are applicable to living organisms, whether or not they are modified, since they are factors that could represent damage to plants, although the risks of genetically modified organisms are not mentioned explicitly because of the time at which the Convention was adopted.

6. The International Convention for the Protection of New Varieties of Plants

The International Convention for the Protection of New Varieties of Plants was approved in 1961 and entered into force in 1968. This Convention has been amended successively in 1972, 1978 and 1991.

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(132) They may also enter into supplementary agreements, at the initiative of FAO, on the basis of a recommendation by a Contracting Party or an initiative by FAO itself, referring to specific regions or to specific plants and plant products, or agreements that in some way supplement the provisions of the Convention in order to solve special plant protection problems that require particular attention or care (Article 3).

The main purpose of the Convention is for the Contracting Parties to recognize and protect the rights of the breeders of new varieties of plants. In accordance with the 1991 amendments, the breeder is the person who has created or discovered and perfected a variety. To achieve its objectives, the Parties formed the Union for the Protection of New Varieties of Plants (UPOV) and established its bodies.

The protected varieties may have been obtained through genetic modification or not, but in any case, the rights of the breeder shall include authorization being required for any activities that involve the marketing, export or import of the variety in question.

7. The Convention for the Protection of the World Cultural and Natural Heritage

The Convention for the Protection of the World Cultural and Natural Heritage was adopted in 1972 and entered into force in 1975. The central objective of the Convention is to establish an effective system for collective protection of the cultural and natural heritage of exceptional value, organized as an ongoing effort and based on scientific and modern methods.

To achieve that goal, the Convention establishes the obligation of the States Parties to identify, protect, conserve, rehabilitate and transmit to future generations the cultural and natural heritage in their territories (Article 4). Other obligations of the States Parties are aimed at the integration of the protection of the heritage in the general planning programmes and the adoption of appropriate legal, scientific, technical, administrative and financial measures to identify, protect, conserve, revalue and rehabilitate that heritage (Article 5).

8. The Convention on International Trade in Endangered Species of Wild Fauna and Flora

The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) was approved in 1973 and entered into force in 1975. The essential purpose of CITES is to protect certain endangered species through a system of import and export permits.

In accordance with the regulatory system adopted by the Convention, its provisions include living or dead plants and animals and any part or derivative of these that can be identified (Article 1).

Appendix I to the Convention includes endangered species whose trade should be subject to particularly strict regulation, while Appendix II covers species that could become endangered if their trade is not appropriately regulated and Appendix III includes the species that any of the Parties wishes to subject to regulation and whose trade requires international cooperation for due control.

Explicit provisions in this Convention (Article 3 and 4) demand that trade in the species included in Appendices I and II require a permit which, among other factors, indicates that the export or import of the species in question will not endanger its survival.

9. GATT 1994 and the Agreement on the Application of Sanitary and Phytosanitary Measures

When the World Trade Organization (WTC) was established in 1994, the 1947 General Agreement on Tariffs and Trade was replaced by the 1994 General Agreement on Tariffs and Trade , which appears as Annex 1 to the WTC Agreement and is known as GATT 1994.

It has been said, and rightly so, that GATT is founded on three basic principles: the obligation of the most-favoured nation, the obligation of national treatment and the prohibition of quantitative measures, which are established in GATT Articles I, III and XI, respectively.

The most-favoured nation obligation consists of the duty of the Member States of GATT to extend, immediately and unconditionally, all privileges or advantages to similar imported products from or to any of the Member countries of GATT. The national treatment obligation consists of the duty to not discriminate between similar foreign and national products, which implies that the GATT Members should give foreign products treatment no less favourable than that given to similar national products. Finally, the prohibition of quantitative measures prevent the GATT Members from imposing on other Members restrictions such as quotas, embargoes, etc.

GATT also includes the so-called "general exceptions", which are applied to all the rules established by GATT itself, including the recently mentioned basic principles. These exceptions include some that have to do with environment, which are found in items (b) and (g) of Article XX of the 1947 GATT and were not amended in 1994. Article XX of GATT states that: "Unless the measures listed below are applied in a manner that would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, no provision in the present Agreement shall be interpreted to prevent any Contracting Party for applying measures: b) necessary to protect human, animal and or plant life or health;…g) related to the conservation of depletable natural resources, unless such measures are applied jointly with restrictions on national production or consumption;…".

This provision is conceived of as a set of exceptions to the GATT principles and, especially, as the idea of non-discrimination on which these principles are founded. Consequently, the application of these general exceptions is limited to cases in which the respective measures: (i) do not constitute a means of arbitrary or unjustifiable discrimination among the countries in which the same conditions prevail, or (ii) a disguised restriction on international trade. The measures referred to in item (b) of Article XX should also be "necessary" to attain the goals expressed therein.

Together with GATT 1994 and as a consequence of the conclusion of the Uruguay Round, various multilateral agreements were signed. Some of these are also important from the standpoint of the relations between environment and international trade, such as the Agreement on Technical Barriers to Trade, the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Trade-Related Aspects of Intellectual Property, as well as the standards and procedures that govern the Dispute Settlement Understanding (DSU) of 1994.

The 1994 Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) is applicable to all sanitary and phytosanitary measures that may directly or indirectly affect international trade. Such measures should be prepared and applied in accordance with the provisions in the Agreement.

The SPS Agreement reaffirms that "no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade".

Consequently, Article 2 establishes the right of Members to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life and health, provided that such measures are not inconsistent with the provisions of this Agreement.

But, the same Article establishes obligations. In fact, it is stipulated that the Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life and health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided in paragraph 7 of Article 5. It should also be noted that this provision includes, with some limitations, the precautionary principle: "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measures accordingly within a reasonable period of time".

Finally, Article 2 stipulates that sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b). Consequently these measures could not be considered contrary to the GATT provisions because they would be based on one of the general exceptions provided for in GATT itself.

Furthermore, the Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. In any case, sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

These provisions are directly involved in the topic of transboundary movements of living modified organisms (LMOs), which is being dealt with in the special regulations of the Protocol on Biosafety now being negotiated.

10. International Technical Guidelines on Biosafety (UNEP)

The guidelines referred to were adopted at a Meeting of the Panel of Experts on International Technical Guidelines on Biosafety convened by UNEP from 11 to 14 December 1995 in Cairo, Egypt.

The purpose of these guidelines is to provide a technical frame of reference based on the common principles and elements contained in national, regional and international instruments and regulations and without prejudice to the possible development of a protocol in the field. Thus, in its introduction, it is stated that the objective is to serve as an interim mechanism during the development and implementation of a protocol on biosafety, as well as to supplement it, once it has been concluded.

The guidelines therefore contribute to implementing the commitments established in Agenda 21 by proposing to assist the Governments, intergovernmental organizations, the private sector and other entities in establishing and maintaining national capacity to attain biosafety, and assist in the development of specialized human resources and in promoting the international exchange of information.

11. The International Undertaking on Plant Genetic Resources (FAO)

The purpose of the International Understanding, adopted by FAO Resolution 8/83 and currently being reviewed, is to secure, for plant improvement or scientific purposes, the exploration, conservation, assessment and availability of genetic resources of economic and/or social interest, particularly for agriculture. Since genetic plant resources are defined as plant reproduction or propagation material, including recently obtained varieties, living modified organisms, whether or not they are modified, form part of its sphere of application.

The Understanding is based on free trade in phytogenetic resources on which the State can only impose the minimum restrictions necessary to fulfil its national and international commitments. At the same time, the Understanding recognizes the need to adopt appropriate measures to protect the phyogenetic resources of the plants that grow in natural habitat areas and stipulates that measures shall be taken to ensure the collection and scientific protection of endangered phytogenetic material.

12. The International Code of Conduct on the Distribution and Use of Pesticides (FAO)

The purpose of the International Code of Conduct on the Distribution and Use of Pesticides is to determine responsibilities and establish voluntary rules of conduct for all public and private entities involved in the distribution and use of pesticides.

Article 9 of the Code contains regulations for an information and prior consent system through which the Governments should inform FAO on prohibitions and restrictions regarding pesticides, and FAO should distribute that information.

If a living organism, genetically modified or not, is developed for use as a pesticide, it is considered to fall within the Code's sphere of application. However, in the Preface to the Code it is indicated that an increase in pesticide use is likely to occur, in spite of the necessary and intensive parallel efforts to introduce biological and integrated pest control systems. This reference could be interpreted as indicating that these biological agents – whether or not they are modified – fall outside the sphere of the Code.

13. The Voluntary Code of Conduct for the Release of Genetically Modified Organisms into the Environment (UNIDO)

The main purpose of this Code consists of establishing a general framework and guidelines to guarantee safety in research, development, trade and use involving genetically modified organisms and providing assistance to the countries in developing their own regulatory frameworks.

The Code is applied to genetically modified organisms at all levels, but its focal point is their release into the environment, since it recognizes that the organisms introduced could potentially cause transboundary impacts and it is therefore recommended that

risk assessment and regulations should focus on the characteristics of these organisms more than on the techniques through which they were created.

14.The International Code of Conduct for Plant Germplasm Collecting and Transfer (FAO)

The International Code of Conduct for Plant Germplasm Collecting and Transfer was approved in 1993 at the twenty-seventh session of FAO. The purpose of the Code is to promote the sound collection and lasting use of genetic resources, to prevent genetic erosion and to protect the interests both of donors and of germplasm collections.

The Code contains procedures for requesting and granting licenses for collection missions, guidelines for collectors and the determination of responsibilities and obligations that extend to the sponsors of missions, those in charge of gene banks and the users of genetic material.

15. The Codex Alimentarius (FAO)

In 1961, the FAO Conference approved a resolution through which it created the Codex Alimentarius Commission and, in 1963, the Assembly of the World Health Organization approved the establishment of the FAO/WHO Joint Programme on Food Standards and adopted the Statutes of the Codex Alimentarius Commission.

The Codex Alimentarius (Codex) is an International Code of Standards in the field of food, whose main purpose is to guide and promote the preparation and establishment of standardized definitions and requirements regarding food, and also to encourage international trade. The fundamental objective of the Codex is to protect human health. In that context, in 1989, the Codex discussed the potential impact of biotechnology on food standards. In 1995 the implications of biotechnology advances on food labelling requirements was discussed by Codex.

16. The regional sphere

Treaties and other international agreements of a regional nature warrant special although brief mention, beginning with the old Convention for Nature Protection and Wildlife Preservation in the Western Hemisphere, which was adopted in Washington in 1940 and entered into force in 1942. This Convention includes provisions regarding the protection of specific species that are listed in an annex (Article 8) and adds that controls should be placed on the trade in specimens and parts of protected flora and fauna. (Article 9).

Discussion of these agreements should also include the 1978 Treaty for Amazonian Cooperation, to which the eight Amazonian countries in the region are Contracting Parties. The purpose of the Treaty is to carry out joint efforts and activities to develop and protect the environment in Amazon territories through the exchange of information and the establishment of operational agreements and understandings, as well as relevant legal instruments.

Finally, note should be made of the Convention for the Protection and Development of the Marine Environment of the Wider Caribbean Region, which was adopted in 1983 and entered into force in 1986. The basic objective of the Convention is to protect and manage the marine environment and coastal areas of the Wider Caribbean Region, and its articles contain explicit references to biological diversity, as is the case with Article

10, which refers to the protection and preservation of rare or vulnerable ecosystems, as well as the habitat of decimated, threatened or endangered species in special protected areas.

The Protocol Concerning Special Protected Areas of Wildlife, which is a protocol to the Convention for the Protection and Development of the Marine Environment of the Wider Caribbean Region, was adopted in 1990, but has not yet entered into force. The purpose of this Protocol is to establish protected areas in the coastal and marine areas of the Wider Caribbean Region and to ensure the protection of endangered wildlife in the region. Its provisions include the obligation of the States to adopt the necessary measures to protect, preserve and control, in a sustainable manner, endangered plant and animal species of special value in the areas located in their jurisdiction (Article 3), as well as the commitment to protect wildlife by identifying threatened or endangered species and take appropriate measure to prohibit the capture, elimination, possession or disturbance of such species (Article 10).

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Chapter IV

The Protocol on Biosafety(*)

1. Introduction

The topic of biosafety is an international issue because of, among other factors, its transboundary impacts and the international trade in living modified organisms. Consequently, it is a topic that requires international cooperation and a binding legal instrument through which the States would assume commitments to guarantee biosafety. This is the importance of the Protocol that is being negotiated. This chapter deals briefly with its background and development up to the present time.

The Protocol on Biosafety is now a major issue of debate and its future is still uncertain. Since the terms of this debate are widely documented, the purpose of this chapter is not to offer an exhaustive presentation of the topic, but rather to provide a general overview of the Protocol on the basis of biosafety policy, law and administration in the countries of the region. In fact, reviewing the Protocol negotiations seems important to understanding modern biotechnology safety or to supplementing the existing regulations, apart from whether the text of the Protocol is adopted or not, and even if the Protocol is not adopted.

The complexity of this task is not completely covered by this review, because the Protocol, in fact, only deals with a segment of the topic, which refers to biosafety, including the transboundary movement of living modified organisms. Consequently, its sphere does not include topics of such importance as those related to the introduction into the environment of exotic organisms, whose effects, as has been previously stated, have so far been much more devastating that those that could be attributed to LMOs.**(133)**

It should be borne in mind that many of the topics of the Protocol are subject to discussion and there are many significant discrepancies, which makes it difficult to refer to specific texts in its articles or, in the best of the cases, only allows reference to the main aspects of the text, without any attempt to prejudge the final version, if it is, in fact, forthcoming.

Finally, it should be noted that this chapter does not deal with all the issues that are being discussed in relation to the Protocol, but only to those that seem most relevant to purposes of this paper.

2. Background

The background of the Protocol dates back to the First Conference of the Parties to the Convention on Biological Diversity (CBD), which took place in Nassau from 28

(*) See **Addendum** at the end of the current document.

(133) In the text of the project being negotiated, but with reservations on the part of most of the countries, it is said that the objective of the Protocol is to contribute to an appropriate amount of protection in the sphere of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that could have harmful effects on the conservation and sustainable use of biological diversity, taking into account the risk to human health and "focusing specifically on transboundary movements" (article 1). There seems to be no discrepancies regarding this last point.

November to 9 December 1994. At that Conference (COP-1), an Open-Ended Working Group of Experts on Biosafety was established. This Group, which met from 24 to 28 July 1995, was, in general, in favour of developing an international regulatory framework in this field. There was, however, no full agreement on the elements of this possible legal instrument, and there have been differing points of view since that time.

At that time, the points considered important to be dealt with in the related regulations included control of all activities linked to LMOs that could affect biological diversity, international and accidental transboundary movements, the release of LMOs and risk assessment, LMO management, procedures for information and prior consent, information requirements and capacity-building. The topics that seemed most controversial – and turned out to be so – were many and included those related to socio-economic considerations, liability and indemnification systems and financial aspects, among others.

At the Second Conference of the Parties (COP-2), which was held in Jakarta, Indonesia, from 6 to 17 November 1995, it was decided to advance towards a Protocol on Biosafety, although there were discrepancies regarding its scope, since some countries focused their attention on the transboundary movement of LMOs, while many others expressed more general concerns regarding not only transboundary issues, but also domestic questions related to the use and handling of such LMOs. The result of this negotiation was Decision II/15, which is dealt with in more detail when the Protocol negotiation process is briefly described.

At the Third Conference of the Parties (COP-3), which was held in Buenos Aires in November 1996, Resolution III/20 was adopted. It called for the preparation of the Protocol to be concluded by the end of 1998 and, at the same time, the Conference tended towards an approach that favoured the application of the UNEP Technical Guidelines on Biosafety, without prejudice to the binding instrument being negotiated.

The Fourth Conference of the Parties (COP-4), held from 4 to 15 May 1998 in Bratislava, Slovakia, adopted Decision IV/3 of this Meeting, "Topics Related to Biosafety", which supported continuing the preparation of the Protocol and the holding of two other meetings for that purpose, the first to be held in August 1998 and the second in early 1999, followed by an Extraordinary Meeting of the Parties to adopt the instrument.

3. The Protocol negotiating process

Decision II/5 of the Second Conference of the Parties (COP-2) provided, as was stated, a specific mandate to form a Working Group on Biosafety (WGB). This Decision promoted "a negotiating process to develop a protocol on biosafety in the field of the safe transfer, handling and use of LMOs, concentrating specifically on the transboundary movement of any LMO that could have an adverse effect on biological diversity".

The terms of reference for the WGB included preparing key terms and concepts, considering procedures for advance informed agreement, identifying important LMO categories and developing a Protocol that would take into account the precautionary principle and would require the Parties to establish national measures.

The path taken to adopt this Decision proved to be arduous and, it seems that the contributions of the countries of the South and of non-governmental organizations played an important role in making it possible. Even so, it only responds partially to the objective sought in Article 19.3 of the CBD, since it concentrates on the

transboundary movement of LMOs, while the Article deals with the topic of LMOs in a broader manner.[(134)]

The Working Group on Biosafety (WGB) initiated its work in 1996 and, since then, it has met on six occasions: in Aarhus, Denmark (from 22 to 26 July 1996), in Montreal, Canada (from 12 to 16 May 1997, from 13 to 17 October 1997, from 5 to 13 February 1998 and from 17 to 28 August 1998) and in Cartagena, Colombia (from 14 to 19 February 1999). At this last meeting, a special effort was made to arrive at a consensus, which unfortunately was not reached. This meeting resulted in a draft text of the Protocol on Biosafety, which was submitted to the First Extraordinary Meeting, but a significant majority of the countries did not feel that it precisely reflected their position. However, the references made to the draft Protocol in this chapter are to this text, which is still being under discussion, although there is no consensus on it.

This last meeting was immediately followed by the First Extraordinary Meeting of the Conference of the Parties (22 and 23 February 1999), which included the participation of almost 600 representatives of 138 Governments, the private sector, the scientific community and non-governmental organizations. At that Extraordinary Meeting it was confirmed that there was no consensus on a Protocol text, and it was decided to suspend it and ask the President and the Bureau of the COP-4 to decide on a date and place for a new meeting, which should, in any case, be held prior to the Fifth Conference of the Parties to the Convention on Biological Diversity.

At the end of this Extraordinary Meeting some factors that remained pending for further clarification were those regarding derivatives, LMO use and content, socio-economic considerations, application of the precautionary principle, liability and indemnification mechanisms and traffic with non-Party States, among other highly controversial and complex topics.

Finally, between 15 and 19 September 1999, the Governments met once again, this time in Vienna, in an attempt to make progress in seeking the consensus necessary to bring the Protocol to a successful conclusion. This meeting was conceived as an informal consultative meeting preparatory to the renewed session of the First Extraordinary Meeting of the Parties to the Convention on Biological Diversity for the adoption of the Protocol. Although some progress in concepts was made during this consultative meeting, no significant headway was made regarding positions on the key points. The renewed session of the First Extraordinary Meeting of COP-4 will be held in Montreal, Canada, from 20 to 28 January 2000.

The complexities of the negotiating process make it impossible to assume a simplistic view of the positions taken. Nevertheless, some lines of thought can be identified and are summarized as indicated below. The way in which they are divided is, of course, very general, because many other divisions could be made on the basis of the diverse groups and subgroups that have been formed around the specific topics throughout the negotiating process.

In that understanding, it is possible to identify a majority group of the countries participating in the negotiating process that share significant concern regarding the potential risks associated with LMOs. Consequently, these countries have their eyes set on a Protocol that could be classified as "strong", with a wide sphere of application and sufficient consideration of LMO impacts, and they therefore argue in favour of strict

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(134) This provision states that "the Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and use of biological diversity."

advance information procedures. A second group of countries would also favour the adoption of a Protocol, but one whose objectives would be aimed more at guaranteeing an appropriate legal framework for trade in transgenic products. In this group there is consequently a greater inclination to reduce the Protocol's sphere of application and to promote simplification of the prior informed consent procedures. Finally, there is a third group whose principal core is identified as the "Miami Group" (Argentina, Australia, Canada, Chile, United States and Uruguay). It is strongly supported by the international biotechnology industry and puts emphasis on the trade restrictions that could result from approval of the Protocol. Among other positions, this group is in favour of making international trade agreements or other bilateral, regional or world agreements prevail over the text of the Protocol.

4. Major topics to be debated in the draft Protocol being negotiated

There are numerous topics under discussion. Some of those that seem to be particularly important have been selected, such as the objective of the Protocol, the Protocol's sphere of application, advance informed agreement, the precautionary principle, LMO labelling, the Protocol's relationship with other international agreements, economic and social aspects, liability and indemnification, and relations with States not parties to the Protocol. There is a certain linkage between all these topics, which means that the countries involved in this debate assume relatively uniform positions towards certain topics and form the groups that were just described above.

5 The purpose of the Protocol

The purpose of the Protocol is defined as "to help to ensure an appropriate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have harmful effects on the conservation and sustainable use of biological diversity, also taking into account the risks to human health and focusing specifically on transboundary movements" (Article 1 of the draft under consideration). The discussion on this topic has focused on the proposals to include mention of derivatives, to highlight the impact on human health and to add references to the socio-economic aspect of biosafety.

6. The sphere of application of the Protocol

Article 4 of the draft Project stipulates that it applies to the transboundary movement, handling and use of LMOs that may have an adverse effect on the conservation and sustainable use of biological diversity, also taking into account the risks to human health. Consequently the Protocol would not apply to LMOs that are not likely to have an adverse effect on the conservation and sustainable use of biological diversity, which should appear in an annex, as well as to the transport of LMOs (with certain exceptions) and to the transboundary movement of LMOs that are pharmaceutical products for human beings.[(135)]

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(135) The exceptions are referred to in Article 2 "General Obligations", Article 4 "Unintentional transboundary movements and emergency measures" and Article 5 "Handling, transport, packing and identification", as well as intentional transboundary movements of living modified organisms for confined use, except in reference to Articles 2, 4 and 15 and to paragraphs 1 and 2 and letters a) and b) of paragraph 3 Article 17 (Article 4 of the draft).

Different criteria argue for expanding this sphere so that it would explicitly include the uses and contents of LMOs and derivatives. In that regard, it is said that recombinant DNA present in transgenic food may appear, and even in considerable amounts, in crops or foods that contain them, persist and be transferred to the intestinal flora of animal or human beings and even to the environment through them, and thus be introduced into the water or land.

The exclusion of LMOs that are not likely to cause adverse effects on biological diversity is being challenged from different points of view. Among other arguments, it is said that LMOs would react differently in different ecosystems and conditions; that there is great uncertainty regarding the potential effects on environment and human health of releasing LMOs or their derivatives; that if adverse effects take place, they could be irreversible; and that acting in this way contradicts the precautionary principle; etc.

7. Advance informed agreement

The procedures for information and advance informed agreement have become a common tool for environmental management and are frequently used in the international sphere – in one form or another – in relation to chemicals, pesticides and hazardous wastes.

It should be remembered that advance informed agreement is provided for in the Convention on Biological Diversity as a component of a possible protocol on the transfer, handling and use of any living modified organisms resulting from biotechnology (Article 19, paragraph 3) and that furthermore, and even apart from the existence of the Protocol, the Convention states that each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction that supplies living modified organisms resulting from biotechnology, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced (Article 19, paragraph 4).

This scheme in the field of biotechnological safety does not differ essentially from the provisions in other international agreements and is based on the idea that LMOs should not be imported or exported across national borders without the agreement or against the will of the importing country.

Since advance informed agreement is one of the key tools in the Protocol (Article 5, 6, 7, 8, 9 and 10), it has become perhaps the most controversial issue, revolving around the fact that in the draft text under consideration there are some exclusions that many countries consider inadmissible.

The draft Protocol states that advance informed agreement is applied prior to the first intentional transboundary movement of a living modified organism to be deliberately introduced into the environment of the importing Party and, furthermore, that the "deliberate introduction into the environment" of the importing Party does not refer to the living modified organisms that are to be used directly as food or feed, or for their processing. Consequently, if an LMO has already been imported into the country, it could be imported again without being subject to advance informed agreement, even if its use has changed. It is added that, according to the existing proposal for Article 6, the transit countries would not be notified. All these topics, just as the respective responsibilities of importing and exporting States are very important.

8. The precautionary principle

The precautionary principle, initially included in the Protocol negotiations as an essential part of risk assessment and management, has now been reduced in the draft Protocol to mere mention in its Preamble and other more or less explicit references in Article 1 – where it appears as "precautionary approach" – and Article 8 (procedures for adopting decisions on advance informed agreement) and in Annex II (Risk assessment).

While one group of countries has argued for greater reference to the principle, in particular in the provisions of the Protocol, others believe that its development in international law is still limited and that, consequently, the reference made in the Preamble is sufficient.

The focal point of the discussion revolving around the precautionary principle lies in the idea that its application should, in fact, be the central objective of the Protocol and the basis for adopting decisions regarding LMOs. Recent discussion on the possible medium- and long-term adverse effects of LMOs has rekindled demands that greater precaution should be required and, consequently, that the precautionary principle should play a major role.

9. The labelling of LMOs

Discussion continues on whether all LMOs should be identified by a label or whether the obligation is valid only for LMOs subject to advance informed agreement procedures. In Article 15, the term "label" has been replaced by "identification" on the grounds that labelling falls under the jurisdiction of national law.

The draft Protocol text, on which there is not yet a consensus, entrusts the Conference of the Parties to examine the need for preparing regulations, and the methods for such preparation, concerning LMO identification, handling, packaging and transport practices, taking into account the results of consultations with other international organizations.

10. The relationship of the Protocol with other international agreements

The draft Protocol under consideration states that its provisions "shall not affect the rights and obligations of any Party to the Protocol deriving from any existing international agreement to which it is also a Party, except when the exercise of those rights and the fulfilment of those obligations would cause serious damage or threaten biological diversity".**(136)**

There are many doubts about whether it would be necessary to subordinate the Protocol, in an explicit manner, to other international agreements, especially to those which refer to international trade.**(137)** In fact, the expression "any international agreement" includes, among many others, the General Agreement on Tariffs and Trade (GATT), as well as the instrument linked to GATT, such as the Agreement on Trade-Related Technical Barriers and the Agreement on the Application of Sanitary and

(136) The text is identical to the first paragraph of Article 22 in the Convention on Biological Diversity

(137) In the North American Free Trade Agreement (NAFTA), it states that the environmental agreements explicitly indicated therein shall prevail over its provisions (Article 301).

Phytosanitary Measures. Nearly all the countries in the world are members of the WTO-GATT multilateral trade system.

GATT is founded on the principle of non-discrimination, which derives from the three basic principles to which reference was made in the previous chapter (the most-favoured nation, national treatment and the prohibition on imposing quantitative measures). Regulation of LMO transboundary movements would involve adopting trade measures for environmental purposes, which would necessarily restrict international trade. In case of conflict between the two, the WTO-GATT system would prevail over the Protocol.**(138)**

11. Economic and social aspects

The inclusion of socio-economic considerations has been particularly debated during the Protocol negotiations. They are referred to in Article 24 of the draft under consideration, which states that the Parties shall take into account certain socio-economic considerations.**(139)**

One of the arguments in favour of including socio-economic considerations is based on the particular importance of the topic to countries that have mega-diversity and are the centre of origin of crops, in view of the genetic and cultural erosion usually associated with the introduction of modern biotechnology. It is also argued that the replacement of crops and the introduction of new technologies reduces the control that farmers have over these processes to an even greater extent.

It has also been recalled that the Convention on Biological Diversity from which the Protocol is derived urges respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities (Article 8, letter j), which would be violated or at least hindered by the introduction of LMOs without taking these factors into account.

12. Liability and indemnification

The draft Protocol does not directly regulate the topic of liability and indemnification, but rather refers to the initial process for adopting a decision on this matter to the First Conference of the Parties.**(140)**

Those whose position is against this solution argue that a large part of the effectiveness and, consequently, the credibility of the Protocol depends on an appropriate liability and indemnification system, and that, consequently, this solution

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(138) The draft Protocol contains some specific provisions that call to mind the WTO-GATT system. Article 22 states that the Parties shall ensure that the measures adopted to enforce this Protocol, including risk assessment, do not involve unjustifiable discrimination between imported living modified organisms and the products of the country, and that the Parties shall also ensure that the measures adopted to enforce the Protocol do not create unnecessary obstacles to international trade.

(139) This provision states that "the Parties, when adopting a decision on imports, may, in a manner compatible with their international obligations, take into account socio-economic considerations resulting from the adverse effects on the conservation and sustainable use of biological diversity, especially in relation to the value of biological diversity to indigenous and local communities" (paragraph 1).

(140) Article 25 in the draft states that "The Conference of the Parties that serves as the Meeting of the Parties shall, at its first meeting, adopt a process in relation to the appropriate preparation of international rules and procedures in the sphere of liability and indemnification for damage resulting from the transboundary movement of living modified organisms, and, for that purpose, it shall analyse and duly take into account any processes under way in the sphere of international law in these matters and shall attempt to complete this process in a period of four years"**.**

postpones a decision that should be adopted now rather than for a period of time that could involve significant delay. In contrast, those who favour Article 25 as it appears in the draft Protocol argue that dealing with the topic of liability in detail could involve an entire complex negotiating process, as is occurring in the case of the Basel Convention.

13. The relationship with States that are not Parties

This topic is important and, even more so, if it is taken into account that one of the leading States in the development of biotechnology is not a Party to the Convention on Biological Diversity, and is unlikely to become a Party to the Protocol.

Discussion on trade with States that are not Parties has even included texts proposing the prohibition of such trade. At the present time, what is basically being discussed is whether the Protocol should allow this type of trade when it is compatible with its objectives and principles or, more strictly, when it is compatible with the substantive articles of this instrument.

The draft Protocol favours the first of these positions, because in Article 21, it establishes that "the transboundary movements of living modified organisms between Parties and States that are not Parties should be compatible with the objectives and principles of this Protocol".

14. Conclusions

What has been said in this chapter gives rise to some topics which, if they have not already been included, should be dealt with in national regulations concerning the transboundary movements of LMOs. These topics include, particularly:

- *The establishment of advance informed agreement*

  It seems evident that, just as is the case with some provisions already in force in the region, advance informed agreement should be required for transboundary movements of LMOs. What needs to be established are the terms in which this should be required, beginning with its sphere of application, which may be more or less broad or more or less restricted; that is, it may range from all transboundary movements of LMOs, case by case, with special exceptions, up to only the first transboundary movements of LMOs, with general exceptions explicitly established.

- *Application of the precautionary principle*

  It seems important, where it has not been done, to clearly establish the application of the precautionary principle in granting advance informed agreement for transboundary movements of LMOs, thereby delimiting the powers of the public authorities in charge of granting such agreement.

- *Economic and social aspects*

  Similarly, it seems important clearly to establish whether the public authorities in charge of advance informed agreement should take into account the socio-economic aspects involved in the transboundary movements of LMOs in question, case by case.

- *Liability and indemnification*

  The transboundary movements of LMOs may cause damage and, consequently, civil, criminal and administrative liability resulting from such damage, including

the liability of the State and of legal persons involved in these acts should be adequately regulated.

- *Restrictions on the transboundary movements of LMOs and the obligations assumed in international trade agreements*

  The regulation of transboundary movements of LMOs involves placing restrictions on international trade. These restrictions should be compatible with the commitments assumed by the country in question in world, regional, subregional and bilateral trade agreements.

It is evident that if a Protocol on Biosafety is finally adopted and the country in question subscribes to it, it should thereinafter regulate all these topics in a manner compatible with the obligations it is assuming through the Protocol.

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Chapter V

Conclusions and recommendations

1. Introduction

The purpose of this chapter is to formulate the conclusions and recommendations that may be drawn from this version of the work contained in this document. As noted in the foreword, a previous version of the same paper was presented to a meeting of experts convened by UNEP and ECLAC, which took place in Santiago, Chile, on 29 and 30 November 1999. The following conclusions and recommendations, just as this entire version of the work, have benefitted from the results of that meeting, but the responsibility for them continues being that of the authors of this document.

Two warnings should be made in advance: first, the differing degree of development in the countries of the region in this and in other topics means that the conclusions and recommendations formulated are not applicable to all of them, at least in the same way; and second, these conclusions and recommendations are the result of initial research and that should be supplemented with other studies that would provide a more complete view of the vast and complex problems posed by the topic of biosafety policy, law and administration. Some of these possible studies are mentioned further on.

The main topic under discussion are the risks that threaten biological safety and, particularly the risks resulting from modern biotechnology, both to human health and to environment. Chapter I of this document has examined the terms of the discussion under way regarding the benefits and risks. It is a field in which, so far, a high degree of scientific uncertainty has prevailed and in which the precautionary principle consequently plays a basic role, which can only decline to the extent that scientific certainty increases.

Biosafety policy, as well as the law and administration that implement it, are the social response to the threat that these risks represent, under the idea of reconciling the need to prevent them and the need to take advantage of the benefits that may be produced by biotechnological developments. This reconciliation is particularly difficult to reach in our countries, not only because risk assessments require bases that are measurable and quantifiable in science and are not easily obtained (especially for long-term effects), but also because there is less capacity to carry out this type of assessment, which causes more emphasis to be placed on the precautionary principle, which is essential, if only from an environmental standpoint, in view of the important natural heritage that should be protected.

Public opinion has progressively become more sensitive to the risks that modern biotechnological developments could pose. That is the case, not only in Europe and the United States, but also in our countries, as has been demonstrated, for example, in the recent events in Brazil. Without entering into the controversy that divides those who are concerned about these topics into opposing camps, it is evident that these risks exist and that they should be evaluated, in principle, case by case.

This document has examined how biosafety, and within it, modern biotechnological safety, is dealt with in the policy, law and administration of the countries of Latin

America and the Caribbean, in a specific international context that includes the presence of the Protocol on Biosafety now being negotiated.

The conclusions formulated below are intended to reflect the situation of these components in biosafety management in our countries, particularly from an environmental point of view. The recommendations which, in turn, follow the conclusions attempt to suggest certain lines of action that could contribute to overcoming the current state of this management. These recommendations take into account the fact that only where there are appropriate systems for the management of modern biotechnology and for risk assessments, accompanied by effective capacity to put them into practice, is it possible to development biotechnology and have its results accepted.

This obviously applies to the transboundary movements of living modified organisms, which is the topic being most strongly debated. However, this should not make us lose sight of the fact that biosafety goes beyond this important matter, and that it is definitely impossible to dissociate these problems from the general problems of biosafety of which they form part and with which they share questions and answers, such as environmental risk assessments within the systems that include prior information and permit and license systems.

2. Conclusions

Biosafety problems are not new in our countries. In general, there is a system to face the environmental risks that stem from exotic species and hybridization processes. These systems operate with varying degrees of success. In many places, for example, the problem of exotic species continues to have an important effect on ecosystems and their components.

In addition to these problems there are now those of modern biotechnology, to which the response has varied, but, seemingly, has been insufficient, considering the diversity and magnitude of these problems.

In fact, as a result of the panorama provided in this document, it may be seen that the development of policy, law and administration of modern biotechnology safety in the countries in our region seems, in general terms, to be limited and, in some cases, nonexistent, and is concentrated, in any case, in a group of countries of medium development. This development has been influenced principally by the pressures of research processes, the industrialized countries and transnational companies; that is, it has merely been a reaction.

This situation contrasts with the need to face these problems fully in our countries, in view of their being nations that combine the planet’s greatest biological diversity with important agricultural production and incipient biotechnological development.

But when facing these problems, it should be taken into account that biosafety goes beyond the framework of strictly environmental concerns and, today more than ever before, it is associated with socio-economic considerations that have to do principally with the use of transgenic organisms in agriculture, as well as strong national and transnational production and trade interests that are involved in the way biosafety is dealt with, as is evident in the negotiation of the Protocol on Biosafety. The idea of sustainable development is being severely put to the test in this case, perhaps more than in others.

It therefore requires an initiative, using the force that is essential when immersed in a resistant environment, to promote policy, law and administration, within which a set of

activities characteristic of biosafety, and especially the safety of modern biotechnology, will have to be developed, as is being done in many countries of Europe and in Japan.

To date, biosafety policy, law and administration in our countries has evolved in an international context that has contributed to its development. The safety of modern biotechnology, however, is posing unprecedented problems, both because of its overwhelming development and because of the magnitude of the problems, which lack an appropriate international framework for support to deal with them at the country level. An important part of these problems could be soundly addressed on the basis of a Protocol that would appropriately regulate the transboundary movement of living modified organisms.

An appropriate Protocol would make possible, for example, the prohibition or restriction of LMOs that are prohibited or severely restricted in the country of origin and, in general terms, better control of LMOs by the countries that receive them, as well as the establishment of basic parameters for the national industry, in cases where it exists, since the industry's obligations based on this international regulation would result in better national environmental management.

What could not be accepted, of course, is a Protocol that imposes indiscriminate liberalization of trade in LMOs, which could pose unacceptable risks such as adverse impacts on human health and the environment.

The difficulties being experienced in the Protocol negotiations call for reasoning on the basis of a scenario in which no such international instrument exists. This means that, whether or not an international agreement in this field is achieved, the countries in the region need to make efforts, which will be required in any case, to develop environmental management that will encourage biotechnological development within our countries, will be capable of assessing the risks involved in modern biotechnology and, thereby, will enable us to share in its benefits in an acceptable manner.

To surmount this situation appropriately, it is essential to develop a clear, adequate and consistent policy on biosafety, including particularly the safety of modern biotechnology. This policy should establish what must be done to assess the risk of such biotechnology and, for its implementation, it should be accompanied by a legal framework that establishes who and how the policy will be applied.

What is now occurring in most of our countries is that policy and law on the safety of modern biotechnology are beginning to be developed on the basis of the traditional frameworks established to protect agricultural production and, secondarily, wild flora and fauna, as well as the environment in general. These frameworks may be used temporarily and even in a complementary or supplementary form in the specific provisions that have been established in the field of LMOs, but this is valid only as a partial and transitory solution which, in no case, eliminates the need to make specific progress in the field of modern biotechnological safety. In reference to the environment in particular, there is a notable absence of environmental considerations in the recent development of biosafety policy and law.

In addition to the above considerations, it is necessary to develop an administration that is capable of effectively applying biosafety policy and law and, particularly, policy and law on modern biotechnological safety. This is possibly the most complicated point, because basic and applied research and development in modern biotechnology is extremely complex and, in our countries, at least in the field of modern biotechnology, there is a lack of material resources and essential technical, scientific and financial capacity.

In other words, our region has neither the necessary infrastructure nor the indispensable knowledge and experience in managing modern biotechnology, which requires specialized staff to ensure that the biotechnological applications are carried out in a way that will not affect human health and the environment. This is essential, not only for those in charge of assessing the biosafety of projects and products, but also for those who work in conducting research in molecular biology and genetic engineering of plants, tissue cultures and clonal propagation of plant species and other organisms, who should be fully aware of the risks and care that should be taken when experimenting with transgenic organisms or introducing or releasing them into the environment.

This situation has to do with the lack of biotechnological development in the countries of Latin America, a problem to which there is no single answer, as is the case with all social problems. That having been said, it should be noted that the limited scope of private economic activities and recurring financial crises make the state investments required in the field of science, technology and education concerning biotechnology increasingly difficult, if not impossible. At the national level, they decisively affect what would be considered normal development of biotechnology in the industrialized countries and deprive our countries of the support that our universities and research institutes could provide in these cases for the development of competitive biotechnology.

The result of the above-mentioned situation is our dependence on external biotechnologies and our lack of capacity to assess them correctly, except when there is support – which is also external – all of which generates adverse conditions for their acceptance. In fact, the deficiencies referred to place many countries in a difficult position at the time previous assessments are made to determine the risks of modern biotechnological procedures and products and, ultimately, create justified reluctance, if not outright rejection, that may result in the failure to take advantage of their potential benefits. But it is unlikely, if not impossible, that our countries will be able to overcome these deficiencies on an individual basis.

The limited capacities of the countries in the region are, in turn, strained by the pressures exerted in a globalizing international context, which commends greater trade liberalization, as well as by national companies that do not have the necessary capability to develop their own biotechnologies, but do have the capacity to apply and market external biotechnologies in their efforts to conquer new markets and create new business opportunities.

The above considerations point up the importance of regional cooperation from many points of view. In brief, regional cooperation should be considered an opportunity to share and, consequently, strengthen the limited capacities in our countries; but, it should also be considered an appropriate mechanism to fulfil the duty of preventing and controlling potential adverse risks derived from exotic organisms, genetically modified or not, whose risks may go beyond the national sphere and, through their transboundary effects, reach a subregional or regional context. Biological safety is a problem that equally concerns all the countries in the region and, as such, it is one of the environmental problems that warrants a regional approach, supplementary to the policies that each country adopts on a sovereign basis.

The topic of biosafety is linked to many other topics, including free trade, as has been highlighted by the Protocol on Biosafety negotiations. These negotiations have also involved the reproduction of some of the same tensions between international trade and environment that exist in the multilateral trade system promoted by the World Trade Organization and have to do with compatibility between trade policies and environment policies.

The questions posed by free trade, technical trade barriers and the application of sanitary and phytosanitary measures are topics pertinent to biosafety, as is the issue regarding intellectual property rights, which is governed by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). In the five years since the WTO was established, there has been no significant progress in this field other than recognition of the existing problems. It seems important for the negotiations on the Free Trade Area of the Americas (FTAA) to give consideration to the relationship between free trade and environment, including the topic of biosafety, so as to clarify, at least at the hemispheric level, some of the many uncertainties arising from the current WTO legal framework.

3. Recommendations

It is necessary for the countries of the region to give special attention to the development of policy, law and administration of biosafety, and especially of modern biotechnology, in order to assess the risks and, consequently, share in the benefits in a way that is acceptable to human health and the environment.

This effort should be made on the basis of a policy designed in each country according to its needs and its capacities, apart from the existence of the Protocol that is being negotiated. It is a task that should not be postponed. The Protocol negotiations have now encouraged the definition of safety policies on modern biotechnology in a significant number of countries in the region, but these policies have not yet attained the precision required. Furthermore, as previously noted, the Protocol would not cover all the safety problems posed by modern biotechnology.

The policy should, however, include among its components a strategy to enable progress to be made in successfully concluding the Protocol, as a project of the policy itself and to the extent possible. The truth is that the Protocol negotiations have reached a stage where it is practically impossible to go back to certain topics. Nevertheless, our countries should be appropriately prepared to take part in an international debate that will not end with the conclusion of the Protocol negotiations, whether they are successful or not, and will probably be renewed from time to time.

Biosafety policy should be comprehensive and, therefore, surmount the division into sectors that now prevails to deal with its components from the traditional perspectives of agriculture, health and environment, to mention only the principal sectors.

This policy should also take into account the relationships between international trade and environment. Issues regarding free trade, technical trade barriers and the application of sanitary and phytosanitary measures, as well as intellectual property rights linked to international trade, are directly involved in biosafety. They should be considered in the biosafety policy and should be projected to related international forums, including, among others, the negotiations on the Free Trade Area of the Americas (FTAA).

Biosafety policy should be sufficiently explicit to leave no doubt regarding its preeminence over other public policies, whether explicit or implicit, that could somehow be incompatible with its objectives.

The debate on biosafety, and especially the safety of modern biotechnology, is filled with ethical issues that go beyond specific beliefs or religious tenets and express concerns that are not limited to modifying the human genome. These issues should be taken into account in formulating policy on biosafety.

Biosafety policy should consider that, in the final analysis, many of the problems that it now faces have to do with the difficulties in assessing the risks involved with living

modified organisms for reasons of scientific uncertainty, but also for reasons that refer to the lack of biotechnology at the national level. Knowledge on the development of modern biotechnology and biotechnological activities in our countries should be promoted by the biosafety policy itself.

Biosafety policy should be implemented by related legal instruments and should be strengthened by the administration of biosafety and especially the safety of modern biotechnology. Important experience has already been gained in the field of legal instruments regarding plant health (phytosanitary protection), veterinarian medicine and health, which have even proved to have certain effectiveness in dealing incipiently with problems related to biotechnological safety. However, this situation cannot and should not continue indefinitely, especially with regard to the effects of biotechnology on biological diversity.

Legal instruments for formulating and implementing biosafety policy should consist basically of laws and, as such, should be the fruit of public debate and the expression of a broad consensus on what should be done to achieve acceptable levels of biological safety. To date, many of the legal measures that have been adopted in the region have been of a purely administrative nature, which raises questions about their constitutionality, since they sometimes assign powers to public authorities and restrict the exercise of certain basic rights. Legal norms of a hierarchy lower than laws should be used only in a strictly regulatory sphere.

The new legislation on biosafety should be the result of a critical review of preexisting legislation and, taking into account the effectiveness and efficiency that it has shown, the new legislation should comprehensively regulate the different facets of the problems of biosafety, establish measures that are suitable from a scientific and technical standpoint, as well as socially acceptable, and ensure that such measures are fulfilled.

The function to be fulfilled by parliamentarians in preparing this new legislation is particularly important, and technical support should be provided for the legislative work.

The new legal instruments should be of a preventive and proactive nature. It has already been noted that the principal problems that have so far arisen have essentially been related to the introduction of exotic species and have been insufficiently dealt with by legislation in the region. It is important that bodies of regulations regarding the safety of biotechnology be designed to prevent the occurrence of the undesirable effects that biotechnology may have on health, environment and agriculture. In that regard, the role that environmental impact assessment could play in preventing such risks should be evaluated.

Aspects that should be given special attention in the legislation include matters regarding liability for damage to persons, their property and the environment, taking into account the specific details of the damage that could be caused by exotic species and transgenic organisms.

It would be highly recommendable for the progress made in the countries of the region in the field of biosafety policy, law and administration to be carried out harmoniously among them, but with full respect for the sovereignty of each country, so that a regional system of biosafety will begin to take shape to safeguard the health of the population and the environment of the region from any damage caused by modern biotechnology or the threat of such damage.

There are some models worth taking into consideration for that purpose, such as the norms established in the sphere of the European Union for the confined use of

genetically modified microorganisms (Directive 219 of 1990), the release of genetically modified organisms into the environment (Directive 220 of 1990), new foods and new food ingredients (Regulation 258 of 1997) and the labelling of specific food products manufactured on the basis of genetically modified organisms (Regulation 1138 of 1998).

As noted in the conclusions, it is unlikely, if not impossible that our countries will be able to overcome the existing deficiencies separately, in particular those in the administration of modern biotechnology.

International cooperation should flow in all directions; that is, both vertically and horizontally. International cooperation at the world level, but also at the regional and subregional level, is a veritable prerequisite for the necessary transformations. Consequently, thought must be given to designing a strategy to develop biosafety policy, law and administration that is based, principally, on international and intraregional cooperation to achieve the results desired.

This strategy should include the establishment of independent centres of excellence or the strengthening of existing centres, which at the regional or subregional level will optimize the resources available through world cooperation or the region itself and will guarantee the effectiveness of their work and the promotion of studies to identify and promote our capacities. Training activities and the establishment of regional structures for such purposes should be strongly encouraged.

In the field of national infrastructure, the provisions adopted should cover the existence of regulating bodies, advisory commissions with consulting duties, reference centres and institutions to be in charge of surveillance and monitoring. Taking into account these elements, very diverse forms of institutional design may be adopted.

An area that should be given special attention is the generation of databases, as well as the development of information systems and exchange in the field at the national, regional and international levels to promote better knowledge on the research and development of biotechnological products and of the norms that regulate their handling, release and marketing and to create the conditions that will allow emergency situations and decision-making processes, in general, to be dealt with effectively. The world databases that now operate in this field should be reviewed, with a view to fulfilling the needs in the region.

In some places it would even be possible to encourage the development of regional systems and legislation. That is the case with the Andean Community. But even if legislation of a regional nature is not adopted, the integration mechanisms in the region can and should incorporate topics related to biosafety if they have not already done so.

In general, regional integration should include the topic of biosafety, among many other elements. An initiative that could be considered within the development of regional integration is the establishment of regional agreements on transgenic-free-zones on borders.

A prior exhaustive inventory of the actual and potential capacities of the countries in the region should be conducted in order to address the challenges of biosafety and, above all, modern biotechnology. Only on the basis of complete and reliable information on these capacities will it be possible to determine the commitments that each country should assume on its own and what their contributions to and needs from the centres of excellence could be.

Capacity building should take place at different levels. In addition to the measures adopted at the national level, encouragement should be given to international

cooperation, including the exchange of knowledge and staff among regulating institutions, scientific centres and universities. University curricula should be reviewed and expanded, to the extent that becomes necessary, to include aspects related to biosafety.

The transformations should be accompanied by information programmes on the benefits and risks of modern biotechnology, as well as other economic and social impacts, so that citizens will be in a position to adopt decisions on the matter. Biosafety management should, by the same token, be essentially transparent and should take into account the diverse public perceptions of the topic, including those of consumers.

In the region, diverse, and sometimes contradictory, criteria on the topic of biosafety make it recommendable to promote discussion forums of different types, in order to reconcile positions to the extent possible. These points of common interest and concern should be identified and developed as a base for greater agreement among the countries.

Among these points of common interest, emphasis should be placed on exchanges and discussions regarding transgenic-related activities in the region, including concrete analyses of crops, such as soybeans and maize, that occupy important positions in the regional economy and have significant impacts on competitiveness and markets.

The topic of biosafety is difficult to separate from the topic of genetic resources access systems, as well as other topics such as the guarantee of food security. They should be considered in conjunction with one another.

In general, efforts revolving around biosafety should be included in the most general policies and strategies on biological diversity. In that regard, it is essential to continue developing knowledge on the biodiversity in the countries of the region.

4. The Form of Ministers of the Environment of Latin America and the Caribbean and the role of international organizations

The strategy that has been set forth on cooperative development in Latin America and the Caribbean of biosafey policy and law, as well as biosafety administration, gives rise to some specific recommendations whose implementation could be promoted by the Twelfth Meeting of the Forum of Ministers of the Environment of Latin America and the Caribbean through international agencies that can and should play an important role in this strategy.

In fact, there are international agencies that have a mandate and important experience in this field. By contributing their experience and applying the resources available to them, these agencies could facilitate international cooperation in general and particularly intraregional cooperation through the diverse forums in which they participate, and, at the request of the Governments, they could provide technical assistance at the regional, subregional and national levels in many of the topics related to biosafety.

As previously noted, Agenda 21 makes reference to the support that international and regional organizations should provide the Governments in the task of building greater awareness of the advantages and risks related to biotechnology. This support can and should, however, be extended to other fields in which the international agencies are in an optimum position to provide support that could be of great importance to our region, particularly in the relatively less developed countries.

It seems urgent to review the existing effective institutional capacity to face the dilemmas of biosafety, and especially the safety of modern biotechnology, in the countries of the region. On that basis it will be possible to design a specific strategy to build that capacity in the context of a policy and legal framework that should probably be reviewed in depth. The Twelfth Meeting of the Forum of Ministers of the Environment could ask international organizations, in their respective spheres of competence, to promote or conduct a specific study on this topic.

Beyond this topic, there are others that could facilitate the implementation of a strategy for cooperative development of biosafety policy, law and administration in our region, such as that proposed in this document. From that standpoint, it seems urgent to develop knowledge on the possible effects of living modified organisms on the environment in our countries, based on case studies that would examine the possible impact of living modified organisms on the most important ecosystems in our region. The progress made in this field would allow a regional policy in this field to be consolidated, and would ensure its implementation through appropriate legal and administrative mechanisms.

Implementing this strategy for the cooperative development of biosafety policy, law and administration in our region should involve not only the Governments of the countries, but also all sectors interested or potentially interested in the topic of biosafety. This means that the strategy should be aimed not only at all the government sectors involved, but also at other public authorities; that is, at the parliamentarians who should prepare new legislation and the judges that should enforce it, as well as the scientific community and civil society in general, including broad sectors interested in biosafety management, especially the consumer sector. International organizations that have relationships with other public authorities and with world, regional and subregional organizations that bring together different sectors of civil society can facilitate the linkage of these sectors to this strategy for the cooperative development of biosafety policy, law and administration.

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Addendum

1. This document on biosafety policy, law and administration in Latin America and the Caribbean, in which special emphasis is placed on aspects regarding living modified organisms resulting from modern biotechnology and the conservation and sustainable use of biological diversity, was finished in December 1999. At that time, negotiations to conclude the Protocol on Biosafety had been under way for five years and were continuing. Consequently, in this document the topic of biosafety policy, law and administration was examined apart from the possible existence of the Protocol.

2. Nevertheless, chapter IV in the document is dedicated to an analysis of the influence that this Protocol would have on this topic, taking into account the stage reached in negotiations when they had to be suspended, owing to a lack of consensus at the First Extraordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity to adopt a Protocol on Biosafety.

3. The renewed session of this First Extraordinary Meeting took place from 24 to 28 January 2000, and did not conclude until the early hours of 29 January with approval of the text of the Protocol on Biosafety by more than 130 States Parties that participated in the Meeting. This implies that the Protocol negotiators made a set of reciprocal concessions on the points being debated.

4. The text approved in Montreal will be open for signature during the Fifth Conference of the Parties to the Convention on Biological Diversity (Nairobi, from 15 to 26 May 2000), and subsequently sent to the United Nations Headquarters in New York – the depository of the Protocol is the General Secretariat of the United Nations – where it will remain open from 5 June 2000 to 4 June 2001. The Protocol will enter into force 90 days after it has been ratified by 50 States or regional economic integration organizations Parties to the Convention on Biological Diversity.

5. The approval of this Protocol, whose officially edited version is still pending, makes it necessary to review the present document, so as to adjust it to the new circumstances created by the commitments that the States Parties are assuming in the Protocol.

6. The revision will not affect an important part of this document, including its conclusions and recommendations, because, as is repeatedly stated in the document itself, the Protocol only deals with a segment of the topic of biosafety, which is that related to biotechnological safety, and only from the standpoint of the transboundary movements of living modified organisms. Consequently, important topics such as those related to the introduction of exotic organisms into the environment and other equally important topics fall outside the sphere of the Protocol.

7. While this revision is being made, this addendum has been prepared to provide a summary of how the main issues in the debate, as they are described in chapter IV of this document, were resolved.

8. In Montreal, approval was given to the text that states that the objective of the Protocol is to contribute to ensuring an appropriate level of protection in the field of the safe transfer, management and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account the risks to human health and with special attention to transboundary movements, all in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration.

9. The Protocol's sphere of application in the approved text is the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account the risks to human health. The Protocol does not apply to transboundary movements of living modified organisms that are pharmaceutical products for human beings and are already covered by other organizations or in pertinent international agreements or arrangements.

10. Advance informed agreement should take place prior to the first transboundary movement of a living modified organism that is to be introduced into the environment of the importing party. This does not apply to products for food, feed or their processing, which are subject to special rules. Through a decision of the Conference of the Parties, there is a possibility that exemption from the procedure may be given to living modified organisms that are not believed to have adverse effects on the conservation and sustainable use of biological diversity, also taking into account the risks to human health.

11. The advance informed agreement procedure does not apply to living modified organisms in transit or for confined use, conducted in accordance with the standards of the importing party. This provision is, when appropriate, without prejudice to the right of the transit party to regulate the transport of living modified organisms through its territory and to notify the Clearing-House Mechanism of any pertinent decision adopted, as well as the right of the importing part to subject all living modified organisms to risk assessment prior to deciding to import it, and the right to establish standards for confined use within its jurisdiction.

12. In the field of the management, transport, packaging and identification of living modified organisms, the approved text stipulates that to prevent adverse effects resulting from such organisms, all parties should adopt the necessary measures for these activities to be carried out safely, taking into account the pertinent international regulations and standards. Furthermore, all parties should adopt measures to require that the accompanying minimum documentation for these activities fulfils the requirements established in the Protocol. The Conference of the Parties to the Convention on Biodiversity, serving as the meeting of the Parties to the Protocol, should examine the need to prepare regulations – and methods for preparing them – in relation to identification, handling, packaging and transporting practices, in consultation with other international organizations.

13. With regard to the relationship of the Protocol with other international agreements, it was agreed to include in the Preamble some statements on the topic. There it stipulates that the agreements regarding trade and environment should be mutually supportive, with a view to achieving sustainable development. Subsequently, it is stated that the Protocol shall not be interpreted in the sense of modifying the rights and obligations of a Party under other any other international agreements. Finally, it is stipulated that the two previous paragraphs are not intended to subordinate the present Protocol to other international agreements.

14. In the field of socio-economic considerations, the approved text stipulates that the Parties, when adopting a decision on importation in accordance with national measures that govern the application of the Protocol, may take into account socio-economic considerations resulting from the adverse effects on the conservation and sustainable use of biological diversity, especially in relation to the value of biological diversity to indigenous and local communities. This should be done in a manner compatible with the international obligations of the Parties. Approval was also given to encouraging the Parties to cooperate in the sphere of information exchange and research on the socio-

economic effects of living modified organisms, especially in indigenous and local communities.

15. The topic of liability and indemnification was deferred to the Conference of the Parties, which, at its first session, should adopt a process for the appropriate preparation of international rules and procedures on these topics, examining and taking into account the international legal processes under way. This process should be concluded within four years.

16. In the field of relations with States that are not Parties, the approved text states that transboundary movements of living modified organisms between these States and the States Parties should be consistent with the Protocol, and that the Parties may enter into bilateral, regional and multilateral agreements or accords on these transboundary movements with States that are not Parties to the Protocol.

17. Finally, the complex conditions under which the Protocol was approved resulted in the Parties establishing an unusual mechanism for the assessment and examination of the Protocol. In fact, five years after the Protocol enters into force, the Conference of the Parties, serving as a meeting of the Parties, should conduct an assessment of the Protocol's effectiveness, including an evaluation of its procedures and annexes. Thereinafter, this assessment should be repeated at least every five years.

18. for the countries of the region, approval of the Protocol implies the commitment to regulate all the elements of the Protocol that are not yet covered in their legislation on biosafety and, if necessary, to make it consistent with the commitments assumed. This will make it necessary to review such legislation in depth. The Protocol will only enter into force when it is ratified by the States Parties in the terms provided for in the Protocol itself. However, it should not be forgotten that the signing of an international agreement obliges the country that signs it to act in a manner compatible with the obligations it assumes through the agreement.

Mexico City, February 2000

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