



# FUNDAMENTS OF THE NATIONAL BIOSAFETY FRAMEWORK OF CHILE

## FINAL REPORT OF THE UNEP-GEF-CONAMA PROJECT “DEVELOPMENT OF A NATIONAL BIOSAFETY FRAMEWORK FOR CHILE”

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December 2005

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**..SUMMARY..**

## ..SUMMARY..

The present report is product of the work of the UNEP-GEF Project "Development of a National Biosafety Framework for Chile", executed by the country's environmental authority, the National Environmental Committee (CONAMA), with the active participation of the Project's National Coordination Committee (CNC). This public-private technical committee was created exclusively for project purposes and steered its development and contents along the three years of its execution. To this purpose, it united all public institutions traditionally related to biosafety, as well as entities representing the productive sector, civil society and the scientific-academic world.

This report tackles a variety of topics focusing on the strengthening of biosafety according to the emphasis chosen by the CNC, with a special attention on the public management of Genetically Modified Organisms (GMOs). It constitutes the basis for the institution of a National Biosafety Framework for the country, as it deepens on those aspects of biosafety which have to be evaluated, developed, perfected, disseminated and publicly discussed for the establishment of a correct and complete framework. Even though the UNEP-GEF Project intended to support and motivate advances in all biosafety-related areas, their results, indicating the needs which it was possible to attend, are of a more technical nature, since policy-development and judicial instruments were not the subject of this Project.

The start of the UNEP-GEF Project coincided with a period of time when the Ministry of the Economy foresaw the potential of biotechnology as a tool to push the country's development and productive competitiveness, the promotion of which should be linked to practices of evaluation, safeguarding and transparency required by this technology. For this reason, the Ministry of the Economy started to draft the National Policy for Biotechnology Development to offer guidelines on various unresolved issues of biotechnology and define priorities for action, especially on regulatory and institutional topics. This Policy, generated by a presidential committee independently from the present Project, is in force since November 2003. Subsequently, and with the purpose of endowing the country with an adequate legal framework for the take-off of biotechnology, the Ministry of the Economy, with the participation of other public institutions competent on the matter of biotechnology, developed and finalized a Bill of Law on the Biosafety of GMOs in August 2005. Additionally, around the same time, the Ministry of Health prepared a proposal for a norm on the evaluation and authorization of "biotechnological events" in human nutrition. These regulations have not been promulgated to this date.

The present report does not expand further on regulatory issues, as the CNC did not participate in the development and discussion of the aforementioned normative proposals. It does, however, maintain the structure suggested by UNEP to address the following work lines: the biosafety regulatory system, the mechanisms of public participation, the management of GMO information, and GMO inspection and control.

The report describes the present situation as to these issues, referring to the mainly governmental initiatives aimed at improving biosafety and the social integration of biotechnology. And, considering a possible future scenario of openness towards GMO-trade, with a greater range of GMOs subject to national regulations, it formulates recommendations, highlights institutional considerations and presents sector positions on these topics. It applies the same perspective on the ultimate ratification of the Cartagena Protocol on Biosafety, the decision on which is still pending. This possible scenario results from the National Policy for Biotechnology Development, in which the promotion of biotechnology is projected, among other ways, through a broader adoption of biotechnological applications, including GMOs, in the productive sector and the widening of the regulatory framework on biosafety. Currently, in Chile GMOs are cultivated only for purposes of research or multiplication of seeds.

It was in the face of this future scenario that the UNEP-GEF Project decided to raise funds, generate inputs and offer a platform for debate and work, which would make it possible to take the necessary decisions regarding the needs and challenges arising from a safe application of biotechnology in the country. And, of course, this would create the favorable conditions to evaluate the national ratification of the Cartagena Protocol transparently and in a participatory manner.

The UNEP-GEF Project achieved important progress precisely in the participation of various sectors and the

propagation of biosafety, the Cartagena Protocol and the government initiatives relating to biosafety. It created a web portal, data bases and information material, and carried out a series of information activities, mainly open seminars, to inform on the national threats from biosafety and biotechnology. Examples of which are the international seminar on the Cartagena Protocol, held with the participation of experts from the European Union, Mexico and Argentina and local specialists, and the debate seminars on the National Policy of Biotechnology Development, which took place in Santiago and the city of Concepción, immediately after the Policy had entered into force. Additionally, several assessments were made, such as the study on the national legislative and institutional framework for biosafety and its relation with the Cartagena Protocol, and the study on national biotechnology, which points out in which regions, and to what purposes projects for research and development of biotechnology are carried out. Equally, a proposal was made to study the national public opinion on biotechnology, considering that the promotion of biotechnology first requires an evaluation of the degree of integration and acceptance of this technology in the Chilean society.

Through the CNC, thematic areas requiring strengthening and actions to address these needs were identified. In this sense, the major contributions of the UNEP-GEF Project could be found in the field of GMO risk evaluation. A series of technical studies were carried out, producing methodological proposals and local as well as international background information to feed and support decision-taking in the matter of biosafety, especially in the face of the possible integration of more types of GMOs into national production. Currently, the law only allows the introduction of plant GMOs into the environment to produce seeds and later export them or to carry out field tests. Due to the importance of agriculture, silviculture and aquaculture, a strong emphasis was made on knowing the scientific and technical considerations regarding aquatic GMOs and to identify wild species in Chile which have been crossed with GMO crops. Another topic studied were the possible financial impacts of the incorporation of GMOs into the Chilean agriculture on the commercialization and value of agricultural and aquacultural export products.

The strengthening of the administrative structure focused on the institutional capacities that would be required, should the Bill of Law on GMO Biosafety be promulgated or the Cartagena Protocol ratified. To obtain a clearer idea on this topic, an in-depth study on these (administrative, technological and analytical) capacities was carried out, focusing on the institutions which would act as "Competent National Authorities". Here it was found that the major challenges lie in the management of information and the technology used to this end, and in the training of the personnel - topics on which the present report formulates recommendations, specifying which areas the efforts should be directed at. The mechanisms of public participation, on the other hand, do not present great deficits, as the norm which is being developed includes instances and spaces for participation which would allow the fulfillment of the requirements of the Cartagena Protocol. However, it was noticed that public management of biosafety would require the destination of greater funds for the management of risks associated with GMOs, and their control and inspection. In these fields the collaboration of the productive sector, the projection of technical-scientific studies, as well as the existence of analytical capacities will be crucial.

As a general conclusion, it is estimated that the promulgation of a biosafety legislation would correct most of the regulatory faults in the current biosafety framework, and would allow the country to take on board the Cartagena Protocol, should it decide to ratify it.

## **..ACRONYMS AND ABBREVIATIONS..**

## .. ACRONYMS & ABBREVIATIONS..

|              |  |
|--------------|--|
| CNA          | Competent National Authorities   |
| BCH          | Biosafety Clearing House   |
| CDA          | Center for Environmental Law, Faculty of Law, University of Chile  |
| CBD          | Convention on Biological Diversity   |
| CDE          | State Defense Council ( <i>Consejo de Defensa del Estado</i> )   |
| CIB          | International Center for Biotechnology, University of Concepción ( <i>Centro Internacional de Biotecnología</i> )  |
| CIPC         | Intergovernmental Committee for the Cartagena Protocol ( <i>Comité Intergubernamental para el Protocolo de Cartagena</i> )   |
| CNC          | National Coordination Committee ( <i>Comité Nacional de Coordinación</i> ) (UNEP-GEF Project)  |
| CNDB         | National Committee for the Development of Biotechnology ( <i>Comisión Nacional para el Desarrollo de la Biotecnología</i> )  |
| CONAMA       | National Environmental Committee ( <i>Comisión Nacional del Medio Ambiente</i> )   |
| CONICYT      | National Committee on Science and Technology ( <i>Comisión Nacional de Ciencia y Tecnología</i> )  |
| COP/MOP      | Conference of the Parties acting as the Meeting of Parties in the Cartagena Protocol   |
| FAO          | <i>Food and Agriculture Organization</i>   |
| FIA          | Foundation for Agricultural Innovation ( <i>Fundación para la Innovación Agraria</i> )   |
| FSS          | Foundation for Sustainable Societies ( <i>Fundación Sociedades Sustentables</i> )  |
| GICONA       | Information Management of the Processes of National Control of the Public Health Institute ( <i>Gestión de Información de los Procesos de Control Nacional (del ISP)</i> ) |
| R+D          | Research & Development   |
| ICGEB        | International Center of Genetic Engineering and Biotechnology  |
| INIA         | Institute of Agricultural and Livestock Research ( <i>Instituto de Investigaciones Agropecuarias</i> )   |
| ISP          | Public Health Institute ( <i>Instituto de Salud Pública</i> )  |
| Min.Agri     | Ministry of Agriculture  |
| Min.Economía | Ministry of the Economy  |
| Min.Salud    | Ministry of Health   |
| Min.SegPres  | Ministry General Secretariat of the Presidency   |
| MNHN         | National Museum of Natural History ( <i>Museo Nacional de Historia Natural</i> )   |
| ODECU        | Organizations of Chilean Consumers and Users ( <i>Organización de Consumidores y Usuarios de Chile</i> )   |
| ODEPA        | Office for Agricultural Studies and Policies ( <i>Oficina de Estudios y Políticas Agrarias</i> )   |
| GMO          | Genetically Modified Organism  |
| OIE          | World Organization for Animal Health   |
| WTO          | World Trade Organization   |
| NGOs         | Non-Governmental Organizations   |
| LMO          | Living Modified Organism   |
| LMO-A        | Living Modified Aquatic Organism   |
| LMP          | Living Modified Plants for Propagation   |
| RAMA         | Environmental Regulations for Aquaculture ( <i>Reglamento Ambiental para la Acuicultura</i> )  |
| REDBIO       | Technical Cooperation Network on Plant Biotechnology ( <i>Red de Biotecnología Vegetal</i> )   |
| RSA          | Food Health Regulations ( <i>Reglamento Sanitario de Alimentos</i> )   |
| SAG          | Livestock and Agricultural Service ( <i>Servicio Agrícola y Ganadero</i> )   |
| SEIA         | System for Environmental Impact Assessment ( <i>Sistema de Evaluación de Impacto Ambiental</i> )   |

|            |   |
|------------|---|
| SEREMIs    | Regional Ministerial Secretariats ( <i>Secretarías Regionales Ministeriales</i> )                                     |
| SERNAC     | National Consumers' Service ( <i>Servicio Nacional del Consumidor</i> )   |
| SERNAPesca | National Fishing Service ( <i>Servicio Nacional de Pesca</i> )  |
| SNIBO      | National Information System on GMO Biosafety ( <i>Sistema Nacional de Información sobre Bioseguridad de los OGM</i> ) |
| SOFOFA     | Society for the Development of Manufacturing ( <i>Sociedad de Fomento Fabril</i> )                                    |
| SubPesca   | Subsecretariat for Fishing ( <i>Subsecretaría de Pesca</i> )  |
| SubSalud   | Subsecretariat for Health ( <i>Subsecretaría de Salud</i> )   |
| FTA        | Free Trade Agreement  |

**..CHAPTER 1..**  
**INTRODUCTION**

# ..1.. INTRODUCTION

## 1.1 -SCOPE OF THIS REPORT

This report is the result of the UNEP-GEF Project "Development of a National Framework for Biosafety for Chile" (henceforward, the UNEP-GEF Project). It represents a summary of the topics addressed by this Project and briefly describes the current situation in the different spheres of biosafety, including the context in which the Project was developed.

With the help of this Project, substantial contributions have been made to the management of Genetically Modified Organisms (GMOs), and faults and specific needs in the matter have been identified, especially in the governmental sector. Even though the public services do have experiences and capacities in the management of biosafety, and an institutional basis for this purpose, their strengthening is still a long way off. It is in this technical and institutional field, that the UNEP-GEF Project has made its greatest contributions, due to which in this report, all Project results and "products"(technical reports, data bases, proposals, etc.) that can be publicly discussed and accessed, and are destined to public institutions involved in biosafety management are highlighted in **colored boxes**.

Although the work carried out by the UNEP-GEF Project essentially centered on the management of biosafety, the results produced on its basis do not constitute a National Biosafety Framework. Further below, it will be explained in detail why the contents of this report represent the inputs and preparatory bases for a future National Biosafety Framework in Chile.

The structure of the present report as well as the areas developed through the UNEP-GEF Project comply with UNEP's indications regarding the central components of a National Biosafety Framework. Consequently, this report addresses the following thematic areas:

### STRUCTURE:

- (1) Biosafety regulations
- (2) Administrative system for the management of requests
- (3) Decision-taking, based on GMO risk evaluation
- (4) Inspection and inspection of GMOs
- (5) Mechanisms of participation and public information on biosafety

As to these components, the present report includes recommendations of the National Coordination Committee of the UNEP-GEF Project, a multi-sector entity in charge of the steering of the Project. And, in the case of some themes, it delivers institutional considerations with a view to a better biosafety management (highlighting more specific requirements) and concrete proposals based on the Project studies. It also formulates a series of considerations regarding the ultimate ratification and implementation of the Cartagena Protocol on Biosafety, although there is a possibility that the country remains a Non-State Party.

The recommendations and considerations presented in this report were formulated with the purpose of contributing to the legislation on biosafety as well as the permanent establishment of capacities and know-how, not only in the public sector, but also in other sectors of society.

These recommendations refer to the high-priority areas in the matter of biosafety and give clear indications on where to concentrate future sectorial efforts.

The UNEP-GEF Project Committee endorsed them to different degrees, and they are therefore divided into those supported by the Committee<sup>1</sup> as a whole (consensus opinions) and those which represent a majority opinion<sup>2</sup>.

Likewise, the report tries to collect, or at least point out, the discrepancies existing between some sectors

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<sup>1</sup> For this purpose, only those members of the CNC who participated in the revision and final approval of this report are taken into consideration.

<sup>2</sup> The majority is reached by a proportion of 6 to 5.

on certain themes, in order to publicize the, sometimes irreconcilably, different opinions roused by the topic of GMOs in the country. This is a result of a direct request of members of the National Coordination Committee of the UNEP-GEF Project to explicitly state the fields of greatest divergence and each sector's visions, when the dissimilarity between their positions makes it worthwhile to.

The different sectors of the Chilean society, represented in the National Coordination Committee and having an interest in the matter of biosafety, all have their own stands, and in some cases, strategies and proposals to tackle the issue. The UNEP-GEF Project could not reconcile all the existing visions of the sectors. However, its execution has encouraged a transparent and joint effort to define national needs in the matter of biosafety, helping to draw these different sectors closer to each other, facilitate dialogue among them and legitimate their positions, through the creation of a multi-sector committee. Thus, the diversity of opinions is considered a valuable resource, and the degree of convergence achieved reflects the greatest existing receptiveness at present to address these issues.

#### ADDRESSEES OF THIS REPORT:

To ensure the continuity of this work, the analyses and recommendations resulting from the UNEP-GEF Project collected in this report shall be submitted to the consideration of two governmental entities of a political character, without thereby excluding the possibility that some Project "product" may also be intended for public services and the general population.

1. - *The Committee for Biotechnology regulations*, an instance chaired by the Ministry of the Economy, destined to deal every aspect related to the definition of internal politics and regulations on the matter of biotechnology and biosafety.

2.- *The National Advisory Committee on the Matter of Biosafety* is presided by the national environmental agency, the National Environmental Committee (CONAMA) and was created with the purpose of advising CONAMA's Directive Council and the Ministry of Foreign Relations on matters related to international agreements linked to biosafety.

The *National Advisory Committee on Biosafety* has proposed to determine to which extent the Government of Chile is prepared to take responsibility for the needs identified and the proposals and actions formulated in this report. On this basis, the National Advisory Committee will propose a working agenda to CONAMA's Directive Committee, in order to address biosafety issues which still need to be developed, discussed and/or treated on an inter- or intra-sectorial basis.

In no case shall the content of this report, including its recommendations, be interpreted as commitments assumed by, or to be assumed by, the State of Chile. Instead, his report presents the progress made, and offers ideas on how to continue advancing, in the matter of biosafety.

In the rest of this introductory chapter follows a narrative of the UNEP-GEF Project in Chile, and the scope and purpose of the present report with the title "Fundamentals for the National Biosafety Framework in Chile" will be explained in detail. Some key terms and concepts referring to the issues addressed will be specified, and a general perspective on the public opinion on GMOs in the Chilean society will be offered, including their acceptance by its citizens and the experiences with GMOs in different State Powers, so as to present the context of the execution of the UNEP-GEF Project in Chile.

## 1.2 - DEVELOPMENT OF A NATIONAL FRAMEWORK FOR CHILE

### 1.2.1 INITIATIVE FOR A NATIONAL FRAMEWORK

Through CONAMA, Chile adhered to the UNEP-GEF Biosafety Project in the year 2001, based on the consideration that greater capacities in the matter of biosafety were needed, especially in the governmental sector and, more specifically, in order to implement the Cartagena Protocol on Biosafety (henceforward, the Cartagena Protocol), an agreement which the country had subscribed to just one month previously.

It was due to this circumstance that, in November 2002, CONAMA formally initiated the execution of the UNEP-GEF Project, with the objective of developing capacities and articulating discussions to clarify how the

country would advance in the strengthening of biosafety and the national application of the Cartagena Protocol. At the beginning of the Project, governmental institutions that had participated in its initial design coincided that after some solid internal and institutional work the country would be in better conditions to evaluate its adherence to the Protocol.

However, as it could gradually be foreseen that the most costly implications and requirements in connection with the ratification of this agreement might be of a commercial nature, a series of questions arose that reached beyond the scope and technical character of the UNEP-GEF Project.

On the other hand, the scenario under which the UNEP-GEF Project was started differed from the one existing at the time of subscription to the project together with UNEP: during that period, the Government had made an important decision: to address biotechnology as a question of opportunity and economic development for the country requiring the implementation of a public policy. This initiative emerged from the Ministry of the Economy, which through a special committee, the *National Committee for the Development of Biotechnology* (CNDB), constituted by Presidential mandate between the years 2002 and 2003, made a lengthy study of the opportunities, risks and challenges of biotechnology for the country and took charge of the drafting of a National Policy for the Development of Biotechnology.

This situation led to a superposition of the roles of the Ministry of the Economy and CONAMA, as there evidently was a convergence, in thematic as well as coordination aspects, between the work performed by the CNDB and the objectives of the UNEP-GEF Project. This was particularly relevant for the regulatory and administrative components which the UNEP-GEF Project hoped to develop or articulate. Finally, it was the task of the CNDB to address the strengthening of the regulatory framework and the definition of the institutional basis and administrative system for biosafety.

This coincidence was detected early, leading to an agreement between CONAMA and the Ministry of the Economy to join forces and harmonize initiatives, so as to achieve a higher level of coordination, synergy and projection of their work lines.

From the beginning, therefore, the UNEP-GEF Project considered itself a technical complement to the political definitions arising from the CNDB and a support to the efforts of the authorities involved in the definition of Biotechnology Policies and in charge of their accomplishment. Definitely, the development of the UNEP-GEF Project in Chile was strongly influenced by the priorities, political guidelines and proposals of the CNDB. Their components would include neither a political framework nor regulatory definitions, but supportive elements for these tasks.

It has to be pointed out, without denying their similarity, that the objectives of these two initiatives are not directly in line with each other. The UNEP-GEF Project did not intend to encourage biotechnological development in the country, but it did coincide with the National Policy of Development of Biotechnology on the need to reach stronger guarantees and clarity in the procedures for a responsible and transparent use of this technology.

An important result of the National Policy for the Development of Biotechnology (henceforward, the Biotechnology Policy) was the determination on legislating on the matter; therefore, this Policy recommends the drafting of a Framework Law, as a priority action to be taken by the government.

### 1.2.2 OBJECTIVES OF THE UNEP-GEF PROJECT

The objectives pursued by the UNEP-GEF Project explain the direction given to the attainment of products. At the time the National Coordination Committee (CNC) of the UNEP-GEF Project was created, the government had decided to draft a national policy to promote and guide the development of biotechnology in the country. Therefore, the objectives of the Project were not of a political nature, but focused on solving practical needs and concerns.

When taking up its work, the CNC defined two objectives in relation with the UNEP-GEF Project: the first, to carry out an "internal restructuring", with a short-term impact and a strong institutional emphasis; and the second, to create conditions that would steer the country towards the ratification of the Cartagena Protocol. In effect, this prioritization tried to contribute firstly to the strengthening of biosafety, especially in the

sphere of public management, and to the implementation of the Biotechnology Policy actions and secondly, to the possibility of reaching a decision regarding the Cartagena Protocol.

Finally, to the aim of identifying the fields in which the UNEP-GEF Project could make relevant contributions, the CNC adopted a consented Plan of Action in mid-2003, to steer the Project execution according to the priorities that had emerged from the discussions within the CNC. These priorities can be summarized as follows:

- Governmental sector: Strengthening of the tools for Risk Evaluation, Training on Biosafety, Protection of Biodiversity at the moment of releasing GMOs into the environment and in the cultivation of aquatic GMOs
- Other sectors: Wider public information on these issues, especially the Cartagena Protocol, Greater participation and receptiveness in the national discussion on biosafety

To summarize the scope of the results of the UNEP-GEF Project and with this, clarify the contents of the present report, the vision of the CNC on the National Biosafety Framework and the corresponding definitions taken should be pointed out:

- The UNEP-GEF Project had no mandate to develop regulations or policy definitions in the matter of biosafety.
- The UNEP-GEF Project had no mandate to reach a decision regarding the ratification of the Cartagena Protocol.
- The results obtained through the UNEP-GEF Project are not intended as a "National Framework on Biosafety", but as elements constituting "the foundations" for a future national framework.
- The Government of Chile maintains that the National Policy for the Development of Biotechnology as well as the Bill of Law on Biosafety (once promulgated) will constitute a central part of the "National Biosafety Framework", although there are sectors with representation in the CNC which disagree on this matter.
- The UNEP-GEF Project sought to offer substantial inputs for the future development of norms and their implementation, as well as to support the tasks of the authorities in charge of the implementation of the Biotechnology Policy.

Descriptions or references to political, institutional or regulatory elements related to a possible future "National Biosafety Framework" contained in this report do not imply that these have been developed, defined or agreed upon in the context of the UNEP-GEF Project.

### 1.2.3 CHARACTERISTICS OF THE UNEP-GEF PROJECT IN CHILE

#### *Duration and Financing*

The UNEP-GEF Project of Chile formally started on December 31, 2002 and planned for a total duration of 18 months, with a possible extension to 26 months and corresponding date of finalization on May 2, 2005. The GEF financed US\$ 200,000 and national counterpart funding of at least US\$ 100,000 was required from the Chilean government (comprising contributions in kind and in cash).

#### *National Coordinator*

The expert Tea García-Huidobro, a biochemist with a Masters in Environmental Technology, was hired for the post of National Coordinator of the UNEP-GEF Project, and in consequence as Technical Secretary of the Committee in charge of steering the Project. She was assisted in her tasks, and especially in the writing of the present report, by Elena Valderas, a Lawyer hired as a Support Consultant for the period between June 2004 and April 2005.

#### *Executing Agency*

CONAMA, as GEF Focal Point and Focal Point of the Convention on Biological Diversity, was the governmental agency in charge of the execution and coordination of the UNEP-GEF Project "Development of the National Framework on Biosafety for Chile", while the general supervision of the Project and the presidency of the National Coordination Committee was delegated to the expert Jaime Rovira, Agronomist and Director of CONAMA's Department of Protection of Natural Resources.

### *National Coordination Committee (CNC)*

The CNC of the UNEP-GEF Project was initially created on the basis of public institutions which historically integrated the Technical Biosafety Committee, coordinated by CONAMA since 1997, with the purpose of firmly instituting the national work on the Cartagena Protocol. In fact, it was the Technical Committee which participated in the definition of the Project Document and directed the first phases of the execution before the CNC was formally constituted, which would have a multi-sectorial character, in conformity with the recommendations of UNEP.

To convene the CNC, at the beginning of 2003 invitations were sent to the productive and academic sectors and civil society to nominate their representatives, who would then be integrated into the committee chaired by the UNEP-GEF Project. These invitations were addressed to entities which had previously participated in the work of the CNDB, a public-private committee which, as explained above, had been constituted by the Ministry of the Economy to define the foundations of the Biotechnology Policy. This superposition of persons in both work groups was intended to guarantee a certain level of expertise in the participation of the private members, as well as a greater continuity in the political work initiated by the CNDB and what would become the agenda of the UNEP-GEF Project.

The list of the members of the CNC for the period between November 2002 and August 2005 can be found in Annex 1, with the names of elected members (T) as well as their deputies (S).

In its first session, the CNC analyzed its functions and agreed on a *modus operandi* for its work which would include the possibility to from *ad hoc* work groups to deal with specific issues, activities and studies. The principle of "administrative silence" was also agreed upon (defining a term for pronouncements) for every decision the Committee should have to take through e-mail.

#### Main functions of the CNC:

- Supervision and guidance of the UNEP-GEF Project
- Mobilization of expertise and information when necessary
- Decision-taking on budget questions
- Approval of Project Activities
- Approval of final products of the Project (in particular, this report)
- Guarantee that the contents of the National Biosafety Framework and/or components generated by the Project are in line with national sector and environmental policies.

## 1.3 - GMOs IN THE CHILEAN SOCIETY

To introduce the scenario in which the issue of biosafety is developing in Chile, some of the positions and opinions on GMOs or biotechnology in general manifested by certain sectors of the Chilean society in recent years shall be described.

Even though this report will focus on biosafety, specifically GMO-related biosafety, Annex 2 also presents a summary of how biotechnological applications have gradually become high-priority issues for the country. This wider description is necessary as biosafety has to be considered in the context of this trend, which can be noted at the level of authorities and enterprises, that regard biotechnology as a necessary tool for the country's economic development, as well as at the level of civil society, which is showing a growing interest to know more about biotechnology and GMOs.

To learn more about the country's biotechnological development (research, commercial applications, tendencies, etc.), the reader can consult Annex 2 or, alternatively, the following study under the UNEP-GEF Project, available at [www.bioseguridadchile.cl](http://www.bioseguridadchile.cl): "*National Assessment and Characterization of Biotechnological Research and its Industrial or Commercial Applications*" (Gil et al., 2004).

### 1.3.1 SOCIETY, GMOs AND BIOTECHNOLOGY

The Chilean public's perception of biotechnology, and GMOs in particular, has been scarcely explored. But at

least two relevant studies<sup>3</sup> have revealed that the consumers are interested in biotechnology and curious to learn more about its benefits and risks, but feel that they lack sufficient knowledge or information. A high percentage holds that the application of biotechnology should be prohibited in food production, but shows a higher acceptance of medical applications. This opinion is also reflected in the results of the survey commissioned by *Greenpeace*<sup>4</sup> in November 2004, which revealed that while 53.5% of consumers had heard of "GMO foods", 58.5% preferred to consume food without GMOs and 95.9% held that these should be labeled.

In general, the information disseminated on these themes is perceived as insufficient and little reliable. This could explain why Chile ranks among the countries with the most negative opinion on GMO foods (73% of the inhabitants of Great Santiago reject them). The evaluation of the authorities' performance is equally negative, as it is considered that they have not fulfilled their regulatory functions nor given the necessary importance to the dissemination of information.

Much like the rest of the world, the Chilean society also debates these topics, on which a consensus remains elusive, as occurs in other countries. In this context, it is possible to identify polarized positions, some openly in support of biotechnology in all its aspects and some rejecting this technology completely. A less rigid critical position recognizes its benefits, but alerts on the precautions that have to be taken specifically in relation with GMOs and transgenics.

The organizations with positions of rejection in this controversy are civil society groups whose main concern is the defense of the environment and biodiversity, and organic farmers who promote an "environmentally friendly agriculture" and express a fear of a possible loss of acceptance of their products by foreign markets. Since 1999, these have organized themselves in the *Network for a GMO-Free Chile (Red por un Chile Libre de Transgénicos)*<sup>5</sup>, composed of more than 20 environmental, consumer and organic farmers' organizations.

As to consumers specifically, the associations with a higher visibility and greater influence on this side are generally local representations of international Non-Governmental Organizations (NGOs), such as *Greenpeace and Consumers International*, although the same is true for the Organization of Chilean Consumers and Users (ODECU), which for many years has maintained a growing leadership. The clear and constant demand of these organizations has been the obligatory labeling of imported foods containing GMOs or their derivatives.

On the other hand, the actors who maintain a position of open acceptance of biotechnology, including GMOs, mostly come from the productive sector<sup>6</sup> and the academic world. They see this technology as a series of opportunities and advantages for the improvement of productive processes as well as the national scientific capacities. They also adduce the risk of not adopting biotechnological solutions to solve local problems in the country. The risks associated with the application of biotechnology in the environment or in food are considered by their defenders to be manageable, and they remind the population that it is impossible to guarantee "zero risk" in the use of this technology, as in any other.

In the productive sector, the farming sector stands out as the one most enthusiastically embracing biotechnology in Chile - it also is the only sector actively involved in transgenics, not only through lines of research, but also of production. The only commercial application of transgenesis occurring in Chile is the multiplication of seeds developed in the northern hemisphere and introduced into the country for their multiplication and later re-export.

Due to the agro-ecological and climatic conditions of the country, the different farming season (opposite to the northern hemisphere), as well as the guarantees of its system of sanitary surveillance turned Chile into an interesting destiny for those seed producers of the northern hemisphere who wished to increase their annual yield.

For this reason, the growth of GMOs for the only purpose of evaluating, multiplying and re-exporting seeds

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<sup>3</sup> These studies are: CamBiotec-Chile, 2000-2001, published by Gil et al. (2001) in *Revista Ambiente y Desarrollo*, vol 17(4) p. 54-58 in December 2001, and Hernandez (2002) together with the Technical Cooperation Network on Plant Biotechnology of the FAO, available at the website <http://rcl.fao.org/prior/segalim/prodalim/prodveg/paper.htm>

<sup>4</sup> [www.greenpeace.cl](http://www.greenpeace.cl)

<sup>5</sup> They demand, on the one hand, a moratorium for the release of GMOs in Chile until it is proved that these do not contain any risks for biodiversity and human health, and on the other hand, respect for the rights of consumers to information on what they consume.

<sup>6</sup> However, there are productive sectors that reject GMOs, such as the producers of salmon, bee keepers and organic farmers.

was authorized in the country in the year 1992, through a specific regulation by the Livestock and Agricultural Service. This activity demanded biosafety measures and/or guarantees that the safety measures for the cultivation of crops for seed production to minimize the probability of cross-pollination with conventional crops or wild relatives, which are still in force today.

### 1.3.2 THE EXECUTIVE BRANCH, GMOs AND BIOTECHNOLOGY

As often happens in practically every fields of human activity (at least in those with a social impact), the need for a legal regulation for this new field of research arose only until after its applications were already on the market. And it has roused doubts and mobilized the efforts of diverse actors in charge of the design of policies and norms on these matters.

Over the last years, the national authorities (each in its own sphere) have had a growing participation in matters related to biotechnology. In this context, the Government adopted a stand or position that was open to the promotion and encouragement of the use of this technology, intervening as much as necessary to ensure the protection of human health, biodiversity and the development of alternative production, especially related to GMOs.

A clear sign of this can be found in the definition of the *National Policy for the Development of Biotechnology*, in force since November 2003 and generated parallel to the UNEP-GEF Project. As a result of a broad and long discussion with diverse actors<sup>7</sup> of society, it contains a series of tasks and targets of different nature, with the common objective of positioning Chile on the path of scientific and economic development with the help of biotechnology, while at the same time preventing its possible negative effects through an appropriate regulation on biosafety.

This Policy addresses, on the one side, aspects related to the promotion and growth of biotechnology, and on the other, the necessary instruments for its control and safe use (i.e., the regulatory framework for biosafety), as both are considered essential conditions for the encouragement and effective productive application of this technology in the country. It is here, in the regulatory aspects, that emphasis has been made on GMOs. Therefore, it can be said that the position of the Executive branch on these organisms lean towards an "adequate regulation" allowing the country to benefit from the opportunities offered by biotechnology, guarantee the assessment of environmental and associated health risks and manage these risks to reach an acceptable risk level.

### 1.3.3 THE LEGISLATIVE BRANCH, GMOs AND BIOTECHNOLOGY

The legislative branch has also expressed a growing concern on the issue of biotechnology and GMOs. Since 1997, there has been a considerable number of initiatives to create laws on different aspects of this technology, such as the cloning of humans or labeling of genetically modified food products, or to introduce amendments to existing laws, such as for example, the Law on Fishing or the General Law on the Environment, which incorporates specific indications for GMOs.

The reasons behind these parliamentary motions and proposals, which generally demonstrate a precautionary stand towards biotechnology, are not only related to the concerns expressed by certain sectors of society, but also to the lack of a Government position until 2003, and the absence of a national policy on the topic as well as a coherent regulatory framework which would allow to consolidate the biosafety of all biotechnological applications.

Now, even if there clearly is a need to revise these legal initiatives in the light of the latest scientific and regulatory advances at the national as well as international level, there is also a visible need to establish better coordination mechanisms between the government services themselves; and for stronger joint efforts of Government and Congress to address, with a common stand, the bills of law presented in parliament, taking into consideration the parliamentary advances in this matter; thus to build adequate levels of social legitimacy and facilitate the generation of legislative consensus and the creation of an efficient and modern

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<sup>7</sup> As will be indicated further on, the representatives of the NGOs, organic agriculture and other sectors who are critical towards genetic engineering did not participate in the Committee that was in charge of drafting the foundations of the National Policy for the Development of Biotechnology. Therefore, they took no part in its decisions, although they were invited to special forums to state their own positions.

legal framework.

#### 1.3.4 THE JUDICIAL BRANCH AND GMOs

Experiences of the judicial branch with GMOs are still recent and limited to the legal actions initiated by some important national NGOs against authorities or food-producing enterprises, demanding the protection of consumers' rights and the environment. Other lawsuits have the aim to protect constitutional rights laid down in the Political Constitution of the Republic, such as every person's legitimate right to life and physical integrity.

Examples are two lawsuits<sup>8</sup> filed by ODECU against various food-producing enterprises, which were generally based on the accusation that the incorporation of genetically modified inputs or GMO derivatives threaten and curbs people's legitimate exercise of their right to life and physical integrity, as there are no guarantees of the harmlessness of these biotechnological products when consumed as food. Both appeals were ultimately rejected, one even by the Supreme Court.

The most emblematic cases are two appeals for protection filed against the President of the Republic: one claiming a failure to label GMO foods, and one case of appeal for legal protection for the right to obtain information on the management and location of certain GMO crops (for seed production).

In the first case, the appeal for legal protection filed by the plaintiffs<sup>9</sup> in June 2001 was founded on the damage caused by not publishing in the Official Gazette (and thus, not officially promulgating) the Decree amending the Sanitary Regulations for Food and allowing the labeling of GMO products, thus granting wider access for consumers to information. This appeal for protection, in which the Council for the Defense of the State (CDE) intervened in representation of the State, was rejected by the first instance by the Santiago Court of Appeals, whose sentence coincided mostly with the reasons contained in the answer of the CDE. Not satisfied with this result, the plaintiffs proceeded to file an appeal against this sentence before the Supreme Court in September 2001, which was ruled in November that same year, confirming the sentence of the first court.

Another case, a little different from this one, is the legal action for constitutional protection filed by the *Consortium of Agricultural Societies of the South (CAS)*, invoking the consumers' right to life and physical integrity on the one hand and the right to equal treatment before the law on the other, considering that the authority gives national farmers a different and discriminatory treatment as it does not allow the local production of GMOs for food, but it does its import. This appeal was also unsuccessful, as it was rejected in the first as well as second instance<sup>10</sup>.

The second case, which became quite famous, was the legal appeal for the right of access to information, filed before the civil courts in August 2001 by a group of plaintiffs<sup>11</sup>. They demanded that the Livestock and Agricultural Service (SAG), an institution of the Ministry of Agriculture in charge of assessing, authorizing and supervising GMO crops for seed production, provide specific information on these crops which were considered to be of top interest<sup>12</sup>. The motive behind the legal action was, basically, to know the geographic location of GMO crops, in order to avoid the establishment of organic crops in the neighborhood.

There were legal grounds for the petition, as Law 19.653 establishes the obligation of public administration bodies to facilitate any information requested by them. The rejection by the SAG was based on the fact that publicizing the information would affect the rights of third parties, that this information was confidential; that its disclosure would obstruct its inspection tasks, as these would become too little reliable for the

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<sup>8</sup> Appeal for protection filed by the Organization of Chilean Consumers and Users (ODECU) against the company Watt's Alimentos S.A. in August 1999 before the Court of Appeals of San Miguel, rejected on 14 January 2000 and appealed against before the Supreme Court, which confirmed the previous sentence. In the second case, an Appeal for protection was filed by the same organization before the Court of Appeals in Santiago, against the companies Soprole, Coprona and Agromaule. It was declared inadmissible due to evident lack of grounds as the damage was unclear; there was no further appeal in this case.

<sup>9</sup> Consumers in Action, Foundation Sustainable Chile and ODECU

<sup>10</sup> Appeal for protection "Consortium of *Consortium of Agricultural Societies of the South (CAS)* and Manuel Riesco Jaramillo versus the President of the Republic and the Health Ministry", ruled by the Court of Appeals and, in the second instance, by the Supreme Court, whose sentence confirmed the appealed sentence of 7 April 2003.

<sup>11</sup> Foundation Sustainable Societies, Association of Organic Framers in Chile (Tierra Viva) and the Austral Center for Environmental Rights.

<sup>12</sup> Basically: approved releases, names of enterprises, locations of plantations, kind of cultivation, modifications introduced, measures of biosafety demanded, among other data.

monitored themselves, and that it would ultimately hinder the SAG from making the safeguarding strategies effective in the case of accidental release.

In December 2001, the first instance ruled in favor of the demand, as the SAG did not present the legal justifications for confidentiality, and SAG was ordered to deliver the requested background information. However, this order was not followed, as afterwards the sentence was revoked by the Santiago Appeals Court<sup>13</sup> at the end of 2002. As the corresponding judicial procedure did not include the possibility of reaching the Supreme Court, the plaintiffs have continued their allegations before the Interamerican Human Rights Committee, quoting various paragraphs of the American Convention, although to this date, no resolution in this case has been taken.

## 1.4 - KEY CONCEPTS AND TERMS

### *Biosafety:*

- For the purposes of this report and the execution of the UNEP-GEF Project, biosafety was defined as the safe use of biotechnology, or the application of measures that contribute to a reduction or avoidance of risks (environmental as well as of public or animal health) associated with the biotechnological applications.
- It has been determined that this definition should be limited, so as to refer specifically to the safety of GMOs, of their commercial applications and of scientific research carried out with them.
- Any activities with living organisms which have not been object of genetic modification were excluded, but the use of GMOs for food as well as pharmaceutical purposes was included.

The concept of biosafety was not extended to bioterrorism (use of living organisms or biological agents for purposes of warfare)

### *Genetically Modified Organism (GMO):*

- GMO is considered a wider and more inclusive term, as it does not allude to the reproductive state of the organisms, nor does it necessarily imply the use of transgenes (i.e. stemming from species different from the one of the modified organism)
- In this report, it is used instead of "Living Modified Organism" (LMO) and as a synonym of "transgenic". There is no desire to highlight the difference between these terms, but, on the contrary, to simplify and unify the terminology of the document.
- Only when referring to "Living Modified Plant Organisms for Propagation" and to the "Aquatic Living Modified Organisms", and in the context of the Cartagena Protocol on Biosafety, the original terminology is maintained, as they are thus quoted in the corresponding national or international norm.

### *Traceability:*

- The term "traceability" is commonly used at the level of governmental institutions as well as enterprises, when referring to the documented follow-up of any kind of export product, from its source of production to its final destination.
- In Spanish, it is used indistinctively from "rastreadabilidad" although "traceability" is technically more correct and backed by the Codex Alimentarius.

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<sup>13</sup> Alleging that: "publicity and the right to request information that is not permanently available for the public is only applicable in the case of administrative acts and the documents which serve as their support or direct and essential complement, and not for any background information, in possession of the administration or of any administrative action or activity" (Santiago Appeals Court, December 2002).

## ..CHAPTER 2..

# THE CARTAGENA PROTOCOL ON BIOSAFETY

## THE CARTAGENA PROTOCOL ON BIOSAFETY

### 2.1 - INTERNATIONAL LEVEL

#### 2.1.1 CHILE IN THE CARTAGENA PROTOCOL NEGOTIATIONS

Chile is a State Party to the Convention on Biological Diversity since 1994 and has signed the Cartagena Protocol on Biosafety (Cartagena Protocol) in the year 2000, but not yet ratified it.

As Article 8 of the Convention stipulates the mandate to regulate biosafety, Chile started to work on the matter of biosafety in 1995. Since then, it has actively participated in the negotiations leading to the finalization and adoption of the text of the Cartagena Protocol. In the last round of negotiations, Chile formed part of the *Miami Group* together with Argentina, Australia, Canada, the United States and Uruguay, an alliance of the major producers of agricultural GMOs in the world, with the exception of Uruguay, which has shared systemic interest.

Since then, Chile has kept contact with member countries of the *Miami Group*, with the purpose of exchanging Protocol-related information and opinions, without any obligation to agree, prior to the official meetings or the convocation of work groups.

Chile has also participated in the three meetings of the Intergovernmental Committee for the Cartagena Protocol (ICCP) held between 2000 and 2002, in order to follow up on the advances of the Protocol's technical agenda. The participation of Chile in this Committee's work contributed to placing the most important issues for the Protocol's entry into force and application on the national agenda.

#### 2.1.2 CHILE IN THE FIRST MEETING OF THE PARTIES TO THE PROTOCOL

During the First Conference of the Parties, acting as Meeting of the Parties to the Protocol (COP/MOP-1), in February 2004 in Kuala Lumpur, Malaysia, Chile participated in the thematic meetings with a special interest to evaluate the convenience of ratifying this Agreement or not. The official delegation consisted of three representatives of the Ministry of Foreign Relations, two of the Ministry of Agriculture and two of CONAMA. The Environmental Department (*Dirección de Medio Ambiente - DIMA*) of the Ministry of Foreign Relations headed the national delegation. A Chilean NGO (*Fundación Sociedades Sustentables*) and academic researchers of the University of Chile also attended the COP/MOP-1.

The Chilean delegation had a lively participation in the discussion of financial issues, compliance of the Protocol (Article 34) and the needs to identify the LMOs which are subject to transboundary movements (Article 18). As to financing, Chile backed Mexico's insistence on the promotion and prioritization of the development of biosafety capacities in countries which are centers of origin of agriculturally significant species.

Among Chile's concerns about Article 18 was the need to avoid taking protective measures which would create unnecessary obstacles to trade, a key issue for an export-oriented country. In particular, in the discussion on the documentation that should be required for commodity goods upon entrance into a country, it was proposed to adapt the documents in use today so that they would collect the basic information required by the Protocol, without complicating its advance or hampering trade.

As to the regime of regulations for the Protocol, Chile, together with various other countries, defended the spirit of the Protocol to help the countries to comply, without applying sanctions. Among the arguments voiced against them was the impossibility to apply sanctions through the Protocol, considering international law and the existence of other international forums and mechanisms for the resolution of controversies, such as the World Trade Organization (WTO).

What was finally agreed upon in the COP/MOP-1 on these issues almost completely coincided with the Chilean wish<sup>14</sup> for a gradual implementation of the measures intended to facilitate compliance of the Protocol and of the interim measure to use and adapt the existing documentation for the identification of commercial LMOs.

### 2.1.3 CHILE IN THE SECOND MEETING OF THE PARTIES TO THE PROTOCOL

Chile participated as observing country, attending the Second Conference of the Parties acting as Meeting of the Parties (COP/MOP-2) as a Non-Party State. Unlike the COP/MOP-1, on this occasion the observing countries had the right to be heard only during the plenary sessions.

The official delegation was larger than for COP/MOP-1, with representatives of new agencies, such as the Ministry of the Economy and the National Forestry Corporation, in addition to the Public Services which traditionally have attended these meetings: Ministry of Foreign Affairs, Ministry of Agriculture and CONAMA. The delegation of Chile in this COP/MOP was chaired by the General Consul in Montreal. One NGO (*Fundación Sociedades Sustentables*) as well as one group of seed and pesticide producers also participated.

The delegation was interested in following the development of the discussions and learning about other countries' experiences in matters considered relevant for our country. Although not all formed part of the work agenda of the COP/MOP-2, it was opportune and convenient to exchange ideas with other countries on these subjects in order to know their degree of progress.

#### Topics followed by Chile during the COP/MOP-2:

- ART. 15 -- Risk Evaluation
- ART. 18 -- Manipulation, Transportation, Packaging and Identification.
- ART. 20 -- Center for Information Exchange.
  
- ART. 22 -- Capacity Building
- ART. 24 -- Non- State Parties
- ART. 27 -- Responsibility and Compensation
- ART. 34 -- Compliance

} Part of the topics addressed in Work Group I of COP/MOP-2

The majority of the Chilean delegation attended the sessions of Work Group I, but participated to a lesser degree in Work Group II - due to the high degree of interest aroused, in the first place, by the discussion of the details of Article 18(2) of the Protocol and the identification requirements that had to be defined; and only secondly by all aspects related to risk evaluation and risk management in the framework of the Protocol.

## 2.2 - NATIONAL LEVEL

### 2.2.1 THE ADVISORY COMMITTEE TO THE CARTAGENA PROTOCOL

The Government of Chile has a *National Advisory Committee on Matters of Biosafety*, created by Decree in November 2000, to advise CONAMA's Directive Council and the Ministry of Foreign Affairs in the drafting of positions on and proposals for the Cartagena Protocol. This Committee is formed by various Ministries and public bodies and is of a political nature; its objective is to define the country's position for international meetings, conduct a probable ratification of the Protocol and guide and prepare the foundations for a possible future application of the Protocol in Chile.

In 2005, the Committee met twice to deliberate on the ratification of the Protocol and the continuity of the work achieved by the UNEP-GEF Project for the development of a National Biosafety Framework. Likewise, it emphasized the need for a permanent participation in the meetings of the Protocol, especially in the Meetings of the Parties, even if only as observing country, since operative aspects of interest for Chile are

<sup>14</sup> The Chilean position did not fully coincide with the positions of the general population represented by the participating NGO, FSS-*Fundación Sociedades Sustentables*.

expected to be solved in this forum. Even though the deliberations and agreements of this Committee will be important at the time of judging the ratification of the Protocol, it has to be remembered that it still is an advisory body.

### 2.2.2 GOVERNMENTAL POSITION ON THE RATIFICATION

The Government of Chile is willing to ratify the Protocol, even though the agreement made to this date is to postpone this decision, considering that the best opportunity still has to be determined, and prior to that, some doubts have to be clarified on the effects of the Protocol's regulations on international trade, as well as advances made in the improvement and establishment of an internal regulatory framework on biosafety.

One of the main issues that have to be solved is the commercial restriction that could arise from the Cartagena Protocol, and specifically, their compatibility with a less restrictive approach of the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization. Therefore, the advances in this field are closely observed and it is expected that the Meeting of the Parties take a concrete decision on the interpretation and operability of Article 18 of the Protocol.

On the other hand, as the implementation of the Protocol requires an adequate legal and administrative foundation, the decision on the ratification of the Protocol is closely linked to the Law on Biosafety presented before the National Congress, which has been formulated by the Government and will be exposed further on.

Given the complex nature of the topic, various representatives of public institutions consider it to be convenient that the ratification of the Protocol be a prerogative of the National Congress.

The ratification of the Cartagena Protocol partly depends on the presentation of the draft Bill of Law on Biosafety by the President to Parliament and the previous clarification of trade questions arising from the Protocol.

### 2.2.3 OPINIONS OF OTHER SECTORS ON THE RATIFICATION

Among the members of the CNC of the UNEP-GEF Project, only the civil society, represented by the Fundación Sociedades Sustentables (FSS - *Foundation for Sustainable Societies*) which coordinates the *Network for a GMO-free Chile* wished to express itself on the ratification of the Cartagena Protocol. Thus, the following statements only reflects the view of this particular NGO.

*The Chilean civil society organized in the Network for a GMO-free Chile believes that it is of fundamental importance for the country to ratify the Cartagena Protocol, in order to offer a greater (though not complete) protection of public health and biodiversity. To ratify it would mean to recognize that GMOs are inherently different from conventional products, that their release implies risks for biodiversity and human health, and that it could cause socioeconomic impacts.*

*The precautionary principle is the central axis of this Protocol, as it allows imports of GMOs only upon explicit approval of the importing country, and rejects these imports in absence of sufficient scientific evidence on their risks and because it considers that they could have a negative impact on the environment or human health, or because of socioeconomic considerations. In the case of accidents or negligence, the Protocol provides a system of responsibilities which has to be negotiated to effectively protect the country from negligence; additionally, this legislation protects against possible conflicts with other countries before the WTO at the moment of rejecting a shipment.*

*Chile's position towards the Cartagena Protocol has proved to be very pro-trade and with little regard for the protection of consumers and the country's valuable and unique biodiversity. The negotiators have not taken into consideration that the country is a major importer of GMO food (corn and soybean from the USA and Argentina) which enters unidentified and could contain*

*dangerous ingredients prohibited in other countries, denying consumers their right to know what they consume. Therefore, it is essential that Chile support a clear and precise identification of the shipments, which would allow placing the burden of evidence on the exporting instead of the importing country.*

*In conclusion, the Network for a GMO-free Chile supports the ratification of the Protocol by Chile, in order to be able to negotiate key elements for the protection of society and biodiversity, from a perspective of non-alignment with the industry of biotechnology and GMO-producing countries.*

## **..CHAPTER 3..**

# **GOVERNMENT POLICY ON BIOTECHNOLOGY**

## GOVERNMENT POLICY ON BIOTECHNOLOGY

### 3.1 - BACKGROUND

Chile does not have a specific biosafety policy, but deals with this issue in the framework of a broader biotechnology policy in force since November 2003, which tackles matters referring to the promotion and strengthening of biotechnology as well as its control and safe use, in order to offer safety and protection as well as incentives for the application of this technology in the country. It addresses diverse topics, including entrepreneurial development, training of human resources, intellectual property, bioethics, biosafety regulations, institutionality, public opinion, among others.

To define this policy, the CNDB (*Comisión Nacional para el Desarrollo de la Biotecnología* - National Committee for the Development of Biotechnology) was created by presidential mandate in July 2002, with the task of drafting a report containing proposals for public or private actions for the creation and/or consolidation of a policy for the development of biotechnology in the country. On the basis of this report, handed over to the President in June 2003, the Government held consultation meetings with MPs and experts, and after having fine-tuned the CNDN's recommendations, a *National Policy for the Development of Biotechnology* was formulated.

This process occurred parallel to the activities of the UNEP-GEF Project, and for this reason the Biotechnology Policy cannot be included among the results of this Project.

Nevertheless, the Government of Chile considers that this political framework will represent the main component of the future "National Biosafety Framework" of the country, a vision supported by the private and academic sectors represented in the CNC of the UNEP-GEF Project.

On the other hand, the NGOs represented in the CNC reject the Biotechnology Policy, because of its objectives (promotion of biotechnology) and the circumstances of its drafting process (as they were not invited to participate in the CNDB); as a result, they do not agree with the motion to build the future National Framework for Biosafety on the basis of this Policy.

The Biotechnology Policy, whose time horizon reaches until the year 2010, establishes a main goal, 4 specific objectives and 23 concrete actions. It contains an Action Plan prioritizing short-term actions (2004/2005). Although this Policy covers a range of short-term actions, we will here only summarize the proposals relating to biosafety.

For a more detailed description of the Biotechnology Policy, please visit [www.bioseguridadchile.cl](http://www.bioseguridadchile.cl) or [www.economia.cl](http://www.economia.cl)

### 3.2 - OBJECTIVES

#### 3.2.1 GOAL

*"Promoting development and the application of biotechnology in Chile, especially in the productive sectors depending on natural resources, with the purpose of enhancing the well-being and quality of life of all Chileans and contributing to the generation of national wealth, guaranteeing the protection of health and environmental sustainability." (CNDB, 2003).*

### 3.2.2 SPECIFIC OBJECTIVES

1. *Private sector development*: Strengthening the development of the national biotechnology industry and promoting the incorporation of biotechnological processes into the different productive sectors, especially producers based on natural resources.

2. *Building of scientific-technological capacities and training of human resources*: Generation and strengthening of scientific, technological, management and infrastructure capacities, as well as training of human resources in strategic areas for the country.

3. *Creation of a regulatory framework*: Establishing a regulatory framework that guarantees a safe, sustainable and responsible development of biotechnology in the country.

4. *Public institution-building and public participation*: Design and operation of an institutional framework that ensures close coordination between institutions in charge of the regulation of biotechnology, and the opening of spaces of participation and public information allowing for the development of informed public opinion.

### 3.3 - BIOSAFETY ACTIONS

Various of the actions contained in the Biotechnology Policy not only address themes important for biosafety, but also coincide with the approach and the objectives of the Cartagena Protocol, so that its implementation would allow the fulfillment of many requirements of this international agreement.

As a positive effect, through its Biotechnology Policy Chile would be trying to strike a balance between control and promotion of biotechnology, placing emphasis on the advantages and opportunities offered by this technology, but recognizing the importance of biosafety and the need to take protective measures. It would definitely indicate that the country would be advancing in a favorable direction for the future adoption of the Cartagena Protocol.

Of the 23 actions contained in the Biotechnology Policy, 11 aim to a greater or lesser degree at biosafety or its better understanding and participation in it. Following is a list of these actions according to the order in which they appear in the Policy:

- Action 11: Training of biosafety capacities in public institutions*
  - Action 12: Regulation of the procedure for the authorization of GMOs for human consumption*
  - Action 13: Regulation of the labeling of GMO food*
  - Action 14: Establishment of a regulated procedure to establish the requirements for cultivation, breeding and use of GMOs, their distribution and processing in the country*
  - Action 15: Definition of a strategy for the establishment of a system for the certification of GMO products for export, including mechanisms of traceability*
  - Action 16: Promoting a Proposal for a Framework Law on Biotechnology*
  - Action 19: Modification of the General Law on the Environment, establishment of responsibilities for environmental damages and crimes resulting from genetic contamination*
  - Action 20: Achievement of a national decision on the ratification of the Cartagena Protocol on Biosafety*
  - Action 21: Creation of the Committee on Biotechnological Regulations*
  - Action 22: Creation of the Biotechnology Forum*
  - Action 23: Strengthening and encouragement of existing public programs for scientific-technological dissemination and education in the country*
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### 3.4 - IMPLEMENTATION OF THE BIOTECHNOLOGY POLICY

#### 3.4.1 NORMATIVE STRATEGY

According to the Biotechnology Policy, Chile should develop a complete and coherent regulatory framework for biotechnology with the purpose of guaranteeing biosafety, i.e., an adequate protection of human health as well as the environment through the establishment of clear rules which will facilitate the development of activities or business linked to biotechnology, as well as an adequate evaluation of these activities, the strengthening of technical capacities and the monitoring of the responsible institutions and the right to information for consumers and the general public. This is proof of the prioritization of biosafety by the Government, as a prerequisite to allow the take-off of biotechnology in the country.

To this end, the Policy proposes the following normative strategy:

- As an immediate action, the use of the *already existing laws* related to the field of biotechnology, in order to act according to regulations and advance with urgent tasks (such as the sanitary approval of GMO food - Action 12 - and the procedure for the authorization of GMO-crops - Action 14).
- Simultaneously, the drafting of a *Framework Law on Biotechnology*, which will address the topic as a whole; the bill has to be debated in National Congress.
- Pressing for these changes through the creation of the *Committee of Biotechnology Regulations*.

#### 3.4.2 PRIORITIES: ACTION PLAN 2004/2005

The Policy's Action Plan 2004/2005 highlights the initiatives that are considered more representative and crucial to put in motion a national biotechnology effort, and identifies the institutions responsible for their accomplishment, and establishes corresponding deadlines.

The prioritized actions to be implemented before the end of 2005 are related to the regulatory framework, institutionality and public participation, with an emphasis on: (i) regulation of the most urgent elements for a safe application of biotechnology; (ii) creation of new spaces of coordination, discussion and participation, and (iii) the drafting of a comprehensive regulation to unify these aspects.

These priority actions can be summarized as follows:

##### Institutionality and Public Participation:

1. *Committee for Biotechnology Regulations*: achievement of a Supreme Decree to constitute the Committee and its Executive Direction
2. *Biotechnology Forum*: achievement of a Decree to constitute the Biotechnology Forum

##### Regulatory Framework:

3. *Framework Law on Biotechnology*: Drafting of a Bill of Law and its presentation before Congress
4. *Sanitary regulation for the authorization of biotechnological events in food*: modification of the Sanitary Regulations for Food and establishment of modalities for the approval of food derived from biotechnology.
5. *Farming regulations to authorize the cultivation of GMOs in the country*: Promulgation of a regulation that complements the current norm in order to authorize the cultivation of GMOs and allows their use and distribution in the country.

#### 3.4.3 IMPLEMENTATION OF AND FOLLOW-UP ON THE BIOTECHNOLOGY POLICY

No agreement was reached within the CNC of the UNEP-GEF Project, nor with the Ministry of the Economy, on whether the UNEP-GEF Project could, or should, take charge of the biosafety actions contained in the Biotechnology Policy, or of their follow-up, mainly because it was not endorsed by the NGOs represented in the CNC.

Consequently, the implementation of these actions did not become a Project task. However, the fact that

the Biotechnology Policy did turn into a political mandate for the Ministries and public services with a role in national biosafety to offer an action framework to guide these institutions' current and future lines of work on biosafety. In spite of the progress made during the period 2003-2005 in the execution of these actions, no detailed description of their state of implementation will be given in this report, but only short indications on the regulatory actions of the highest priority.

- **DRAFT BILL OF LAW:**

Since the approval of the Biotechnology Policy, the Government of Chile has progressed in the drafting of a bill of law which has been the fruit of coordinated work of public agencies linked to biosafety and biotechnology. This effort was started at the beginning of the year 2004 with the creation of the *Committee for Biotechnology Regulations*. The bill of law has advanced to the point of now lying before the General Ministry Secretariat of the Presidency, a body in charge of, among other functions, determining, coordinating and pressing the legislative agenda of the Executive Power. The bill has not yet been presented to Congress.

It has to be mentioned that the bill of law has changed its intention, limiting its range of application exclusively to the safety of biotechnology<sup>15</sup>, a fact also reflected by its present title: *Bill of Law on Biosafety of Genetically Modified Organisms*.

- **NORM ON FOOD:**

At present, there is a proposal for a norm developed by the Health Ministry that shall be presented to *the Committee for Regulations on Biotechnology* for its consideration

### 3.5 -POLICY RECOMMENDATIONS

The Biotechnology Policy states that a target of a part of the country's business sector should be the incorporation of new biotechnological applications into its productive systems, with GMOs being one of the available options. This scenario would be promoted with the development of new norms lifting the current restrictions of the local production of GMOs to GMO-seeds exclusively.

This new willingness to authorize commercial production and internal consumption of GMOs brings new demands and challenges, not only for the authorities and their biosafety management capacities (which will be commented further on), but also in the definition of the country's priorities and needs in the field of biotechnological development, and especially in the use of GMOs in the national production.

To emphasize some fields in this new scenario:

The National Coordinator of the UNEP-GEF Project of Chile believes that the promotion of biotechnology and the use of GMOs in the country entails the need for a broader and stronger dialogue between the productive sector, the scientific world and the Government, in order to harmonize priorities and options that integrate the country's economic development, scientific interest and the conservation of the natural heritage.

From this perspective, the National Coordinator recommends:

1. That the promotion of biotechnology, an issue to be considered in the future in conformity with the regulations proposed by new bodies such as the Committee for Biotechnology Regulations and the Biotechnology Forum, is not only channeled towards areas for farming, silviculture and aquaculture and with a focus on GMOs, which are commercial species introduced from outside, but also towards the approval of native genetic resources, without necessarily resorting to transgenesis. In the pursuit of biotechnological solutions, our own genetic heritage can be studied and appreciated and serve as a basis for the development of commercial or industrial products.

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<sup>15</sup> Prior to that, it was planned to include topics such as the promotion of biotechnology, research on biodiversity (access to genetic resources), intellectual property and agricultural co-existence, among other topics in connection with the take-off of biotechnology in the country.

2. That the productive sector as well as the academic world establish inter-sector spaces for the discussion of the biotechnological development of the country according to their interest, in order to generate their own strategies or positions and share them with government authorities and/or civil society. This would promote an exchange of different visions of themes such as agricultural coexistence, responsibility and fulfillment of standards, research and development, biosafety, and others.

## ..CHAPTER 4..

### BIOSAFETY REGULATIONS

## ..4.. BIOSAFETY REGIME

### 4.1 - CURRENT SITUATION<sup>16</sup>

To evaluate the institutionality and norms currently in force for GMOs and biotechnology, under the perspective of the Cartagena Protocol, including their relation with trade agreements signed by Chile, the UNEP-GEF Project carried out a study, through the University of Chile, titled "Assessment of the regulatory frameworks, institutionality and national trade obligations in relation with the Cartagena Protocol and mechanisms for public participation for environmental decision-making " (CDA, 2004).

For this Chapter, information was extracted from the study and complemented with the description of the regulations applicable to Aquatic GMOs, contained in "Assessment on the development, use and control of aquatic genetically modified organisms" (Díaz & Bermúdez, 2004).

Both studies are available at the site [www.bioseguridadchile.cl](http://www.bioseguridadchile.cl)

From a strictly normative point of view, the regime of national regulations on biosafety presently in force in Chile is characterized by a high degree of sectorization, with multiple authorities and institutions intervening in different ways in the matter, exercising political as well as normative and inspection authority; it is possible to find a significant number of institutions dedicated to carrying out and promoting research in the field of biotechnology.

The judicial regulations follow the same pattern, in the sense that there are no legal norms referring to biosafety directly or specifically or in connection with other matters. There is only a series of administrative norms, dictated by these authorities strictly for application in their own realms and, thus, for specific aspects.

For a complete description of the institutions intervening in matters of biosafety and/or biotechnology, please consult Annex 3. A summary of the key existing norms and institutions implicated in biosafety will be presented below.

#### 4.1.1 BIOSAFETY REGULATIONS

In the matter of GMOs, there are specific (and sectorial) norms as well as norms contained in general dispositions, as for example, in the case of the Law on Fishing. The Resolutions of the Livestock and Agricultural Service (SAG), the main state actor in the matter of biosafety, constitute the only specific norms on GMOs, the most important ones being Resolution N° 1523 (2001) and N° 3136 (1999). In change, the general dispositions containing any article referring to GMOs are those related to human health, aquaculture and the evaluation of the environmental impacts. Ultimately, the only control of GMO research and development activities is through compliance with a voluntary norm.

##### *Specific norms*

The four most important administrative dispositions for the regulation of some GMO aspects were dictated by the SAG exclusively for the farming sector and are consequently of a very limited scope.

##### *1). SAG Resolution N° 1523/2001: establishes norms for the introduction of living modified plants for propagation*

This norm establishes procedures for the entry and introduction into the environment of plant GMOs for propagation. It specifies that all living modified plants (LMPs) introduced into the country have to be duly identified and authorized, and that their cultivation is only permitted for the purpose of seed multiplication,

<sup>16</sup> For the description of this regulatory framework, the report " Legal aspects of the Safety of Modern Biotechnology " by CDA-FIELD (2002) was used, in addition to the studies of the UNEP-GEF Project quoted in the table.

after a risk assessment and applying biosafety measures, for subsequent re-export.

The resolutions authorizing introductions and release into the environment are issued on a case-by-case basis and establish the biosafety measures to which the authorized GMO shall have to be submitted, as well as the final destination of the GMO and of its products. No other kind of genetically modified crops have been regulated or authorized for any other uses, neither for the forestry sector, nor have norms been dictated for the use or production of genetically modified animals.

*2). SAG Resolution N° 3136/1999: Establishes general biosafety norms for biotechnological pharmaceutical products containing GMOs*

Establishes general and special biosafety norms for pharmaceutical products for veterinary use, developed through biotechnological processes and containing GMOs. For example, it indicates that the recipe for these products shall be withheld and that they have to carry a label indicating their biotechnological origin in addition to the warning to notify the veterinarian of any negative effect on the health of the animal.

*3). SAG Resolution N° 2004/2000: Establishes an Advisory Committee and Technical Secretariat in the matter of deliberate introduction of GMOs into the environment.*

The main function of these bodies (the Advisory Committee and the Technical Secretariat) is to advise the National Director of the SAG to help take informed decisions on matters related to LMPs, and they are fully involved in the processes of risk assessment.

*4). SAG Resolution N° 3970/1997: Authorizes corn that has been genetically modified for resistance to insects (BT), Glufosinate ammonium (Basta) or glyphosate (Roundup) for animal consumption.*

This is the only norm on the use of genetically modified material in animal food. It authorizes animal consumption of grains of corn with a genetic modification to make it resistant to certain herbicides (Roundup and Basta) and lepidoptera (BT). Its only purpose was to authorize animal consumption of these grains of GMO-corn as a measure to destroy remnants.

In summary, the only specific biosafety norms are intended for the farming sector and are issued by the Livestock and Agricultural Service (SAG), an agency of the Ministry of Agriculture.

It is the SAG that, with the advice of subsidiary bodies, evaluates, authorizes and monitors the cultivation of plant GMOs, i.e. their release into the environment, as well as pharmaceutical products for veterinary use containing GMOs, and the use of remains of GMO crops for animal use. In the future, it would also fall to the SAG to regulate GMO livestock, though no specific norm exists yet for this purpose.

*Norms in General Dispositions*

*A). SubPesca Supreme Decree N°320/2001: Environmental regulation for Aquaculture (RAMA)*

One of the articles of this Supreme Decree issued by the Ministry of the Economy, of which the Subsecretariat for Fishing is a division, prohibits the release of living aquatic GMOs into the water. It also establishes that cultivations of these organisms require the explicit authorization of the Subsecretariat for Fishing, but does not establish a procedure for the use of GMOs in aquaculture.

In summary, the Subsecretariat for Fishing (SubPesca), as the agency in charge of implementing the Environmental Regulations for Aquaculture, has the faculties to regulate, evaluate and authorize the use of Living Modified Aquatic Organisms in the country (be they aquatic plants or animals), although at present these types of GMOs are not being used for productive purposes, nor for sale anywhere in Chile. However, should they be at any time, RAMA would require a previous authorization by SubPesca for their cultivation and local production.

*B). MinSalud Supreme Decree N° 977/1996: Food Health Regulations*

To this date, no GMO food has been approved for human consumption in the country, as the technical norms

required for this have not been dictated yet. Once in force, these norms would be based on Article 3 of the Sanitary Regulations for Food, which indicates that food and its inputs and derivatives modified through biotechnology have to appear in a register required by the Health Ministry. Furthermore, it establishes a procedure for the labeling of these food items in case it is needed for nutritional reasons.

During the preparation of this report, the Ministry of Health was defining the procedure according to Article 3 of the Sanitary Regulations for Food, which would allow a risk assessment and the sanitary approval of "biotechnological events"<sup>17</sup> to be used in food for human consumption, as well as the regulation of the labeling of GMO food products. The requirement of labels would only apply if these had different nutritional qualities or characteristics from traditional products, in conformity with the principle of "substantial equivalence".

*C). Min.SegPres Supreme Decree N° 95/2001: Regulations for the System of Environmental Impact Evaluation*

This Regulation originates from the General Law on the Environment (Law N° 19.300), which has also been the basis for the constitution of the National Environmental Committee (CONAMA) as the national environmental authority, subordinated to the Ministry General Secretariat of the Presidency (Min.SegPres).

This Regulation identifies the categories of projects and activities (mainly productive and industrial) which are susceptible to being evaluated for their environmental impact, and thus to enter the System of Environmental Impact Assessment (SEIA - Article 3). In none of these categories the existence of GMOs in the project appears as a condition to enter the System. Article 6 of the Regulation indicates that one of 17 criteria defining whether the organization implementing the project has to present an Environmental Impact Study (an extensive document on risk assessment) or a Declaration (the procedures for the latter being simpler and shorter) is the introduction of GMOs into the environment. I.e., the existence of GMOs in the project only defines the route the project takes within the System of Environmental Impact Assessment, not whether it enters or not into the System.

Thus, the introduction of GMOs is not a sufficient reason for a project or activity to enter the SEIA and, therefore, the environmental impact of GMOs is not regulated nor evaluated through this regulation, but through the one applied by the SAG. In fact, agricultural and forest cultivation do not constitute activities qualifying for the SEIA, as opposed to cellulose production, mining industry, aquaculture and agroindustry (yeast, poultry and pigs).

In short, as to GMOs, the SEIA Regulations establish that investment projects comprised in certain categories and including the use of GMOs have to present a Study, not a Declaration, on Environmental Impacts, which has to be analyzed and resolved by CONAMA, be it at the national level (Directive Council) or the regional level (the COREMAS).

*Voluntary norm*

The National Science and Technology Committee (CONICYT) is governmental body which allocates funds to projects related to biotechnology, among other areas of national Research and Development (R+D), and which watches over the application of good scientific practices by the national academic and research institutes. As such, it worked out a "Manual for Biosafety Norms", including voluntary technical norms for laboratories and for the intentional release of genetically modified organisms into the environment.

Even though this Manual is a voluntary norm, it is known and respected by all researchers applying to the CONICYT for funds, who upon presentation of their projects they have to declare that they know and observe these norms.

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<sup>17</sup> The approval of "events" (i.e., specific GMOs) and not "GMO foods" means that the presence of an "event" (in any proportion and even occasionally) in any kind of food, processed or not, will be allowed in the country, as long as this event has obtained the authorization by the Ministry of Health and is incorporated into its register of approval

#### 4.1.2 CHILE'S INTERNATIONAL COMMITMENTS

The national regulatory regime also consists of all those international instruments ratified by Chile and trade agreements signed with other countries which include environmental concerns. Following are the most important ones:

a. Convention on Biological Diversity

Promulgated in Chile by Supreme Decree N°1963 of 1994 by the Ministry of Foreign Affairs. At present, Chile is undertaking a series of actions planned in the context of a National Biodiversity Strategy, formulated precisely in order to effectively implement the measures and achieve the aims of the Convention.

Particularly important in relation to biosafety is Paragraph 3 of Article 19 of the Convention, which establishes the release of information among State Parties interchanging GMOs, in order to contribute to a higher degree of safety in the management of GMOs.

b. Agreements of the World Trade Organization

Chile has been a member of the World Trade Organization (WTO) since 1995. Consequently, and since the WTO and its Agreements on SPM and TTB have recognized the norms and recommendations of the Codex Alimentarius and the World Organization for Animal Health as norms of reference, these are applied and continue to be parameters and guidelines for different internal purposes.

c. Political and Economic Association Agreement between the European Union and Chile This

Agreement has been fully in force since February 2005, adding political and cooperation aspects to the commercial regulations in force since February 2003. It contains only a marginal relation to biosafety, as no explicit reference is made to it nor to GMOs; they are even explicitly excluded from the initial application of the Agreement. Nevertheless, this instrument can be definitely applied to events related to the trade or use of GMOs.

d. Free Trade Agreement with the United States

Approved by National Congress, the Free Trade Agreement between Chile and the United States of America (FTA) was published in the Official Gazette on 31 December 2003 and entered into force on 1 January 2004. The State of Chile now has to make certain legal decisions in order to adapt its legislation to the requirements of the Treaty. As to environmental matters, the Parties manifest their decision to apply the Treaty in such terms that environmental protection is guaranteed, and each Party's right to fix its own level of environmental protection is recognized, always promoting high levels of protection. Both Parties commit to fulfilling the current environmental legislation, which makes monitoring and control particularly relevant.

e. International Treaty on Phytogenetic Ressources for Food and Agriculture of the FAO

Although it is not a State Party, Chile signed this Treaty of the United Nations Organization for Food and Agriculture (FAO) in November 2002 and is currently studying its ratification. The Treaty addresses conservation and sustainable use of phylogenetic resources for food and agriculture (specifically of 64 food and forage crops). It tries to establish an efficient, effective and transparent multilateral system to facilitate the access and just and equal distribution of benefits derived from their use, based on the Normalized Agreement on Transfer of Materials currently under negotiation.

#### 4.2 - CRITICAL REVIEW OF THE CURRENT NATIONAL REGULATIONS

The contents of this section fundamentally follow the analysis made in the book "*Legal Aspects of the Safety of Modern Biotechnology in Chile*" (CDA-FIELD, 2002), in addition to the study of the UNEP-GEF Project mentioned in the previous section (CDA, 2004). It does not reflect the opinion of all public or private agents forming the CNC of the UNEP-GEF Project, but the opinion of external experts.

*The regulatory framework described just about satisfies the need for an adequate, uniform, harmonious and efficient ordering of GMO-related activities. In fact, although several provisions can be recognized, the formulas established until now by the ordering are mostly of a sectorial,*

*administrative and regulatory character, many times arising as "reactive" legislation for the solution of punctual problems. This lack of systematization produces a sensitive scenario with a high level of administrative discretionality and a certain degree of judicial uncertainty. This means that there is no clear regulation for biosafety, or, in the widest sense, for biotechnology.*

*The norms which address the topic of GMOs directly and comprehensively are exclusively related to agricultural and livestock production. In other sectors, such as aquaculture, human health and environment, it is only possible to find provisions included inorganically and isolated from more general norms.*

*Consequently, GMO regulations only have a specific scope, limited to certain areas, which is also a result of the fact that they are dictated by different administrative authorities with normative competence. And this leads to an evident lack of coordination among them. As a consequence, this current regulatory framework is **not only insufficient to comply with the Cartagena Protocol, but to face the challenges of biotechnological progress in general.***

- The norms and provisions on biosafety generally do not reach beyond the administrative realm, which generates a certain degree of judicial instability, because they are stipulations which, in a concrete case, can lose their validity faster than those stemming from proper laws. This should be no impediment to dictate, with due competence and within the pertaining attributions, specific resolutions to cover special situations which are not sufficiently addressed by the law and which could require an immediate and ad hoc solution.*
- The current norm does not apply to all sectors; the farming sector is clearly predominant, which evidently leaves important voids. The reason is that most of the development of biotechnology has taken place in this field. There are other productive sectors interested in the application of this technology, either because they intend to use it or because they want to have guarantees that their use will happen under adequate protective measures. One sector which is presenting clear deficits in this sense is the forestry sector, where biotechnological research achieved shows that in little time regulations on biotechnology will become necessary.*
- Not all types of GMOs are regulated, nor all phases of development of one and the same GMO. In fact, the activities planned until now are those which have a practical application, due to the interest of dictating norms that are urgently necessary, without considering future projections. As a result, a legal void opens up in the field of microorganisms, ruled by no particular authority with clear competences, as in the case of GMO-related scientific activities.*
- The assessments have also revealed the absence of specific legal stipulations on liabilities for damages to the environment caused by GMOs.*

Even though the issue of responsibility remains complex and unsolved at the international level, there seems to be a trend towards the approval of regimes of objective responsibility, whereby, among other advantages, the presentation of evidence becomes easier for the affected parties. Due to its general character, the Chilean General Law on the Environment offers a system of subjective responsibility, which in "genetic" cases considerably hampers the efficiency of the system, as the affected parties will have to document the damage, guilt or deceit or the cause-effect relationship between fact and damage.

- Another significant weakness of the current system is the high number of intervening authorities, exercising different faculties with diverse competences on biosafety matters. In fact, more than 10 authorities are involved, to a higher or lesser degree, in themes related to biotechnology; however, the political, normative and inspection competences do not converge but, on the contrary, are dissociated from each other. And as each of these competences are instituted in more than one authority<sup>18</sup>, there is a tendency towards a lack of coordination inside as well as among the corresponding institutions. There is no single authority<sup>18</sup> with the role of a guardian, but there are various, each acting from the perspective of its respective sector.*

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<sup>18</sup> (Min.SegPres). Meanwhile, normative and/or monitoring faculties belong to agencies such as the Livestock and Agricultural Service (SAG), the Ministerial Regional Services, the Customs Service, the National Fishing Service and the Institute of Public Health.

In the past, the CNDB made a similar assessment during the development of the Biotechnology Policy, and came to the conclusion that it was necessary to modernize the regulatory framework for silviculture and aquaculture, in order to allow the expansion of the commercial use of GMOs, as the current regulations did not offer favorable conditions for this objective. The solution finally formulated in the Biotechnology Policy, as has already been mentioned in the previous chapter, consists in the creation of a Law to address biosafety in a comprehensive manner.

### 4.3 - PROPOSALS CURRENTLY IN PREPARATION

#### 4.3.1 DRAFT BILL OF LAW ON BIOSAFETY

In conformity with the Biotechnology Policy<sup>19</sup> and as has previously been pointed out, a bill of law is currently being studied to unify the regulations on the safety conditions of GMO-related activities. It is called the Bill of Law on the Biosafety of GMOs and its last draft dates from June 2005.

After sending the draft to the main Ministries involved in its preparation, it is now in the Ministry General Secretariat of the Presidency, which means it is still being discussed internally in the Government.

This bill of law was prepared by the Ministry of the Economy, with the participation of diverse other Ministries. Its aim is to complement and complete the legal attributions of the sector institutions, so that all would share a legal basis which allows them to develop norms to guarantee the biosafety of future biotechnological activities.

It would establish a coordinated authorization procedure for activities involving GMOs, which would allow the institutions to proceed in a coordinated manner before their authorization.

A general description of the structure, range and contents of this bill can be found in Annex 4.

It is expected that this norm, once in force, will be complemented more specifically by regulations dictated by the President of the Republic in exercise of her regulatory powers, as well as by a series of sectorial regulations.

The bill has not yet been made available to the CNC of the UNEP-GEF Project, nor to the public or to non-governmental sectors in general, and its contents cannot be presented in this report. Its revelation is subject to a pending decision by the Min.SegPres on whether to submit it to public consultation prior to sending it to Congress.

Parallel to this, there is an agreement between CONAMA, the Ministry of the Economy and the CNC of the UNEP-GEF Project to make a formal consultation with the CNC prior to the parliamentary steps, in order to allow this multi-sector entity to give diverse actors involved in biosafety the opportunity to review the bill and issue their judgment on it. Even if this consultation is not yet taking place, and the UNEP-GEF Project is soon to be finalized, it is expected that the members of the CNC will be consulted before the bill is sent to National Congress.

There is a high level of discontent among the NGOs represented in the CNC of the UNEP-GEF Project on the fact that the procedure in which the bill was drafted did not include the participation of civil society or the CNC.

The representatives of the private sector equally consider that this report should not deepen on the bill, as the UNEP-GEF Project did not participate in its preparation, nor has any information of it reached the CNC.

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<sup>19</sup> Regarding the effect a new law, the Biotechnology Policy states: "...The approval of a Framework Law has become necessary, as it represents a new theme for society, with wide repercussions in essential aspects for the personal and social life of humans, which deserves a debate at the highest possible level of civil representation. On the other hand, a Law will make it possible to cover regulatory voids and will be an efficient means of achieving the necessary normative coherence."

In contrast, a consultation process has started on the proposal for a technical norm on GMO food, which has been presented to representatives of both sectors (though not to the CNC).

#### 4.3.2 PROPOSAL FOR A TECHNICAL NORM FOR THE AUTHORIZATION OF BIOTECH-FOOD PRODUCTS

Another norm being currently studied is this technical norm requested by the RSA, explained in the previous chapter. It consists of a Decree, whose objective it is to provide the necessary guidelines for the evaluation of biotechnological events which modify food (or nutritional primary materials) for human consumption, including a register of approved events kept by the Health Ministry in conformity with Article 3 of the RSA. Its content consists basically of an approval procedure and risk assessment.

Preliminary texts of this decree were submitted during the year 2004 to bilateral consultations with interested sectors, and the opinion of the stakeholders who are mainly affected or benefited by this future regulation was gathered. The decree could be promulgated once it is approved by the *Committee on Biotechnology Regulations* and signed by the Health Ministry.

### 4.4 -RECOMMENDATIONS FOR FUTURE LEGISLATION

To formulate the recommendations of the CNC of the UNEP-GEF Project described below, it had to be assumed that the above mentioned bill would solve most of the diagnosed regulatory flaws. Another assumption was that it would faithfully observe the principles and purposes stipulated in the Biotechnology Policy<sup>20</sup>, although not necessarily the same fields of action, and that, through this law and in conformity with the political mandate, a Committee on Regulations and the Biotechnology Forum would be created as new entities of political coordination and public participation, respectively.

It could also be assumed that the bill would establish the guiding principles and necessary norms to guarantee a regulatory consistency; but nevertheless, recommendations were formulated on the judicial and political aspects considered to be the most important ones: the core aspects of the Cartagena Protocol and the most critical factors to reach the desired harmonization and coordination in the different institutions linked to the development of biotechnology.

The bases for the formulation of these recommendations and considerations can be summarized as follows:

#### The Future Law on Biosafety:

1. Should cover all kinds of GMOs and regulate all GMO-related activities
2. Should base all decision-making and authorizations on a case-by-case risk assessment
3. Should create a new governmental institutional framework around biosafety for the political as well as administrative coordination
4. Should maintain the sectorial model currently operating for the decision-making on GMOs, without modifying existing authorities or areas of competence
5. Should build a national system of information on GMOs existing in Chile
6. Should formalize new instances and mechanisms of public participation
7. Should establish a national system of coordinated GMO-authorization with a "one-stop shop procedure" to minimize bureaucracy

#### CNC RECOMMENDATIONS

It is a consensus within the CNC of the UNEP-GEF Project that the Bill of Law on Biosafety or any future legislation on biosafety should:

1. Be compatible in all its objectives, ranges, processes, terms and deadlines with the Cartagena Protocol.
2. Propose the most adequate institutional framework, in order to achieve an optimization of the authorization procedures for more cost-efficiency through intra- and inter-institutional coordination and

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<sup>20</sup> This policy states that one of the objectives of the Law would be "to tackle the themes related to development and safety of modern biotechnology, ensuring the administrative coordination between the authorities and complementing their capacities".

communication.

3. Should regulate the scientific activity on GMOs (R+D) in order to effectively monitor, instead of controlling it.
4. Clearly resolve which institutions shall have competences regarding GMO-microorganisms and establish a regulatory regime for these, considering the difference between their confined use and their release into the environment.
5. Allow public participation in decision-making on GMOs.
6. Grant the authorities the necessary discretionality to manage information on the location of GMO-cultivations (plant or animal) and plantations in order to facilitate the development of other agricultural, forestry or bee-keeping activities.
7. Create a system of centralized information management on GMOs for the entire region, based on a platform offered by internet which allows a speedy access for the general population and could be linked to the "Biosafety Clearing House " (BCH) of the Cartagena Protocol.
8. Create mechanisms to revise decisions taken and authorizations conceded in the light of new scientific, technical or commercial evidence or of new local factors relevant for the decision.

The following recommendations by the CNC were not approved by the FSS, which, among other NGOs, represents the civil society of Chile in the CNC:

9. Provide labels with nutritional information on GMO-food or derivatives.
10. Grant public access to all information related to decisions taken regarding the use of specific GMOs in the country.
11. Set higher biosafety requirements for new GMOs in the country, in conformity with the precautionary criteria applied today by the SAG on GMO plants.

It is the majority opinion of the CNC of the UNEP-GEF Project that:

1. Congress should be presented the Bill of Law on Biosafety as soon as possible, after a previous process of public participation and consultation.
2. The Technical Norms for the evaluation and authorization of the use of biotechnological *events* in food for human consumption should be promulgated as soon as possible.

The majority opinion<sup>21</sup> of the CNC of the UNEP-GEF Project is that, in addition to including the precautionary principle, the central axis of the Bill of Law on Biosafety or any other future legislation on the matter of biosafety should be the operability and integrity of the system of coordinated authorization.

The main challenge of a new biosafety legislation will be the operation of an integrated and comprehensive system of decision-making, based on the characterization of risks and benefits of each GMO in diverse scenarios of use, as in each single case different institutions will have to determine jointly the acceptable and manageable risk level. Given the challenges, the majority of the CNC recommends that:

1. The biosafety legislation should contain a clear assignment of functions and attributions for the authorities involved in the decision-making process.
2. The institutions should formally establish advisory bodies for the decision-making process.
3. Taking decisions and its step-by-step application for the potential future commercial release of new GMOs should take place on the basis of sufficiently consolidated institutional capacities, in order to face the demands, challenges and particularities of each case, so that these decisions may not constitute "reactive" responses.

The majority of the CNC of the UNEP-GEF Project considers that for the future regulations in relation with the Law on Biosafety:

1. Decisions which arose from the Meeting of the Parties (COP/MOP) to the Cartagena Protocol should be taken into consideration, especially those referring to the strengthening of regional and sub-regional frameworks and the development of common methodologies (particularly for risk assessment) and international standards, for example for the formats employed in the exchange of information between countries.

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<sup>21</sup> These recommendations are not supported by the NGO *Fundación Sociedades Sustentables* (FSS) as it considers that the central axis of any legislation should be the precautionary principle.

2. The bilateral, regional and international relations of the country should be strengthened with respect to biosafety-related regulations, so as to promote future mutual acceptance of data and the trustworthiness of the exchange of information on any transboundary movement of GMOs involving Chile.

#### 4.5 - INSTITUTIONAL CONSIDERATIONS

The study mentioned in the table evaluated the administrative, technical, technological and informational resources of the institutions (the CNAs) which have functions regarding biosafety, or will probably have them in a future scenario, considering the following fields of action: definition of policies and regulations, risk assessment, decision-making, information management and GMO monitoring.

To contribute to a better understanding of the institutional capacities involved in the potential future entry into force of the Law on Biosafety and the Cartagena Protocol, the UNEP-GEF Project carried out a study to analyze and assess existing capacities as well as needs in institutions considered Competent National Authorities in relation to these potential future legislations. This study, titled "*Assessment of Institutional Capacities and Needs of the Competent National Authorities and other biosafety-related entities vis-à-vis the Law on Biosafety and the Cartagena Protocol*" (BioEnlaces, 2005) can be found at [www.bioseguridadchile.cl](http://www.bioseguridadchile.cl)

The following institutions were examined:

|   |   |
|---|---|
| <b>HUMAN HEALTH:</b>                                    | -- Ministry of Health (Min.Salud), specifically the Public Health Subsecretariat (SubSalud)<br>-- Public Health Institute (ISP)<br>-- Ministerial Health Secretariats (SEREMIs de Salud)                |
| <b>AGRICULTURE, SILVICULTURE AND LIVESTOCK FARMING:</b> | -- Ministry of Agriculture (Min.Agri), specifically the Office for agricultural Studies and Policies (ODEPA)<br>-- Livestock and Agricultural Service (SAG)<br>-- Subsecretariat for Fishing (SubPesca) |
| <b>AQUACULTURE:</b>                                     | -- National Fishing Service (SERNAPesca)  |

An important assumption in the study was not only the possible future promulgation of a new legislation on biosafety, but in connection with it, also the gradual evolution of more openness, leading on the one hand to a gradual increase of applications for GMO use in the country and, on the other, to a variety of GMOs which have to be evaluated.

The division of functions assumed by these institutions under the aforementioned legislative scenario are summarized below, according to the fundamental considerations resulting from the study's assessment on decision-making on GMOs.

| FUNCIÓN                                | HUMAN HEALTH SECTOR <sup>22</sup> | FARMING SECTOR <sup>23</sup> | FISHING SECTOR |
|--|-----------------------------------|------------------------------|----------------|
| Definition of policies and regulations | Min.Salud (Subsecretariat)        | Min.Agri (ODEPA) + SAG       | SubPesca       |
| Decisión-making (resolution)           | Min.Salud (Subsecretariat)        | SAG                          | SubPesca       |
| Risk assessment                        | ISP                               | SAG                          | SERNAPesca     |
| Information management                 | Min.Salud (Subsecretariat)        | Min.Agri (ODEPA)+ SAG        | SubPesca       |

<sup>22</sup>Includes food for human consumption and drugs for human use produced from GMOs

<sup>23</sup> Includes agricultural or ornamental GMOs, GMO animals and GMO feed, drugs for veterinarian use produced from GMOs, and forest plantations of GMO trees

|                           |                  |     |            |
|---------------------------|------------------|-----|------------|
| Monitoring and evaluation | SEREMIs de Salud | SAG | SERNAPesca |
|---------------------------|------------------|-----|------------|

- ▶ New scenario: Some changes representing challenges for the future Chilean system, especially concerning the range of the risk assessments and administrative decision-making processes are:
  - Evaluation of the nutritional use of GMOs (events), in the first place considering the current imports and, in the second, the national production - The evaluation of locally developed GMOs which have not been previously evaluated in Chile or any other countries.
  - The differences between GMOs destined to for release into the environment in field tests and the production of GMOs at a commercial level - These will have implications, on the one hand, on the characterization of related environmental and commercial risks and, on the other, on the control and inspection measures requested by the authorities.
  - The authorization of GMOs for multiple uses, whose evaluation has to take into account a potential change of use.
  - The consideration of GMOs in industrial applications whose investment projects have to pass the SEIA, regardless of the authorization process and the risk assessment applicable to GMOs as such.
- ▶ New GMOs: Special attention has to be placed on how the step-by-step principles and administrative terms and deadlines of the authorities for decision-making will be applied on new cases in Chile. In spite of the fact that there have been field tests in the past in Chile, there is no previous experience with the commercial production of GMOs, nor any experience with non-agricultural GMOs with innovative applications requiring more than one kind of authorization (for example, GMO crops for pharmaceutical products).
- ▶ Staff training: The majority of national authorities cannot make the necessary investment for trainings in the field of modern biotechnology or GMO biosafety, although professional staff are motivated to be trained.
- ▶ Legal mandate: A diagnosed limitation, which has impeded some institutions' to progress in capacity building, the definition of methodologies or the provision of resources for future biosafety management, is the lack of a legal mandate to act on this matter and include biosafety as a work area inside the institution. While there is no law to explicitly assign biosafety-related functions and attributions, many institutions<sup>24</sup> cannot carry out activities in this field, nor act proactively, in anticipation of a future role backed by a legal norm.
- ▶ Coordination: Undoubtedly, the need arises to install formal and effective coordination mechanisms in order to face the different scenarios for the coordinated authorization for GMOs in the best possible way. This coordination must be intra-institutional as well as inter-institutional, as weaknesses have been detected in both levels, and the need has arisen to create and formulate communication channels between the institutions which will be involved in the decision-making on GMOs (the CNAs).
- ▶ Decision-making: It will be a challenge to ensure a high level of technical as well as administrative speediness and integrity in the decision-making processes for a coordinated authorization. This integration, in dependence of the model chosen, will require a less segmented work style and more team work, with smooth communication mechanisms, independent of personal criteria, initiatives or contacts, but ensuring a formal collaboration between institutions and divisions within the same Ministry.
- ▶ Local innovations: Chile will have to permanently watch the world-wide tendencies, without losing sight of the evolution of national and international science, nor of consumer opinion, when choosing to innovate with new crops or markets. The development and cultivation of transgenic varieties, of species relevant for national exports, such as fruits and salmon, has to be evaluated correctly, not only in the light of possible productive advantages, but also considering the acceptance of the general population underlying market forces, as well as the possible impacts on exports of similar and GMO-free products (organic and other).

<sup>24</sup> This is the case of the National Fishing Service (SERNAPesca) and the Public Health Institute (ISP), although there have been initiatives taken by certain departments of the ISP to train its personnel on how to carry out qualitative GMO-studies in practice.

## **..CHAPTER 5..**

### **ADMINISTRATIVE DECISION-MAKING SYSTEM**

## ADMINISTRATIVE DECISION-MAKING SYSTEM

In this chapter, the structure of the administrative procedures for the adoption of decisions authorizing GMO-related activities is described, especially their risk assessment. Likewise, a series of recommendations and considerations is made on administrative matters and with an emphasis on aspects related to information management and to the initiative of legislating on biosafety, with a view to the ratification of the Cartagena Protocol.

### 5.1 - ADMINISTRATIVE DECISION-MAKING PROCEDURES

To identify and evaluate the administrative biosafety management capacities installed in the Competent National Authorities, the UNEP-GEF Project, through the consultant BioEnlaces, carried out a study titled " *Assessment of Institutional Capacities and Needs of the Competent National Authorities and other biosafety-related entities vis-à-vis the Law on Biosafety and the Cartagena Protocol*" (Bio Enlaces, 2005), available at [www.bioseguridadchile.cl](http://www.bioseguridadchile.cl).

As mentioned in the chapter about the regulatory regime, four authorization procedures apply to GMOs according to the current national legislation; in practice, however, only one of them has been effectively applied to this date, as will be explained below.

#### 5.1.1 AGRICULTURE

*Authorization for the import and introduction of LMPs into the environment, produced in the country or abroad. (SAG Resolution 1523/2001)*

In conformity with Resolution 1.523, LMPs can only be imported into the country and introduced into the environment with the authorization of the SAG, which is granted after the risk assessment and the presentation of a favorable report by the competent authority. This report has to be provided by the competent authority of the country of origin and has to declare that the introductions to the environment have not caused any adverse effects in that country. In the case of LMPs developed in Chile, the favorable report is prepared by the SAG itself and has to declare that the tests carried out before its introduction into the environment have not shown any adverse effects.

The resolutions authorizing the introduction or release of LMPs are issued in a procedure with a case-by-case application, in which it is possible to identify a series of phases. This procedure can be simplified, if the request is to authorize an LMP whose introduction to the environment has been authorized in previous cases. Under such circumstances, the request has to be presented only with 3 copies, not 11, as required by the general rule, and the term for a resolution for the SAG is of 45 to 20 days.

##### (i) Request for Authorization:

The steps in the authorization process are: presentation of the request for authorization in an official form, together with complementary background information which allows the corresponding analysis and risk assessment. The *application form* has to contain the following information:

- Declaration that the information contained in the application as well as the complementary information is truthful, complete and precise;
- Name, address, telephone, fax, email, institution, post of the applying entity;
- An abstract with the following data: applying entity, port of entrance into the country; variety, line or race, scientific or common name of the LMP; introduced genetic modification; transformation event; kind of permission requested; region of destiny inside the country; previous authorization and national registration (if any).

The *supplementary information* has to be presented in a more detailed form, listed in the Annex to the application form, on the basis of which the SAG will carry out a risk assessments and resolve the case. In this part, the applicant has to repeat the aforementioned basic data and additionally:

- a) Describe the characteristic of the material. Here, the donor species and the vectors (including the marker genes and their level of expression) have to be described, the genetic product identified and the affected metabolic channel identified and a description made of the effect of the genetic product on the plant material.
- b) Describe origins or previous introductions into the environment, the country or the location where the donor organism has been taken or developed and/or produced, the receiving organism and the vector or vector agent, and give a list of the countries or states where the tests and first releases were carried out.
- c) Describe in detail the objective of the experiment;
- d) Describe in detail the methods and biosafety procedures used in the country of origin and those which will be employed at the national level; if the request involves field tests, the place and its map location has to be described, as well as the size and number of lots, quantity of material to be used and a map of the cultivation, proposed measures for reproductive isolation, proposed methods to detect the transfer of genes from the genetically modified plant to the biotic environment.
- e) Describe in detail the final as well as intermediary destiny proposed, the use and/or distribution of modified plants, their products and of all the material included in the experiment.
- f) Describe in detail the method proposed for the final disposal of the LMP and of all the material included in the experiment; in the case of field tests, the treatment of the land and the post-harvest monitoring of the field, the future use of the land, subsequent controls to put into practice and the destination of the harvested material.
- g) Indicate, in the case of accidental release, the control method used.
- h) Describe the means of transportation for the LMP until its final destiny.

In the case of a request for the cultivation of pest (insect)-resistant LMPs, a contingency plan or some other safety system should be created, dependent on the species.

Decision on these requests only takes place in the city of Santiago at the Department for the Defense of Agriculture, which carries out the risk assessment. By concentrating the decisions in one single national entity, "a single judgment" is guaranteed for the decision.

*(ii) Publication of the abstract of the application:*

Resolution 1.523 gives instruction for the publication of the abstract in the application by the applicant in the Official Gazette, after which interested parties have a term of 15 days to present their written observations to the SAG.

Although this publication allows the presentation of possible oppositions and guarantees a window for public participation in the process, the applicant may keep part of the information contained in the application confidential.

*(iii) Risk Analysis and Assessment:*

Carried out by the SAG, specifically in the Technical Secretariat, with the support of the Advisory Committee and in consideration of the supplementary information annexed to the application, as well as the favorable report issued by the competent authority (i.e., by the country of origin for LMPs whose import is planned, or by the SAG itself for national cases.)

*(iv) Decision of the SAG:*

The SAG will accept or reject the application in a term of 45 or 20 work days<sup>25</sup>, in the case the LMP has been previously authorized in Chile. If the study of the background information yields an unfavorable result for the applicant, he/she can appeal before the SAG within a term of 10 days. If, on the contrary, it yields a favorable result, he/she has to pay the fee corresponding to the following step, the authorization of the import of the LP and biosafety quarantine of the crop.

*(v) Content of the resolution for authorization:*

The resolutions authorizing imports and releases will establish the biosafety measures for the LMP for the

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<sup>25</sup> Counted from the end of the term for the presentation of observations, or from the moment any missing information required by the SAG is completed.

authorized introduction (for field tests or multiplication of the material), as well as the final destination of the LMP and its products.

(vi) *Quarantine for crops under biosafety norms:*

The quarantine is a series of protective measures which apply during the growth season for a GMO, in order to minimize potential risks of its introduction to a specific ecosystem. This period concludes with the delivery of a final report detailing, among other things, the GMO's name, the transformation event, the incorporated genetic modification, the final objective and design of the test, the characteristics of germination and plant growth, the results of the test and the monitoring of pests and diseases, the harvest, the results expected in the experiment and/or the deliberate introduction, the final disposal of the harvested GMO-material and the method employed, and the treatment of the soil.

### 5.1.2 AQUACULTURE

#### *Authorization for aquaculture cultivations with GMOs*

According to the only existing norm for aquatic LMOs, any situation involving the cultivation of these GMOs will require the explicit authorization of SubPesca and will be resolved on a case-by-case basis. However, this norm does not establish a special procedure for these applications; accordingly, the procedure for the import of aquatic species, contained in the Regulations on the First-Time Import of Species, will have to be applied (Supreme Decree N° 730/1995).

The procedure for the concession and authorization of aquaculture, contained in the corresponding Regulation (SubPesca Resolution 290/1993), which considers, among other factors, studies related to the species to be cultivated in the authorizes spaces, should also be taken into consideration.

Even though in both cases, the authority with the power to resolve is the Subsecretariat for Fishing (SubPesca), it is the National Fishing Service who carries out the risk assessment for the species involved (SERNAPesca).

### 5.1.3 FOOD FOR HUMAN CONSUMPTION

#### *Authorization for the production, distribution and commercialization of GMO-food and raw materials for human consumption*

By mandate of the RSA, it is biotechnological events that undergo approval to then be incorporated into a register of events authorized for their use in or as food for human consumption. The approval of these events remains, however, subject to a structured procedure which the RSA dictates should to be defined through a "technical norm" that still has to be prepared in the Ministry of Health. To the date of this report, this norm was in the last stages of being formalized.

The competent authorities responsible for the application of the sanitary norms established in the RSA are the Regional Ministerial Health Secretariats (SEREMIs de Salud) and the Subsecretariat for Public Health of the Health Ministry.

### 5.1.4 ENVIRONMENT

#### *Environmental Impact Assessment of the processes identified in Law 19.300, if an introduction of GMOs into the national territory is planned*

As we have stated above, projects with the aim of introducing GMOs into the environment are not necessarily entered into the SEIA. Rather, the consideration of the GMOs is indirect. It only determines that, instead of a Declaration, a project is submitted to the procedure of an Environmental Impact Study, in the case this project is on the list of activities which have to be entered into the SEIA and includes GMOs.

## 5.2 - INFORMATION MANAGEMENT

### 5.2.1 INSTITUTIONAL CAPACITIES

The study of the UNEP-GEF Project on institutional capacities (BioEnlaces, 2005) included an assessment of the technological and informational resources installed in specific departments of public institutions, which exercised or will exercise functions related to GMOs (i.e., the CNAs).

Through this study, it could be demonstrated that, in general, the majority of the ANC have a very good technological and informational basis, although the data processing system, internal communication and management of information of some of them is deficient, inefficient and out of date. Other insufficiencies, such as a deficient equipment with computers (hardware) and internet connection, were also detected in the regional offices of some institutions.

The most evident and cross-cutting deficiency is the absence of information management for the electronic management of applications and a smooth internal communication, the case of the SAG being the most emblematic and significant one. In general, this does not only have repercussions on data storage, the follow-up on applications and their public availability, but also for an effective communication within the institutions as well as between them (for example, through an intranet-system).

Other institutions, in change, present a different picture, as they already have operational systems which could be adapted to the needs and specifications of biosafety management. The best example is SERNAPesca, which has a modern system<sup>26</sup> for entering applications and good computer equipment, with a technological information unit supporting SERNAPesca as well as SubPesca in their daily work.

Another good example is offered by the ISP Project, named GICONA (*Gestión de Información de los Procesos de Control Nacional* - Information Management of National Control Processes), which is still in its initial phase and involves the users directly, allowing them to carry out operations on-line, such as the obtainment of sanitary registration and export certificates. An immediate consequence of its implementation will be: a reduction of the delays of applications in progress, facilitation of the access of information to users and the speeding up of processes in general. Additionally, this system is on-line with the National Customs Service for border controls, which has required both institutions to homogenize the format of the information they manage.

### 5.2.2 BIOSAFETY CLEARING HOUSE OF THE CARTAGENA PROTOCOL

As a contribution of the UNEP-GEF Project, a brief training was held about the Biosafety Clearing House (BCH) of the Cartagena Protocol to technical representatives of diverse services and Ministries with competences on biosafety.

This introductory training had the purpose of informing on the BCH, its contents, its purpose and its operational logic. On this occasion, the BCH was presented more from the point of view of the "authorized user", who enters it to insert or edit information, than of the "general user", who uses it only as a system to search for information.

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<sup>26</sup> SERNAPesca has subscribed to the "one-stop shop" program instituted by the Ministry of the Economy for electronic administrative procedures. It has various systems for the management and the administration of data bases through different programs, in addition to an "Intranet" tailored to each department and to which it is possible to give restricted and selective access. In addition, it has a system for internal and external documentation through a bar code annexed to each document (Documentation Follow-up System), which allows retaining the information on the requests managed in the institution in the system for a maximum of five years.

## 5.3 - RISK ASSESSMENTS FOR GMOs<sup>27</sup>

### 5.3.1 AGRICULTURAL SECTOR: CROPS

At present, the risk assessment carried out in Chile for the release of GMOs into the environment is limited to plant material for propagation (mainly seeds of annual crops such as corn), although in more recent years, it has been tried on other kinds of GMO tree and fruit species.

Each import or release of GMO plant material (LMPs) has to be previously authorized by the SAG. The authorization is only issued for the purposes of multiplication and export or for field tests (of material previously tested in at least one country), once the corresponding risk analysis has been made.

The risk assessment is carried out through cycles of questions and answers between the applicant and the SAG, specifically the Technical Secretariat, which in turn has an Advisory Committee for a more specific dialogue with experts. Through this interactive process, the initially required information can be obtained in order for the authority to take a decision and accompany it by a series of recommendations in relation to the proposed activity. To guide and systematize this process, the levels in charge of the risk assessments have developed a Procedure Manual and put it into practice by themselves.

The phases for risk assessment are: (i) characterization of the GMO; (ii) evaluation of the risks associated, identifying the adverse effects which could occur in the interaction between the GMO and the receptor, and evaluating the probability of this impacts; (iii) estimation of the magnitude of the consequences of these effects; and finally, (iv) application of strategies for risk management and measures to reduce or minimize identified risks. In other words, the system endeavors to know and mitigate risks through the establishment of biosafety measures.

Thus, the resolutions authorizing the import and release of GMOs determine measures and conditions for the management of the cultivations applied for, as well as their final destination.

#### *Categories of evaluated GMOs*

The majority of the applications presented to the SAG referred to crops genetically modified for herbicide-tolerance or insect-resistance. Although more recently, tests with crops genetically modified for male sterility, increased yield and other more novel characteristics have been authorized, such as:

- a. Reduction of plant height
- b. Reduction of plant height and increase of transformation frequency
- c. Mechanic resistance of cane
- d. Resistance against the fungal pathogen *Botrytis cinerea*
- e. Resistance to Sharka or plum pox virus
- f. Profile modification of oil
- g. Expression of the dog gastric lipase protein
- h. Expression of the FeP protein
- i. Expression of the A protein

During 2004, the SAG received 140 applications for the import of such crops, 17 of which corresponded to new events. Among the authorized species, the majority are for farming purposes (annual crops), such as canola, safflower (*Carthamus tinctorius*), corn, wheat and soybean, and some vegetables and fruit such as melon, zapallo (*Cucurbita moschata*) and tomato, as well as forestry and fruit species such as pine, eucalyptus, apple and plum.

The majority of the applications refer to GMOs created abroad, but two events processed by the SAG referred

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<sup>27</sup> Two studies were used for the description of this section, both executed in the framework of the UNEP-GEF Project: "Assessment of Institutional Capacities and Needs of the Competent National Authorities and other biosafety-related entities vis-à-vis the Law on Biosafety and the Cartagena Protocol" (Bio Enlaces, 2005), complemented by: "Proposals for methodologies and criteria for risk assessment and measures for the control and follow-up of productive activities with GMOs and the use of GMOs as drugs" (CIB, 2005).

to genetically modified crops produced in Chile, specifically by the Institute for Agriculture and Livestock Research (INIA). One is a potato resistant to bacteria disease (*Erwinia* spp.) and the second are GM-vines (grapes).

Finally, it has to be pointed out that as an authority for livestock as well as farming activities, the SAG should also be in charge of carrying out risk assessments for any genetically modified animals for livestock-breeding, destined to be deliberately introduced into the environment - as could be the case of a GMO-insect as a biological control agent.

### *Principles*

In Chile, risk analysis observes classic principles such as a case-by-case evaluation, familiarity and "the applicant pays", key being the case-by-case principle, which is based on the fact that each transformation *event* is unique, as each receiving environment where the GMO is planned to be introduced. The variation of each of the following conditions would mean the processing of a new case:

#### *Elements defining each CASE:*

##### **The applying company or entity**

The transformation event (limited to the modified species and including an introduced modification and the acquired characteristic)

The scale of release (this involves the geographic location)

The ecosystem or natural environment where the release takes place (local environment)

The fact that in Resolution 1.523 a simplified procedure is applied on LMPs previously approved in the country, is based on the principle of familiarity; however, the biosafety requirements associated to this activity can be maintained.

On the other hand, granting special importance to previous authorizations of a GMO in other countries shows a precautionary stand towards the GMOs which are new for the country (for its environment as well as the evaluating authority). If the LMP is a case of first-time import and has not been introduced before in at least one country, then the application is rejected on the basis that, in Chile, the precautionary principle is applied to the release of LMPs which have not been cultivated commercially in other countries. To approve the LMP in question, it must have been approved at least in three countries where this LMP is produced, such as, for example, the United States. This criterion of protection can, however, not be applied on locally developed GMOs.

Another common practice is to ask the applicant to present the total background information for the introduction of the GMO into the environment, requiring that the risks and their possible impacts are identified and described in the application, so as to allow the experts and officials of the regulating agency to revise the existing data and analyses and evaluate their validity and coverage, the trustworthiness of their methodology and, finally, the precision of the interpretation of information.

Given that in Chile there are no commercial GMO crops, it has not yet been necessary to apply the step-by-step principle, according to which the next step of a specific scale or activity depends on the results obtained in the previous steps or tests.

The risk assessment carried out by the SAG also applies special considerations regarding the protection of biodiversity. When evaluating the magnitude of the possible impact that an LMP could have on a species or the ecosystem, it is regarded that it will be higher if the species or ecosystem presents conservation problems (for example if the ecosystem is highly fragmented), if the species is endemic or if the country or area where the LMP will be introduced is the center of origin or genetic diversity of the species. It has to be mentioned that Chile is the center of origin of the Chilean Strawberry (*Fragaria Chilensis*) and a subcenter of the potato and the tomato.

When an application concerns one species for which Chile is the center of origin or biological diversity, the norm stipulates that biosafety measures normally applicable to these types of crop could NOT be lifted, no matter what the degree of familiarity is with that given crop.

### 5.3.2 HEALTH SECTOR: FOOD

#### *Human Consumption*

At present, the ISP has only faced GMOs theoretically, i.e., there is personnel with knowledge or experience in this issue, but in its institutional practice, no evaluation of GMO foods has taken place yet.

This would change with the promulgation of the Technical Norm of the Ministry of Health; it should be mentioned that the ISP has external consultants (professional staff of the National Institute for Food Technology and the Faculty of Biochemistry of the University of Chile) for the evaluations of food health or harmlessness, if required.

#### *Animal consumption*

Although, for the time being, there is no procedure for the evaluation of food inputs for animal consumption derived from biotechnology or containing GMOs, all nutritional inputs for the livestock sector are submitted by the SAG to an evaluation through a process monograph. It is requested that it should indicate the qualitative and quantitative formula of inputs, detailing the origin of raw materials (animal, plant or mineral), in order to evaluate and verify its components and their physical form as a finished product (powder, granulate, pellets, solutions, etc.), but it is not required that the applicant indicate whether the food item does or does not originate from a GMO, or whether any of its ingredients originate from one. Generally, the standards in sanitary analysis are similar to the ones employed in the European Union.

### 5.3.3 HEALTH SECTOR: DRUGS

#### *Veterinary use*

The SAG possesses a norm on pharmaceutical products containing GMOs for veterinary use, but there is no real experience in the evaluation of this kind of product, except for one single approval, 4 years ago, of a vaccine against canine distemper. The specific norm only defines some parameters for working with these products, making it necessary to process each application on a case-by-case basis. And demanding that every application for registration or experimental testing be evaluated, additionally to what is requested from the normal channels of registration, by the very same Advisory Committee supporting the SAG in the evaluations of genetically modified crops.

The work load for the registry of veterinarian drugs is high, due to the fact that more than 100 applications are received each year, and approximately 20% of them are decided within the legal term (6 months). In general, risk assessments are made for pharmaceutical products and at the same time, but on the basis of informal mechanisms, a collaboration takes place with laboratories and other institutions which are directly or indirectly involved in the decision.

#### *Human Use*

Contrary to food, it is considered that the risks associated with drugs tend to be lower, as their possible impacts are limited to a reduced number of persons. As to drugs for humans produced through biotechnological means, in Chile a drug is not considered genetically modified if it contains combinations derived from GMOs, as in the case of recombinant insulin.

A specialized department of the ISP prepares the required reports for the applications for the registration of new products or modification of existing registers, and it processes approximately 80 modifications and 150 registrations per month. The deadlines to resolve these applications are three and four months, respectively, although in practice, more time is invested into these processes, and between six and eight months are required for an answer.

As to the risk evaluations currently under way, there is a Committee of external examiners specialized on the issues dealt with. Its professional staff comes from different national universities. They present reports and later submit the approval or rejection of the examined product to vote. These external advisors are especially designated for the analysis of new products, and it is a requirement for their selection that they are neither linked to the ISP nor to the companies interested in the process.

#### 5.3.4 FISHING SECTOR

In the field of aquatic LMOs, the current regulations only take these organisms into consideration when regulating the environmental protection of aquaculture. The applicable procedure, according to the RAMA, to obtain the explicit authorization by SubPesca for the cultivation of aquatic LMOs, has never been applied in practice. The reasons are, on the one hand, that the entrepreneurial sector has not yet presented applications for aquatic LMOs, and on the other, that the specific requisites to this end (the procedure itself or the parameters and criteria for acceptance) have not been established either. Thus, the risk analysis for the introduction of aquatic LMOs would be considered in the framework of the process for a first-time import of non-certified and certified species.

Even though SERNAPesca carries out risk assessments corresponding to these first imports, the evaluation process is not standardized and follows guidelines available in the manual of the OIE. This Service has a technical committee and advisors of the Faculty for Veterinarian Sciences of the University of Chile (who also advise the SAG) for the analysis of high-risk diseases, but does not have external consultants in the field of GMOs.

#### 5.3.5 CONTRIBUTIONS OF THE UNEP- GEF PROJECT

##### *Risk Assessment Methodologies*

In order to provide a valuable input to strengthen risk assessments that are carried out or should be carried out in the country for present or future GMOs, the UNEP-GEF Project made a study with the purpose of collecting and examining the scientific-technical methodologies, criteria and bases used in other countries and or international recommendations on risk assessment and control of GMOs for their commercial authorization.

This study, comprising drugs derived from biotechnology and also including an assessment of the national situation, was titled "Proposals for methodologies and criteria for the risk assessment and measures for the control and inspection of productive activities with GMOs and the use of GMOs as drugs" (CIB, 2005). It was carried out by the International Center for Biotechnology (CIB) of the University of Concepción and is available at [www.bioseguridadchile.cl](http://www.bioseguridadchile.cl)

##### *Native Wild Flora and Agricultural Crop*

Another study by the UNEP-GEF Project, conceived as a potential tool for decision-making, sought to collect a great quantity of information on the native wild flora and its distribution and state of conservation in the country, as well as information on agricultural crops existing in Chile today, transgenic as well as conventional, so as to compare both groups of data and be able to estimate the risk of gene flow between related or sexually compatible species.

This is a joint study by the Institute of Agriculture and Livestock Research (INIA) and the National Museum for Natural History (MNHN) of the year 2004 and with the title "Assessment of the Presence and State of the Chilean Flora related to Genetically Modified Crops, with an emphasis on the Risk of Gene Flows" and is available at [www.bioseguridadchile.cl](http://www.bioseguridadchile.cl)

This study also produced an extended report, an interactive data basis, which allows the user to assess, on a screen, the risk represented by the introduction of a new kind of transgenic crop in a specific geographical area from the conservation perspective. The criteria for this assessment model combine subjective as well as objective factors and are not free from assumptions and uncertainties, but these can be adjusted and updated, the more information, studies and scientific evidence emerge to back them.

Therefore, it is seen as a valuable tool for decision-making, as it could provide an important input with national scope to the SAG to support its present and future assessments of the risks associated with transgenic crops.

### 5.3.6 SECTORIAL POSITIONS

#### *Government of Chile*

Inside the Government, there is a concern about strengthening risk assessments, at present carried out in the agricultural sphere, vis-à-vis the challenges linked to the potential diversification of GMOs and the increase of areas covered - and particularly to the potential introduction of GMOs in the forestry sector. Therefore, the development of international guidelines is closely followed, with a special interest in the effects of the Cartagena Protocol. Internal standards for risk assessments are permanently reviewed in order to allow the country to address growing market demands on the one side, and on the other, to give the necessary environmental and sanitary guarantees.

In the aquaculture sector, efforts are centered on the pro-active development of risk assessment methodologies for aquatic GMOs. They have not yet been developed in the country, but their use in different fields of aquaculture is probable in the near future.

As to the use of GMO microorganisms in the environment, the lack of specific norms and previous experience in the assessment of their risks implies that several Ministries will have to develop the necessary methodologies to implement the corresponding norm.

In the field of public health, there is a clear responsibility of the State to assess the health risks of the consumption of GMOs in food, as for any other food. The Health Ministry tries to take charge of this through the norm it is currently developing. As to drugs derived from modern biotechnology, these will be evaluated the same way as all drugs for humans are at present.

#### *Civil Society*

In addition to the governmental sector, only civil society, represented by FSS in the CNC of the UNEP-GEF Project has expressed itself on risk assessment. The following opinions are exclusively its own.

*The civil organizations are worried about the risk assessments in the farming sector, where commercial releases take place, because they consider that there is no legislation to protect biodiversity, centers of origin and non-GMO productive activities. Additionally, to our judgment, the environmental impact and field studies carried out do not allow a correct evaluation of the GMO risks. Neither have there been evaluations of the effectiveness of applied biosafety measures. It is necessary to order the information on release sites and make it transparent, so as to allow non-transgenic productive activities; however, we consider coexistence to be almost impossible and that the country should declare itself GMO free. Finally, we are concerned about crops for pharmaceutical purposes which are rejected in other countries but released in Chile (in field tests), in spite of the fact that very little information and few studies exist on their real impacts for human health and the natural environment; we believe they should be prohibited.*

## 5.4 - RECOMMENDATIONS TO THE ADMINISTRATIVE SYSTEM

As has been previously pointed out, a change of the legislative scenario for GMOs makes it imminently necessary to gauge the technical and administrative burden it means for the institutions involved to develop a system for coordinated authorization, to face new kinds of GMOs in risk assessment and manage a growing amount of information, files and resolutions on GMOs transparently, efficiently and comprehensively.

The following recommendations are based on the assumption that, in the future, the authorization of the release of GMOs at a commercial level will be allowed, which definitely will have to be accompanied by improved management capacities. Even though this assumption is susceptible to change, the current Bill of Law on the Biosafety of GMOs points into that direction. *Fundación Sociedades Sustentables* (FSS) did not endorse the recommendations of this section on information management and risk assessment, because it

considered that all kind of capacity building should be destined to the application of the precautionary principle and protective measures.

#### 5.4.1 RECOMMENDATIONS OF THE CNC: INFORMATION MANAGEMENT

The majority opinion of the CNC of the UNEP-GEF Project is that biosafety-related information management is an administrative matter which requires more transparency, impulse and formalization inside the authorities; thus:

1. In the short term, the country should pro-actively designate its Competent National Authority(ties)(ANC), as well as its Focal Point for the Biosafety Clearing House (BCH), considering the different roles played by these entities and recognizing that all these functions can be assigned to one single institution. It has to be remembered that these designations can be modified, if necessary, once a legislation on biosafety is promulgated or the Cartagena Protocol ratified.
2. In the short term, the competent authorities should participate in the Biosafety Clearing House, submitting information voluntarily to the central web portal, even if Chile remains a Non-State Party.

This, in order to:

- a. To become familiar with the standardized formats and the common terminology, according to the guidelines developed by the Secretariat of the Protocol, to help the Parties enter information into the BCH.
- b. To identify in time the technological and operative needs of the competent authorities (for data processing as well as staff trainings)to achieve a more effective and complete participation of the country in the BCH when becoming a State Party, and their budget projection.

#### *PROPOSAL FOR THE DESIGNATION OF CNAs*

The present CNAs should be those institutions which take decisions on the use of GMOs in the country, or which could do so in future, and possess and manage information of interest for the Protocol, since the CNAs are the ones who enter these data into the BCH. In Chile, these institutions are: the SAG, Subsecretariat for Fishing and Subsecretariat for Health.

The Focal Point of the BCH should be an entity with the power to *validate* the information submitted to the BCH by each ANC before the Protocol Secretariat. At present, the BCH-Focal Point of Chile is the DIMA (of the Ministry for Foreign Relations), so that this designation could be maintained, or reviewed, and CONAMA or the Ministry of the Economy<sup>28</sup> considered as alternatives.

If the Bill of Law includes a "one-stop shop" for the applications for authorization of GMO-activities, one and the same entity could be in charge of receiving, channeling and entering the CNAs' information and decisions into the BCH, as well as validating them before the Secretariat.

3. The information management system planned for a future Law on Biosafety should be:
  - a. a centralized system of information management
  - b. accessible via internet
  - c. configured with various security levels, depending on the user, in order to grant controlled access to "authorized users" and access for the general public, without the right to modify the information.
  - d. easy to use and surf for both kinds of users
4. The national information system should become a management tool and not only an information gateway on biosafety for the general public; it should include: different information layers; uniformed forms of storage; access for registered users; different security levels for confidential information; and codes for the follow-up of files.

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<sup>28</sup> This proposal was not supported by the NGO Fundación Sociedades Sustentables (FSS)

5. The national information system should include the CNAs' regional offices into the system of entry and access to data (as authorized users), since a unification of all levels of the institutions involved is indispensable for GMO management.

6. In the medium term, the CNAs which do not have electronically-based information management systems should try and replicate the investment of the ISP and SERNAPesca in this field and benefit from the lessons learnt by these institutions on the management, maintenance and improvement of these systems.

7. In the long term, once the commercial use of GMOs is authorized in Chile, the CNAs should consider the definition of a harmonized system of codes for the files of GMO-applications in process, so as to optimize the follow-up of the processing stage of each application and the subsequent verification of the events authorized by the country.

#### 5.4.2 RECOMMENDATIONS OF THE CNC: RISK ASSESSMENT

The majority opinion of the CNC of the UNEP-GEF Project is that risk assessment is the most important instrument for a rigorous science-based decision-making on GMOs; therefore, the following recommendations are directed at the authorities that are presently, and possibly in the future, in charge of assessing GMO-related risks:

1. To consider declaring those areas in Chile which are classified as *centers of origin or genetic diversity* of these species, as restricted for the potential future commercial release of genetically modified tomatoes, potatoes or Chilean Strawberry (*Fragaria Chilensis*). These areas should be clearly demarcated on the basis of available information about the distribution of these species.

2. To evaluate the feasibility of classifying those areas where old varieties of corn are still cultivated, especially in the North of the country, as restricted areas for the commercial release of corn because of the genetic diversity hosted in them.

3. To use the information offered by the data basis on wild and cultivated species of flora (generated by the UNEP-GEF Project) for risk assessments and decision-making on GM-plants, in order to have information on their distribution and estimate the probability of cross-overs and gene flow between them.

For a better use of this data base, the following proposals are made:

a. It should be installed in the SAG's Department for Agricultural Protection, which makes the risk assessments of releases of GM-plants into the environment.

b. The SAG should manage the data basis as well as its periodic updating with the help of the INIA.

4. A data basis on genetically modified aquatic species currently developed world-wide should be designed and include the most important biological factors to be considered in the risk assessment (for example, the reproductive characteristics). As new relevant studies are made, this basis could be complemented with data on native and/or wild aquatic species susceptible to cross-overs with transgenic aquatic species. It could also be designed on the basis of the study on aquatic species carried out in the framework of the UNEP-GEF Project.

5. The information contained in the BCH on existing guidelines, principles and criteria for risk assessments for GMOs, collected and summarized by the Secretariat of the Cartagena Protocol for the COP/MOP-2 should be accessed. This collection is contained in the annex to the document UNEP/CBD/BS/COP-MOP/2/9, available at the site: <http://www.biodiv.org/doc/meeting.aspx?mtg=MOP-02>

6. The designation of advisors should be made publicly transparent, considering that conflicts of interest can arise at the moment of resorting to external laboratories or advisors for the evaluation of samples or applications, due to the fact that these specialists or consultants may at the same time be advisors to the companies presenting the applications.

7. In the medium term, a list of multidisciplinary experts should be designed for the possible future creation of advisory committees, or for *ad hoc* consultancies, which considers the participation of regional specialists, so as to better reflect the local realities and ecosystems of the entire country in the risk

assessments made.

8. Pro-active steps should be taken in the training of staff for decision-making on GMOs, even in absence of a legal mandate, as these initiatives are backed by the National Policy for the Development of Biotechnology, which defines lines of action for the creation of biosafety capacities.

9. The productive as well as governmental forestry sector should be encouraged to start working on the development of technologies to assess risks related to forestal GM-species, with a view to applying transgenics to the pine production promoted by this sector at the national level.

10. The training of professional staff in charge of the GMO-risk assessments should be stimulated, in order to strengthen, broaden and update their scientific knowledge on transgenics, especially as to new applications of GMOs ("novel traits"), the presence of various transgenes in one LMO ("stacked genes") and the technologies for molecular containment to minimize the probability of gene flow.

To this end:

- a. The approval of the top-level of the ANCs and their commitment to hold this training should be obtained.
- b. The counsel of international experts on the application of new guidelines, principles and criteria in risk assessments should be asked, any time their travel to Chile could be financed through the program of the Foundation for Agricultural Innovation (FIA) or through funds of the International Centre of Genetic Engineering and Biotechnology (ICGEB) in Italy, or through other funds.
- c. A program of short courses to be held in Chile should be designed, each addressing specific issues related to biotechnology and biosafety. This program should be designed with the participation of local experts, as well as foreign experts mentioned above.
- d. The application to existing specialized courses should be facilitated and encouraged, such as the distance-learning Degree on Biosafety<sup>29</sup> of the University of Concepción; the course on Biosafety annually offered by the ICGEB<sup>30</sup> in Italy; the course of the Norwegian Institute of Gene Ecology<sup>31</sup> of the University of Tromsø in Norway; and the course on agricultural biosafety<sup>32</sup> of the Michigan State University in the USA. These international courses offer (partial or full) scholarships, and the FIA also offers scholarships for the training of public officials on biotechnology management.

## 5.5 - INSTITUTIONAL CONSIDERATIONS

As a result of the study on institutional biosafety capacities (BioEnlaces 2005), a series of administrative challenges related to the undertaking of new biosafety tasks arose, in addition to legal and institutional considerations. In the case of an increase of GMO activities, the number of authorities involved would rise, as well as their powers and, thereby, the complexity of the administrative system. In addition to the already formulated recommendations, following are some specifically institutional recommendations on this future scenario.

### 5.5.1 ADMINISTRATIVE SYSTEM

- ▶ Diversity of institutional competences: although the same institutions will basically stay in charge of decision-making, it is anticipated that, if the present distribution of competences is kept, then sometimes, within one and the same sector, one institution will be in charge of resolving applications, while another will have to carry out the corresponding risk evaluations, and a third will exercise the inspection and surveillance functions. Such is the case of the food sector, where the attributions of the Subsecretariat for Public Health, the ISP and the regional SEREMIs de Salud converge. As a consequence, different authorities will have normative, political, decision-making, inspection and sanctioning faculties regarding the same kind of activities.
- ▶ Capacity versus demand: It would be recommendable that public institutions make an inventory<sup>33</sup> of their

<sup>29</sup> [http://www.forestal.udec.cl/post\\_diplomado.php](http://www.forestal.udec.cl/post_diplomado.php)

<sup>30</sup> <http://www.icgeb.trieste.it/>

<sup>31</sup> Holistic foundation for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms

<sup>32</sup> Biosafety - An International Short Course in Environmental Aspects of Agricultural Biotechnology

<sup>33</sup> For a global vision on their present capacities - year 2005 - the authorities can consult the study "Assessment of Institutional Capacities and Needs of the Competent National Authorities and other biosafety-related entities vis-à-vis the Law on Biosafety and the Cartagena Protocol" (Bio

capacities (especially for risk assessment, the processing of applications<sup>34</sup> and the inspection on the ground) and, if possible, qualify and quantify them, so as to periodically revise their adequacy in the face of increasing demand.

- ▶ Technical exchange and dialogues: The benefit of developing a strategy to approach the different sectors and institutions to each other, especially the public sector to the academic community, should be considered, in order to stimulate the exchange of information and knowledge between scientists and technical staff (inside and outside the institutions), as a form of keeping decision-takers informed on the advances of modern biotechnology, increasing the transparency on State actions and promote joint actions leading to a higher level of cooperation and coordination on the matter of biosafety

#### 5.5.2 INFORMATION MANAGEMENT SYSTEM

- ▶ Intra-institutional communication: Besides the need, common to most CNAs, for information management software tailored to their current and future tasks, any future information management system will have to equally attend the communicational needs of institutions with regional offices, with which they interact, or will have to interact, in order to integrate their biosafety tasks.

SERNAPesca: The "on-line" management of information carried out by SERNAPesca<sup>35</sup>, which after 2003 was extended to all regional offices of this Service, allowing each regional division to register sectorial information simultaneously, is a good example for the kind of resources other sectors will have to mobilize for the internal integration and coordination of their labors.

SAG: The management requirements are especially relevant for the SAG, whose technical departments, together with the advisory committees, will have to fulfill functions such as the evaluation of different kinds of GMOs (destined for release into the environment, feed or veterinary use) and maintain an effective coordination with the laboratories, regional offices and customs agents, for the tasks of sampling, monitoring and control.

- ▶ Inter-institutional communication: When operating the administrative procedures resulting from a possible future Law on Biosafety, the degree of integration and smoothness in communications between the institution in charge of the "one-stop shop" for the reception of applications and the different authorities in charge of resolving these applications will be highly relevant.

ISP: As a positive experience in this field, the ISP's GICONA project can be mentioned, which directly involves users and is on-line with the National Customs Service. It not only responds to the understandable tendency to facilitate access to information and speed up authorization processes through on-line operations, but also to the necessity of unifying the format of the information managed by public institutions with regulatory functions.

- ▶ Investment: As to the informational and infrastructure needs of institutions for a future biosafety information system, in some cases an initial investment would be needed to use new technologies in the management of applications. In other cases, the existing system will have to be adapted through software changes. Innovation in both cases will be part of the modernization of the public system promoted by the Government. The installation of this system to remove the incompatibility of systems between different institutions would represent a key investment for the solution of institutional weaknesses.

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Enlases 2005) carried out in the framework of the UNEP-GEF Project.

<sup>34</sup> The requirement of Law 19.880 as to the maximum duration of 6 months of any public administration process has to be taken into account.

<sup>35</sup> This equipment, together with the one already described, has allowed SERNAPesca to optimize its work enormously and reduce the corresponding bureaucratic workload, as well as the duration of the processing of applications. This marks a considerable difference to the SAG, where communication takes place mainly per fax or telephone between the central level and regional offices, which do not have "one-stop shop" or on-line processing, as not all offices are connected to the internet.

## **..CHAPTER 6..**

### **RISK MANAGEMENT, MONITORING AND INSPECTION**

## ..6.. RISK MANAGEMENT, MONITORING AND INSPECTION

### 6.1 - BACKGROUND

#### 6.1.1 INTRODUCTION

As in other fields of biosafety, GMO-specific risk management, inspection and monitoring are concentrated to the farming sector, but also carried out in other sectors, in the framework of more ample ministerial powers.

As an example, little can be said for the human health sector on the inspection of GMO-food or genetically modified drugs, as to this date there is no specific norm for these products. However, the ISP's functions include, at any rate, control and monitoring tasks for a diversity of products which can be indirectly applied to GMOs.

On the other hand, it is the agrarian sector, or more specifically the agricultural sector, where contact of GMOs with the natural environment has led to the application of biosafety measures (or risk management measures) under field conditions, and significant experience has been gained in this matter. Considering the possibility of an open framework in the future, this experience has to be at the height of the technical and operative complexities involved in agricultural coexistence, where transgenic, conventional, organic and other crops should not be incompatible as productive options. Recently, the need to monitor the production of GMO crops has been extended to the post-sales phase for agricultural export products. Monitoring after the release into the environment has also become an increasing market demand, leading to the tailoring, on the initiative of the productive sector and with the help of the Chilean Government, of a system of traceability for agricultural export products, which will be able to ultimately include GMOs.

#### 6.1.2 SECTORIAL POSITIONS

The greatest divergence of opinions between the different sectors of the Chilean society regards GMO risk management. There is no agreement on the magnitude or relevance of potential environmental or sanitary impacts associated with these organisms.

Together with the Government's vision on GMO risk management, we will present the position of the FSS, one of the NGOs representing civil society in the CNC of the UNEP-GEF Project.

##### *Government of Chile*

The Government recognizes that there are risks which have to be assessed prior to planning the use of a GMO. And it definitely considers that these risks are manageable. Every authorization for the commercial use of a GMO needs, or will need, mechanisms for the monitoring after it is released into the environment or the introduction into the market of the corresponding product. In the case of the laboratories employing or developing GMOs, it will be necessary to have more information about their activities.

An eventual opening towards the commercial use of GMOs will require greater inspection capacities, even though valuable experiences have already been acquired, thanks to the efforts carried out by the agricultural authorities for many years. Ultimately, the work and the responsibilities for an adequate management of the risks associated with GMOs are not only of the government, but also of the productive sector using these organisms and the researchers and scientific establishments developing them, as biosafety is a shared responsibility.

##### *Civil Society*

*The FSS considers that risk assessment measures have to be imposed to help prevent adverse effects of GMOs or their products on the natural environment and on health, considering the phytosanitary impacts, non-target species, biodiversity, centers of origin, genetic resources, soil fertility, water bodies, natural environment, and impacts on health.*

*The competent authority has to commission field studies to measure the impacts of the different transgenic crops released in Chile since 1992 to collect information on these impacts and, in the case of adverse effects, adopt measures for the case-by-case risk management.*

*We believe it to be necessary to evaluate the efficiency of the present biosafety measures through field studies to detect contamination, impacts on non-target species, effects on soil fertility, etc. The results of governmental studies in various regions on the impact of GMO-crops have to be made public in order to represent a contribution to national biosafety. The technical capacity to detect genetic contamination has to be increased, and, very importantly, it has to be guaranteed that conventional seeds are GMO-free. Their introduction into the country should require the certification of absence of genetic modification, to avoid any illegal introduction of GMOs without any biosafety measures. Other measures would be the labeling of imported GMO-food that could be used as seeds, with a prohibition on their use for cultivation.*

## 6.2 -ENVIRONMENTAL RISK MANAGEMENT: CURRENT SITUATION

### 6.2.1 AGRICULTURAL CROPS

On the basis of the risk assessment for LMPs, a set of measures is designed with the objective of controlling or mitigating their potential risks, including the monitoring of their agronomic behavior during their growth. Thus, in Chile biosafety measures are applied in all phases of LMP-production, from their import to their export, including the cultivation, harvest and post-harvest handling.

Nevertheless, risk management measures have to comply with certain internationally accepted principles, such as the need for their application (focused on protection) and their proportionality to the identified risk. Another common principle is that any risk-related measure or decision has to be scientifically or technically justified, an aspect which intends to lend the process objectivity and avoid arbitrary determinations.

In the application for authorization to release, the applicants propose the management plan and they assume the costs for risk management, i.e., the implementation of the required biosafety measures. These measures, also known as quarantine measures, serve the purpose of avoiding or diminishing, to the highest possible degree and considering cost-efficiency aspects, the gene flow between the GMO-species and other neighboring crops (of the same species), or other related wild species (local biodiversity).

#### BIOSAFETY MEASURES IN CHILE INCLUDE:

- the physical isolation of the GMO-crop (safety-spacing of crops);
- seasonal isolation (the GMO is cultivated in a different season from other crops so that the times of blossoming do not coincide);
- use of barrier and trap crops (to catch pollen), which can be the female GMOs themselves;
- detasseling (the male part of the plant is eliminated to avoid the generation of pollen);
- male sterility is achieved through the traditional improvement, in order to inhibit the dispersion of pollen;
- coverage of the cultivated surface and the flowers with meshes and bags to prevent contact with pollinating insects;
- controlling the time of harvest (for example, before full maturity), in order to minimize the dispersion of seeds.

According to the current regulations, no partial or total biosafety measures are needed, if they have not been taken in the country of origin either, or if the national developments in the past allow for this decision. However, species for which Chile is a center of origin or genetic diversity are exempted from this rule; in these cases, biosafety measures may not be lifted.

On the basis of risk analysis and the previous experiences of field release (i.e., the principle of familiarity), the SAG has suspended the measures of physical isolation requiring a biosafety quarantine for certain herbicide-resistant corn and soybean species, and for insect-resistant corn. Thus, this material can be

multiplied without having to comply with a quarantine growing period, but the regulations on a case-by-case import authorization and the prohibition for industrial use or human consumption<sup>36</sup> are maintained, and the remnants of the harvest and selected plants have to be destroyed and the generated seeds re-exported.

An additional biosafety measure is applied to LMPs which need to be treated more cautiously, for example new events for Chile, or crops considered to be of high-risk (like canola). Therefore, the first time a shipment of these contents imported from abroad is opened, SAG inspectors have to be present, even if the quantity of seeds imported is small.

Another biosafety example are genetically modified forest and fruit species authorized by the SAG for confined experimental evaluations, i.e., high-security greenhouses (isolated from the environment), where measures such as double meshes are applied, in order to avoid any probability for insects to enter, negative pressure in the case any insect does so, and a cement floor to avoid contact with the soil, among others.

At present, case-by-case biosafety measures are generally accepted by the seed companies, because of their interest in ensuring the purity of the harvested species. And in fact, complying with the quarantine helps them to prevent a "genetic contamination" of their products and at the same time contributes to minimizing the gene flow towards neighboring fields and ecosystems.

As a result, the biosafety in the different phases of production has been, partly, a concern of the seed producers themselves, who have applied some sort of self-regulation independently from regulations in force. However, organic farmers and NGOs have expressed their doubts as to the real effectiveness of these biosafety measures.

A very distinct scenario is assumed for the time after a biosafety legislation, when coexistence of crops will be a great challenge for authorities as well as farmers. For this reason, the Ministry of Agriculture, through the FIA, started an exploratory study in the year 2004, which was planned to finalize in November 2005, on systems of agricultural coexistence in other countries, with the title "*Comparative study of the international situation of agricultural coexistence and proposal for a model applicable to Chile*".

Although this initiative did not arise from the UNEP-GEF Project, an agreement was made with the Ministry of Agriculture to incorporate a member of the CNC, namely a representative of the private sector, into the counterpart of the study. By integrating the agro-exporting sector of the UNEP-GEF Project, an attempt was made to create a link between them and obtain their contributions to this initiative.

#### 6.2.2 POST-HARVEST MONITORING

A less visible, but equally important aspect of risk management in biosafety is the monitoring and inspection of GMOs on the ground, once they are released into the environment. This sort of biosafety applied to the environment has roused great attention and requires rigorous monitoring; therefore, in December 2001 the Ministry of Agriculture started a project to study, among other things, the occurrence of genetic flow between transgenic and wild species on the ground. This project, unrelated to the UNEP-GEF Project, is still in execution (it ends in December this year) and is carried out jointly by various levels of the Ministry (INIA, SAG and FAI). It covers corn, canola and potato and is titled: "*Development of a system for molecular traceability and evaluation of local biodiversity for plants modified by transgenesis*"<sup>37</sup>.

It is expected that this project, which includes building scientific-technical biosafety-related capacities, will additionally serve to define new biosafety measures or ratify existing ones, as well as to strengthen the tools and the empirical information for risk analysis. It aims at developing, in the first place, a technique for molecular verification of the gene flow and, in the second place, a methodology of predicting the probability of its occurrence among sexually compatible species.

This will allow estimating the gene flow between species and the associated risk prior to the release of specific LMO crops, and already knowing the national distribution of wild species related to these crops. A

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<sup>36</sup> Since February 1998, only animal consumption of these remnants of corn cultivation and those with a modification for male sterility have been allowed.

<sup>37</sup> INIA: Institute of Agricultural and Livestock Research. FIA Foundation for Agricultural Innovation. Both are entities of public-private law and dependencies of the Ministry of Agriculture.

complement to this is the data basis on wild species related to agricultural crops, developed in the framework of the UNEP-GEF Project, a tool which is expected to be used in decision-making processes. Its continuous use and updating would contribute to giving background information for the definition and review of biosafety measures applied on GMO plants throughout the territory.

### 6.2.3 LIVESTOCK FEED

Biosafety in the livestock sector is very specific: measures and instructions on the use and monitoring of remnants of LMP-seeds in animal food and veterinarian drugs containing GMOs. In the case of the latter, measures are applied to product commercialization and will be explained in detail in the following section.

If a remnant of LMP-seeds<sup>38</sup> is detected in the selected plants, livestock feed can still be used as such, in conformity with Resolution No. 3970 of the SAG. The receiver of this remnant has to inform the SAG, through a letter, on the name of the animal food companies where it will be used and has to register all sales of these remnants. To follow-up on other types of food derived from non-seed GMOs, the same system is used as for conventional food, which is efficient, according to the opinion of the SAG. Animal food is regulated by Decree 307 of the SAG (of 1979), in which, among other matters, the SAG inspectors are authorized to take samples to analyze the products. If violations are discovered, the SAG can apply fines on the respective company.

## 6.3 - POST-SALE CONTROL AND MONITORING

As the commercial use of GMOs is prohibited in Chile, logically there is no post-sale control or monitoring of these products at the national level, except for veterinarian drugs containing GMOs, classified by the SAG as drugs or immunological products.

Decree No. 3136 of the SAG requires the post-sale retention of the veterinarian prescription for veterinarian pharmaceutical products containing GMOs. The retained prescription is an important means of control, as it is kept for two years in the establishment which sold the product, and the veterinarian who prescribed it keeps a copy for the same period of time. Decree N° 3136 also demands that both the establishments which manufacture and those who import this kind of pharmaceutical products, as well as the veterinarians who prescribe them, are compelled to maintain a system of pharmaceutical surveillance. Its objective is to detect potential adverse reactions, and in case there are any, the information must be remitted to the SAG's livestock department once a year.

On the other hand, the commercial follow-up of agricultural and livestock products beyond the phase of cultivation or production is a goal the country's export sector has proposed itself, motivated by the increasing demands of the markets in Europe, Japan and the United States, which recently have imposed requirements of information on origin, registration and labeling of food.

It is clear that the demands for certification or labeling of GMO foods entail economic consequences, as a system of segregation and documented follow-up of all GMO inputs and products through the productive chain has to be installed. For that reason, the traceability of these products has become the main trade concern for GMO-producing and exporting countries. Thus it is not surprising that the Biotechnology Policy contains a line of action specifically aimed at this challenge: "*Definition of a strategy for the establishment of a system for the certification of GMO products for export, including traceability.*"

As to TRACEABILITY, the Biotechnology Policy states the following:

*"The demands for labeling and traceability of GMO by the European Union and other countries [...] make it necessary to establish systems for the certification and/or official information to respond to these requirements."*

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<sup>38</sup> According to Resolution N° 3970, the consumption of other products which are not seeds or grains is not permitted, but at present, the SAG is authorizing the feeding of remnants, subproducts and waste (stubble, high- or low caliber seeds, etc) of GMO crops indicated in Resolution N° 3970, on a case-by-case basis and as a measure to destroy remnants.

*These systems have to include procedures for logistic traceability, which allow the tracing of GMO products along the entire chain of production and distribution, and systems of analytical traceability of genetically modified DNA or proteins. These procedures are complex, and the sectorial authorities - in conjunction with the private sector - will have to establish the necessary systems for the information and certification of GMO products for export."*

The current worldwide scenario in GMO trade has generated a complex situation for Chile, as on the one hand our exporters have to operate in markets which are more or less open to biotechnological products, and to GMO foods in particular, and have different regulations, and on the other hand because our potential GMO-food exports could negatively affect the exports of conventional and organic products, due to a potential reluctance of consumers and/or rejection by regulating entities, which could suspect a "transgenic contamination" in these products.

These negative effects on the image of the country and the agro-food sector, which could lead to the creation of customs-like barriers, a loss of export value (in price and volume) as well as major transaction costs due to traceability requirements, were the object of a study commissioned by the UNEP-GEF Project to start envisioning the potential economic impacts and externalities associated with the production of GMOs. In Chile, this problem has been brought forth by salmon producers, fruit and vegetable companies and bee keepers in particular, and by a group of farmers who are starting the development of organic cultivation.

The study "*Impacts of the national incorporation of GMO crops on the commercialization and value of agricultural, livestock and aquacultural products*" had the objective of identifying and quantifying the potential economic impacts on the export-oriented agro-food chains, which could result in the incorporation of GMO products in the national productive systems. It was carried out by Fernández & Gutiérrez (2005) and is available at: [www.bioseguridadchile.cl](http://www.bioseguridadchile.cl)

Faced with this dilemma, the export-oriented productive sector has been pro-active in promoting the future incorporation of GMOs into the traceability system for forestry, agricultural and livestock products which is currently being designed. This initiative, called "TrazaChile", is led by the Chile Foundation and tries to respond to demands, mainly coming from the European Union, emerged parallel to the requirements of the Cartagena Protocol. Its standards are, generally, stricter and more extensive than those of this international agreement.

## 6.4 -INSPECTIONS

The general attributions authorities currently possess for the control of products and activities are particularly relevant for the control of products and activities and the application of administrative sanctions. As to biosafety, only the SAG has specific faculties with respect to GMOs. The current capacities for monitoring, inspection and analyzing samples, installed in the CNAs or externalized, shall be examined in view of a possible future biosafety legislation and a national opening towards GMO use, as well as the application of sanctions in the case of infractions.

### 6.4.1 AGRICULTURAL SECTOR

For on-the-ground inspections, the SAG inspectors are the ones who have to verify compliance with the biosafety measures stipulated in the resolution to authorize one particular LMO, such as measures of isolation, stubble management, harvest and re-export or elimination of seeds. Additionally, it is verified that the infrastructure conditions the company has declared to possess effectively correspond to what is found on the ground. To perform these tasks, the SAG has offices available throughout the country.

When inspecting the merchandise at the border points<sup>39</sup>, the SAG inspectors cooperate with officials of the National Customs Service. Generally, it is the applicant himself who interacts directly with Customs and the SAG, first passing through Customs control and then through plant and animal health checks by the SAG.

<sup>39</sup> The most important SAG offices for border surveillance are, due to the volume of their activities, in Region V, mainly the ports of Valparaiso and San Antonio, and Los Andes; and Santiago, which controls the entry of all kinds of products at the airport. Furthermore, there are the cities of Talcahuano, Arica and Punta Arenas, which are also ports of entry for different products.

For the detection of GMOs, the SAG has qualitative technological capacity in the Department of Laboratories and Quarantine Stations. Here, commercial ELISA systems are employed for the detection of transgenic proteins (such as the Bt toxin) and “real time” PCR for the detection of specific DNA sequences found in commercial GMOs of the first generation (such as the CaMV-35S promoter or terminator *nos* of the *Agrobacterium tumefaciens*).

For a quantitative analysis using real time-PCR, there is no installed capacity yet, although progress has been made in that aspect. Nor are methodologies available for the study of transgenic material found in animals, pharmaceutical products or food, as until now, the techniques used and the capacities developed by the SAG have centered on the analysis of plant texture and seeds. Thanks to a joint project with the European Union, the SAG is in the process of creating a Biotechnology Unit with a high-tech laboratory, which will be available for any SAG department requiring specific analysis. It will also include a Referral Laboratory for the testing of remnants for any kind of food material, including GMO-foods, and into which new techniques of remnant detection under ISO norms will be integrated, with the purpose of harmonizing standards with the European Union and with a view to satisfying the demands of the Cartagena Protocol as to the detection and identification of transgenic events in seeds and bulks for import and export<sup>40</sup>.

The GMO assessment can also be carried out in other establishments<sup>41</sup>, but these are not accredited by the SAG (as the accreditation for GMO analysis is pending), which implies that the certification of the GMO presence in commercial products issued by these institutions is not officially recognized by the SAG.

#### 6.4.2 HUMAN HEALTH SECTOR

As to food for human consumption, the ISP acts as National Referral Laboratory, which means that among its capacities for analysis are all the analytical procedures related to food control defined in the RSA and the Codex Alimentarius.

For this purpose, there is a specific center within the ISP which carries out applied research and develops and validates methods of molecular detection for food-related pathogens. Although this center has not yet had the need to detect LMOs for regulatory purposes, it handles the techniques for PCR, ELISA, RAPD, Western Dot blot and the electrophoresis of proteins, among others. In the short term, the arrival of a “real-time” PCR is expected, which will allow the ISP to quantify the presence of GMOs. At present, the methodologies of GMO-detection are being developed, and for that reason the ISP would already be prepared to carry out qualitative analyses of the most common foods, such as soybeans, if necessary.

As to drugs, the ISP manages a program named Shelf Control, through which drugs selected on the basis of their sales index are controlled. Through this program, approximately 40% of the active principles available on the market have been assessed, and visits to randomly chosen companies have been carried out to monitor the correctness of their sales.

#### 6.4.3 FISHING SECTOR

It has been observed that SERNAPesca, as the inspection institution, does not possess the formal means (protocols and programs) for GMO surveillance, for a systematized control of import products or of aquacultural activities. The reason is that, until now, this productive sector has given signs of tranquility. The producers of this sector, and in particular the salmon producers, have declared their intention not to use GMOs, because they consider that the international market is not favorable to these.

Nevertheless, in order to develop the necessary analytical capacity to perform its inspection tasks, SERNAPesca works with several referral laboratories which provide services for the analysis in various areas of aquacultural health, especially as to the sanitary certification of live species for export. All the service laboratories authorized by SERNAPesca have received the accreditation of their analytical techniques and methodologies, or are currently in the process of accreditation. On the other hand, SERNAPesca also works with verification laboratories, generally belonging to national universities, for special analyses. This group is listed in an Register of Certified Laboratories.

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<sup>40</sup> According to the statements in the Management Review 2004 and Thematic Priorities 2005 of the State Policy for Chilean Agriculture (January 2005)

<sup>41</sup> In the INTA (Food Technology Institute) and INIA (Institute for Agricultural and Livestock Research)

## 6.5 - RECOMMENDATIONS & GENERAL CONSIDERATIONS

From the studies carried out under the supervision of the UNEP-GEF Project, it could be understood that the inspection staff of the CNAs does not dedicate itself exclusively to this function, but also performs other tasks. Therefore, it will be necessary to review the existing inspection structures and programs, so as to strengthen capacities which are increasingly demanded and complement what is especially required for GMOs.

Following are some reflections on these capacities, and the control activities required, which are then developed into recommendations.

### 6.5.1 GENERAL CONSIDERATIONS

- ▶ Unapproved Events: The inspection of biotechnological *events* will have limitations when dealing with events not approved in the country. The limiting factor will not be the detection of transgenesis *per se*<sup>42</sup>, but rather the determination of the specific identity of any transgene not officially authorized in the country. In these cases, the inspection authorities will not possess the relevant information or the necessary genetic sequences to define the transgene and differentiate it from others, although they may have certainty about the fact that the product contains GMOs.
- ▶ Deviation of Use: A prevision which has to be taken into account regarding the approval of *events* or GMOs for specific uses or activities is that this will imply the need to control and minimize the possibility of change of use, i.e., that an *event* or GMO is accidentally or intentionally used in a way for which it was not authorized. The improper use of GMOs will, undoubtedly, be an item to be included in the inspection of productive activities with GMOs, but its prevention should already be taken into account at the time of authorizing *events* or GMOs<sup>43</sup> for differentiated or specific uses.
- ▶ Biosafety measures: In addition to biotechnological *events*, the fulfillment of biosafety conditions in relation with GMO activities authorized in the country has to be monitored on manufacturing premises as well as agricultural or forestry lands.
- ▶ Border controls: The border control for the entry of authorized GMOs will be a new function for the SAG inspectors and/or the National Customs Service (especially in the case of non-plant GMOs), for which they probably will require training and a registration and documentation system.
- ▶ Outsourcing of services: It is interesting that the Bill of Law on Biosafety allows authorities with inspection attributions the outsourcing and delegation of the analysis of genetically modified substances to others; because it is probable that the authorities in charge will prefer to outsource, and this will imply the necessity to unify criteria for the certification of laboratories and the standardization of the techniques for the detection of genetically modified substances.

The analysis of genetically modified substances is commonly done through PCR<sup>44</sup>, which requires trained staff, expensive equipment and reagents and specially designed protocols to achieve the required precision and sensitivity. It will be indispensable to make concerted efforts to reach a harmonization of results between different laboratories.

- ▶ Application of sanctions: There is, in general, an adequate institutional preparedness for the exercise of punitive competences, fundamentally because these institutions already have experiences in that field. However, there are deficits as to specialized technical know-how, and fundamentally, as to inter-

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<sup>42</sup> There are very simple and inexpensive methods to detect the presence or absence of the majority of transgenes commercially used today. For the monitoring of GMO activities, the mere detection of transgenes will suffice to determine whether the activity is or is not legal.

<sup>43</sup> This is not only valid for GMOs destined to nutritional use, where the main consideration (of a risk assessment) is the feasibility and cost of keeping GMOs for animal use separated from those exclusively destined to human consumption, but also for GMOs which are pharmaceutical or animal products.

<sup>44</sup>The "final time" PCR test gives semi-quantitative results with a sensitivity of nearly 0.05%, while a "real time" PCR test generates quantitative results of a higher precision and with a detection sensitivity of nearly 0.01%, at least for plant material. However, both techniques are adequate to satisfy the requirements of the programs for the traceability and detection of genetically modified substances.

institutional coordination. This is due to the fact that several institutions participate simultaneously in the mission of guaranteeing the fulfillment of the norms, but some without any competences to impose penalties (only inspection competences), which generates a potentially inefficient distribution of functions.

- ▶ **Monitoring:** The authorities as well as researchers and environmentalists have concerted on the need of monitoring and studying the real impacts of GMOs on the Chilean biodiversity and of evaluating the rigorousness and effectiveness of the biosafety measures for sanitary, livestock-related or environmental purposes.

For this reason, in situ GMO monitoring studies by public institutions are important, as they will allow, on the one hand, to build scientific-technological capacities, and on the other, to achieve better risk assessments based on empirical and local results in the future. The activities developed with this goal, such as the (empirical) research by INIA and the (theoretical) case study of the UNEP-GEF Project, are a first example of the kind of investigations that will contribute to strengthening the risk analysis for the release of GMOs into the natural environment. It is possible to predict that if the State makes no strategic investment in these areas, this monitoring will probably remain in the hands of independent researchers or NGOs with an interest in following up GMOs at the national level.

- ▶ **Systems of Traceability and Coexistence:** The first and most evident challenge associated with risk management which would emerge from a change of the present scenario of GMO production, and has commercial as well as environmental implications, is the establishment of a framework for agricultural production which allows the coexistence of conventional, organic and GMO cultivation. Secondly, and directly related to it is the need to establish a GMO traceability and certification system that responds to the particular requirements of the target markets of our exports and the national norms. Both have repercussions on Chile's image as a GMO-producing country, besides requiring inspection systems and public-private agreements to guarantee the fulfillment of the corresponding norm.

This means that in addition to the technical and operative complexities of agricultural coexistence, the costs of a segregated, documented and certified commercialization has to be counted in. However, it should be mentioned that in the case of Chile the possibilities of a future GMO production lie particularly in the vegetable and fruits sector and in the forestry sector, whose exports are not subject to the problems of follow-up or segregation faced by countries which produce grains or cereals, exported as commodities. Thus, in these fields, a future system of traceability would be feasible and, if installed at the beginning of the production, would not generate the same costs as its subsequent imposition.

On the other hand, and with a view to the Cartagena Protocol, it has to be considered that the requirements for the import of GMOs and their products imposed by the European Union, and now by the United States through the Bioterrorism Act, are stricter and more extensive than the demands of the documentation of the Protocol; therefore, it is probable that the Chilean farming and export-oriented sector will have to assume the costs associated with these requirements, independently of whether or not the country ratifies the Protocol.

#### 6.5.2 RECOMMENDATIONS OF THE CNC

It is the majority opinion of the CNC<sup>45</sup> of the UNEP-GEF Project that inspection and surveillance in the matter of biosafety, being essential links in the risk management system, should be strengthened and become permanent activities of the authorities, especially as the GMO activities in the country are increasing.

Therefore, at the time of legislating on the matter, the following will be important:

1. That the Bill of Law on Biosafety includes the monitoring or inspection of GMO-R+D laboratories as well as the establishments which produce or process GMOs, or, if necessary, enforce compliance with the corresponding biosafety measures;

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<sup>45</sup> The FSS did not agree on these recommendations, which are based on the assumption of a higher acceptance and regulation of GMOs in the future, as they consider that this scenario can change and that monitoring and surveillance are necessary activities to maintain the country GMO-free.

2. That the Bill of Law on Biosafety, or any other future legislation on the matter, delegates the technical and inspection agencies to carry out surveillance actions on the potential effects of GMOs on human health or the national biodiversity;
3. That only the use of GMOs or biotechnological events are authorized in animal food if they have been approved for human consumption. For reasons of technical feasibility, a differentiated authorization of these GMOs is not considered prudent, due to the high probability of a change of their use;
4. That in the responsible institutions<sup>46</sup>, the human and technical resources are strengthened, as well as the regional and customs capacities destined to monitoring and control actions, considering in particular the needs of the SAG, which will be in charge of the border control in many entry ports of the country (by land and air), and the increased demand for the inspection of R+D premises;
5. That progress is made in the training of specialized personnel in all authorities with inspection attributions, in particular the National Customs Service.
6. That, to the extent that the demand for GMO analysis increases, an authorization is given to perform detection processes in other institutions, especially to the SAG<sup>47</sup> and SERNAPesca, and to demand from those delivering these outsourced services to use techniques in conformity with international standards.
7. That internally, a specialized unit is created in the ISP to tackle the GMO theme, to centralize and verify all the information referring to the analysis of data presented by stakeholders, for food as well as drugs, and that it is given the capacity to carry out experimental tests requested by the Ministry of Health in conformity with a future technical norm on GMO foods and others.
8. That it is guaranteed that the internal (intra-institutional) coordination becomes more effective and integrated, as now the distribution of functions (regulatory, administrative, evaluating, inspection, etc.) defined for the main sectors (agriculture, fishery and human health) is dispersed.
9. That, when enforcing sanctions for unauthorized GMO activities or use of biotechnological events, infractions implying GMOs or events which are not submitted to the due assessment and authorization process are distinguished from infractions following a denial of authorization by the competent authority. Clearly, the second case deserves a higher penalty.

It is a consensus in the CNC of the UNEP-GEF Project that the prevention of the change of use for GMOs or *biotechnological events* authorized in the country will also be a key element in risk management; the responsibility for this will fall on private actors using GMOs as well as the public entities authorizing their use.

For this reason, it will be important that:

1. A tentative analysis on the possibility of a change of use for each type of GMO submitted to an assessment is incorporated early into risk assessment, considering that situations may arise when a product, for systemic reasons or due to negligence related to the stages of the production chain and/or processing, is destined to another use. Thus, the assessment will be comprehensive and the authority will be granted for a particular use or activity.

It is the majority opinion in the CNC<sup>48</sup>, that in view of the needs for GMO follow-up in a scenario of agricultural coexistence in the country, it will be the task of every sector of the society to make greater efforts in those risk management aspects with a high technical complexity and long-term implications:

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<sup>46</sup> There is a different appreciation of the needs of the SEREMIs de Salud in these processes, as these institutions were not incorporated into the study on institutional biosafety capacities, because the re-structuring of the Ministry of Health and its central and regional dependencies had not yet been implemented at the moment of this study

<sup>47</sup> At present, the SAG is building a framework for the drafting of a future Regulation on Accreditation, which considers the technical requirements and the practices to be used by the applying laboratories.

<sup>48</sup> The FSS did not agree with these recommendations as it considered that agricultural coexistence is not possible with the country's present capacities, and that the best option is to declare the country GMO-free, or alternatively define GMO-free zones.

1. Collecting elemental information and making long-term studies to begin to know about, discard or reaffirm the great uncertainties around GMOs. It is essential that the inspection and monitoring of GMOs and the biosafety research, more than trying to qualify these organisms as beneficial for or adverse to biodiversity, be performed with a view to studying the biological processes determining potential impacts and the effectiveness of the demanded biosafety measures;
2. Strategically promoting local research in the field of biosafety and the specific impacts of GMOs, their genetic behavior and evolution in the agriculture and the national ecosystems;
3. Encouraging a new round of discussions on agricultural coexistence and the establishment of a corresponding framework (voluntary or normative), taking into account the Ministry's advances and proposals on this issue.
4. Studying, with the participation of the Ministry of Foreign Relations, Ministry of the Economy , Chile Foundation and other sectorial actors, the implications and costs of incorporating or associating the requirements of documentation in Article 18 of the Cartagena Protocol (section 2(b) for GMOs destined to be released into the environment, as well as section 2 (a) for GMO foods) into the TrazaChile system, which is currently being created.

## **..CHAPTER 7..**

### **MECHANISMS OF PARTICIPATION AND ACCESS TO INFORMATION ON BIOSAFETY**

## MECHANISMS OF PARTICIPATION AND ACCESS TO INFORMATION ON BIOSAFETY

### 7.1 - INTRODUCTION

The complexity of public decisions and their synergy effects have created the need to articulate mechanisms to channel public participation in public decision-making processes. Timely access to adequate information constitutes an essential element for this articulation. To achieve a view on public participation and access biosafety information as a whole, the most relevant national and international instruments on this matter were studied by the CDA<sup>49</sup> (2004) in the framework of the UNEP-GEF framework.

The regulatory and political frameworks existing in the field of GMOs are very limited and so are, as a consequence, participation and the accessible information. It is essential to analyze them, as they are of a more general nature but treat public participation as a cross-cutting theme of public administration. These frameworks allow the application of a perspective of "accountability" of decisions and commitments assumed by the State, while reflecting the political will behind the promotion and recognition of public participation and access to information.

Due to their more indirect connection with biosafety, these frameworks will not be dealt with more extensively here; rather, attention will be focused on the relevant sectorial frameworks (environmental, agricultural and nutritional) and on the form in which public participation is handled, detailing institutional and instrumental aspects of the respective legislation. The contributions of the UNEP-GEF Project will also be examined as to public participation and biosafety information, as well as the recommendations of the CNC of the Project on those themes.

As to the way access to information is treated in this Chapter, it can be dealt with from different angles, for example the public's right to access information, stipulated by the State as a form of control and verification of the background of governmental decisions. However, this perspective implies an *ex post* participation faced with already established facts, and requires the use of constitutional actions for the safeguarding of some fundamental rights, such as appeals for legal protection, or other legal actions such as an appeal against denegation of access. Even if in Chile these means have had a certain impact and effectiveness in environmental matters, they are not included in the concept of access or exchange of information, as defined by the Cartagena Protocol, so that this particular aspect of access to information will not be treated in this Chapter.

### 7.2 - GENERAL FRAMEWORKS

The fact that public participation and access to information are becoming more and more part of the general rules stipulated for a range of issues related to public administration generates a favorable scenario for the incorporation of elements of participation on biosafety matters, either through the ratification of the Cartagena Protocol or the possible future promulgation of a Law on Biosafety.

These general frameworks can be quoted in the following order; the most important achievements, from the point of view of chronology or legal hierarchy are Law N° 19.880 and the specific Policy on public participation:

- . Convention on Biological Diversity
- . Law on the General Bases of State Administration
- . Law on Administrative Probity (Law N° 19.653)
- . Law on the Fundamentals of Administrative Procedures (Law N° 19.880)
- . Environmental Policy for Sustainable Development
- . Public Participation Policy

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<sup>49</sup> The study is titled "Assessment of regulatory frameworks, institutionality and national trade obligations in relation to the biosafety protocol and of public participation mechanisms for environmental decision-making" (CDA, 2004), available at: [www.bioseguridadchile.cl](http://www.bioseguridadchile.cl)

## 7.3 - SECTORIAL FRAMEWORK

### 7.3.1 AGRICULTURAL SECTOR

#### *Regulated Participation*

i) Resolution N° 1.523 Resolution No. 1.523 of the SAG establishes a procedure to authorize the release of the plant LMO GMO into the environment, explicitly stipulating mechanisms of public participation. It can be affirmed that these mechanisms are fully in line with the provisions of Article 23 (2) of the Cartagena Protocol.

The procedure starts with the submission of a request for the introduction of plant LMOs into the country and their release into the environment, which has to be accompanied by supplementary information and an extract with specific background information. The Resolution requires that the information included in the extract be submitted *"to public consultation through its publication, by the applicant, in the Official Gazette, with a copy of this publication to the Livestock and Agriculture Service"*.

This public consultation allows any interested person to present, within a term of 15 days after the date of publication in the Official Gazette, his/her substantiated observations on the application in writing before the SAG. These observations must be taken into account by the SAG in the evaluation of the application.

Of course, the participation resulting from this simple procedure is based on an "advertisement" and depends on the periodic revision of the Official Gazette by those who are interested in publications on GMOs. Nevertheless, this allows access to essential information which could support later observations on their part. These observations have to be "substantiated", which implies that arguments have to be given to justify the observations in order to guarantee the seriousness of the process.

In short, this Resolution includes participation mechanisms at different levels, offering a window to interventions by third parties in the decision-making process and allowing access to specific information used in the evaluation and providing a procedure for appeals, even if only on part of the applicants. The inclusion of all these aspects into a limited and well-structured framework has allowed to transparently and predictably articulate the SAG's procedure for the evaluation of and resolution on LGMO-related applications.

ii) Advisory Committee: There is an instance which could be regarded as a modality of participation, articulating different visions and approaches in the SAG's decisions on GMOs: the Advisory Committee on the intentional release of GMOs into the environment, created to advise the National Director of the SAG in the "informed resolution" of the applications it receives.

In addition to the SAG experts, the Advisory Committee brings together different academic and multidisciplinary experts of high scientific level, who do not seek to represent nor defend specific interests in the cases they evaluate.

Although the Resolution creating the Committee does not specifically indicate so, it can be derived from it that these scientific experts can be invited *ad hoc* or regularly to the Committee, so as to participate in the discussion of specific themes related to their respective specialization. The constitution of this Committee, which is not compulsory for the Director of the SAG, could be an example for the opening of participatory spaces for decision-making on GMO-related matters, even if certain requirements have to be respected, such as confidentiality and impartiality.

#### *Access to Information*

By publishing the extract of the above mentioned application in the Official Gazette for public consultation, it becomes possible to access to part of the information managed by the SAG for decision-making. The information which may be published is indicated in Article 28.b) of Resolution 1.523; however, it is the supplementary information defined in Article 29 which permits the SAG to collect all necessary background information to carry out the risk evaluation. Thus, the public has no access to certain categories of information, among it, the location of the sites or areas where the GMO tests are taking place - this information is kept confidential because it is considered of commercial interest.

*Resolution 1.523 (SAG) -- Article 28 b) -- Content of the Extract to be published:* 1) applying entity; 2) Port of Entry; 3) Variety, line or race, scientific and common name of the Modified Organism; 4) Introduced genetic modification; 5) Transformation event; 6) Type of license requested; 7) Objective of the requested license; 8) Region of destiny in the country; 9) Authorization and previous registration.

There are no other channels available to the public to access additional information, except through lawsuits. Of course, there is an emblematic case in Chile, already cited at the beginning of this report, which brought the limits and conflicts in the management of private information by the State before the public eye: its dissemination could have compromised the interests and safety of the implicated companies, which constitutes an important precedent in the matter of judicial actions.

### 7.3.2 HEALTH SECTOR: FOOD FOR HUMAN CONSUMPTION

#### *Regulated Participation*

As to food, the main body of regulations referring specifically to LMOs are the Food Health Regulations, Supreme Decree N° 977/96 of the Ministry of Health. This Regulation does not establish instances for direct public participation, although as regulations of the Health Code, its stipulated procedures and instances for the presentation of protests and dockets are applicable, if these mechanisms are used to protect rights which are possibly violated, but not truly participatory instances to intervene in decision-making processes (such as is the case of Resolution 1.523 of the SAG).

#### *Non-Regulated Participation*

The Ministry of Health is developing a similar initiative to the SAG's through the *Committee for the Revision of the Food Health Regulations*, composed of diverse levels of productive and academic sectors, such as the Society for the Development of Manufacturing (SOFOPA) and consumer associations, with a view to collect the opinions of the sectors interested in the reform of this Regulation (Supreme Decree 977/96).

The regular and permanent functioning of this multisectorial work group<sup>50</sup>, created in the year 2001, has helped to articulate an open and continuous discussion on the subject of food health, including topics related to the Cartagena Protocol and its treatment of LMO-foods, and the definitions of the Codex Alimentarius as to foods produced through technological means.

#### *Access to Information*

The most relevant body of laws on food-related information is *Law N° 19.496 on the Protection of Consumers' Rights*. One of the fundamental rights stipulated in this law is the "right to information", laid down in Article 3, stating that consumers have "*the right to a truthful and timely information on the goods and services offered, their price, contract conditions and other characteristics which are relevant for them, and the duty to inform themselves responsibly about them*", as well as the right to a "*safe consumption of goods and services, the protection of health and the environment and the duty to avoid any risks.*"

Another relevant element for consumers' access to information is the "labeling requirement". In the case of the commercialization of goods subject to labeling norms, Law N° 19.496 stipulates the obligation of adequate compliance with the labeling norms. In the case of food, this obligation is established in the Food Health Regulations.

There is an ongoing debate on the labeling of GMO foods, on the one hand in connection with the exercise of consumers' rights and, on the other, with the need to inform on sanitary aspects of these foods. The former aspect, the right of a consumer to know what he or she ingests, has aroused a heated debate on the utility and relevance of information on the presence of a biotechnological "event" in a food product after it has

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<sup>50</sup> It is composed of: 2 representatives of the academic community, 2 representatives of the industry, 1 representative of the consumers, 1 representative of SERNAC (Ministry of the Economy), 2 representatives of the ISP, 2 representatives of SESMA; and of the Ministry of Health: 1 representative of the Nutrition Unit, 1 representative of the Legal Department and 2 representatives of the Environmental Health Department.

been duly authorized in conformity with sanitary regulations. As to the second aspect, the sanitary label would not inform on the "biotechnological" origin of a particular food item, but on its nutritious or quality aspects in comparison to the same but non-modified food item. Thus, only the lack of "*substantial equivalence*" would motivate the description of the nutritional benefit of the "improved" food item on a sanitary label, in the case that this "improvement" is not present in the corresponding conventional product.

### 7.3.3 ENVIRONMENTAL SECTOR

The main spaces for community participation on the internal processes of State administrations can be found in the field of environmental management, specifically through Law 19.300 on the *General Law on the Environment*. This law establishes the precept that public participation must be taken into consideration in the definition of environmental policies and in the development of the environmental management. It recognizes the right to information, environmental education and judicial action, as well as the establishment of various specific spaces for the community to participate in the decision-making processes.

Since GMO-releases into the environment are not regulated under this legal framework, we will only mention here, briefly and as an example, the formal instances and the modalities of participation based on the environmental management instruments established by Law N° 19.300.

Among the formal instances, the *Consultative Council*<sup>51</sup> should be mentioned in the first place as an advisory body with the competence (among other functions) to deliver opinions on the bills of law and norms for environmental quality and conservation, and to resolve the consultations formulated by CONAMA; and secondly, the *Council for Sustainable Development*, which has a broad representation and acts as an advisory body to the President, essentially for studies and proposals of actions to foster and safeguard sustainable development.

In spite of not being addressed in Law 19.300, biosafety aims at saving the natural heritage (biodiversity), which indeed is a subject matter of this law, and this theme has been a concern for both Councils, in particular the *Council on Sustainable Development*, which has emphasized the importance of its regulation. Although the recommendations of these Councils are not binding, the creation of legitimate spaces for intervention and social discussion through Law 19.300 is recognized as a great step forward.

Likewise, the instruments with participatory modalities derived from this Law deserve to be mentioned, because they support the right to information and participation. The first is the *System of Environmental Impact Assessment (SEIA)*, administrated by CONAMA. With its help, the environmental impacts of investment projects are assessed, and prior to the authorization of their activities, the conditions and measures for the control and mitigation is determined. This system includes formal spaces for the general public to obtain information about the contents of the Environmental Impact Assessments and make their own observations. The second example are the processes of dictating environmental norms, which, in conformity with Law 19.300, have to gradually incorporate consultations with competent public and private agencies, the analysis of formulated observations, as well as adequate publicity.

## 7.4 - CONTRIBUTIONS OF THE UNEP-GEF PROJECT

The contributions of the UNEP-GEF Project in the field of public participation can be distinguished at two levels: In the first place, there are the participatory spaces provided during the Project execution itself, which generated positive experiences and advances towards more plurality and a higher degree of participation in the national discussion on biosafety; secondly, there are those activities which were carried out through the Project, with the purpose of stimulating dialog and an exchange of opinions between "citizens" and "experts", or facilitating access to information on biosafety.

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<sup>51</sup> It has representations in about 13 regions of the country and is conformed mainly of scientists, scholars, environmentalist NGOs, businessmen, plus a representative of the President of the Republic.

*(a) The Project Committee*

The CNC is a good example of a positive experience of multi-sectorial participation, which generated a platform for encounters and coordination highly appreciated by those participating. It was able to consolidate itself into a formal, but friendly work instance, where decisions are openly shared and discussed, and where the diversity of visions is seen as a potential. This instance was recognized as a contribution to participation, as it was the first public-private committee, formed by the Government to address biosafety issues, where all actors participated under equal conditions.

The fact that the CNC was constituted on the foundations of a pre-existing governmental committee, into which various members of the CNDB, created by the Ministry of the Economy to formulate the bases for the Biotechnology Policy, were integrated. This ensured a high level of continuity and agreement with the previous political work and an effective use of the existing expertise and personal and institutional relationships. It also integrated civil society organizations (acting in defense of the environment or consumers' rights) and entrepreneurial sectors which oppose the application of transgenesis for productive uses, and which had been absent in the two previous instances.

*(b) Debate seminars*

At the end of 2003, the UNEP-GEF Project carried out two open seminars in different towns (Santiago and Concepción), both titled "A National Biotechnology Policy: the Challenges of Biosafety". In the first seminar in Santiago, the convocation was very broad and a particularly high attendance was reached (more than 170 persons); participants came from all kinds of sectors and almost all regions of the country.

In addition to Santiago, the city of Concepción was selected for the second seminar, as it is the regional capital with the strongest momentum in the matter of biotechnological development, and the Regional Government and the University of Concepción are actively seeking to position the theme as an opportunity for regional development. Although with a smaller audience, this seminar counted with the presence of regional authorities and integrated local scholars linked to biotechnology into the panel.

Both seminars placed an emphasis on the stimulation of a debate between the assisting public and a panel of experts, more than on the rhetorical and passive dissemination of information. Its interactive style marked an innovative form to communicate these themes to the general public.

These events constituted landmarks in the execution of the UNEP-GEF Project, because they not only helped to highlight the project itself, setting this and other governmental initiatives onto the public arena and achieving press coverage for both cases, but they also reflected a growing maturity in dealing with the problem, a greater knowledge and the accomplishment of more work - and, especially, a greater openness on part of the Government to deal earnestly and publicly with an issue of uncertain, complex and subjective nature, which has been difficult to resolve at the national level.

*(c) Data bases*

Generated by the UNEP-GEF Project and accessible through the website [www.bioseguridadchile.cl](http://www.bioseguridadchile.cl), these data bases constitute an example for interactive products destined to foster the publics' interest in biosafety, as well as their interest to keep informed. These two databases provide broad and unbiased access to updated and specialized information on aspects of national biosafety, studied by local experts.

Even though the information is highly technical and detailed, it concerns our native species as well as the biotechnological research made in the country, and thus it is probable that their subjects awaken specific interests, especially of those who look for information on the advances and the know-how produced in the country in the last years.

The availability of this information through internet also responds to the growing use of technological means, such as in educational and municipal establishments and in State management, to facilitate access to specific information.

## 7.5 - RECOMMENDATIONS ON PARTICIPATION AND INFORMATION

### 7.5.1 RECOMMENDATIONS OF THE CNC: PUBLIC PARTICIPATION

It is the consensus of the CNC of the UNEP-GEF Project that public participation in the matter of biosafety has to be effective and pluralistic, in order to contribute to the administrative and strategic decisions of the authorities on GMO use in the country.

Therefore, the following recommendations are made:

1. To fulfill the specific objective<sup>52</sup> of Biotechnological Policy in relation with public participation, in order to enhance the transparency and credibility of the biosafety regulations.
2. That the future biosafety legislation should establish the obligation of creating formal and transparent instances, as well as opportunities for participation, for example through public consultations before the authority makes the corresponding risk analysis, in order to allow stakeholders to get informed and intervene in the sectorial decision-making processes prior to the final resolution. These consultations are a decisive opportunity to receive comments which make an effective contribution to the decision-making process.
3. The participation modality should be, at least, equal to today's consultation procedures of the SAG in the framework of Resolution 1.523 or of the SEIA in the framework of Law 19.300, but it should also establish the requirement disseminate the contents of this application and its background on the internet through the future national system of information, in addition to the publication of the application extract in the Official Gazette<sup>53</sup>.
4. The Biotechnology Forum should be soon legally constituted, regardless of the advances made in the biosafety legislation, as this is one of the priority actions on the Action Plan 2004/2005 of the Biotechnology Policy.

The Biotechnology Policy designates the Biotechnology Forum as an instance of participation and consultation to open a permanent dialog between the authority and the "users" of biotechnology, with a clear role in the establishment of new biotechnology regulations, a function which is highly opportune in the light of the current legislative efforts<sup>54</sup>.

If the mission of the forum is the promotion of a pluralistic and impartial public debate on the challenges of biotechnology and biosafety in Chile, its constitution should respond to the following criteria:

- a balanced and equitable sectorial representation
- the invitation to the business sector has to include Chilean enterprises as well as branches of international companies
- the Invitation to the academic and scientific sector should include specialists in transgenesis /genetic engineering and other forms of applied biotechnology, in addition to specialists on the conservation of biodiversity
- the invitation to the civil society should include, at least, environmentalist and consumer rights organizations
- the appointments should be as representational as possible
- membership should be renewable for periods of not more than three years

### 7.5.2 RECOMMENDATIONS OF THE CNC: ACCESS TO INFORMATION

It is the majority opinion of the CNC of the UNEP-GEF Project that, in order to guarantee a higher transparency in biosafety management, the authorities should establish clear and homogenous rules

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<sup>52</sup> One of the four Specific Objectives of the Biotechnology Policy states the following: "To design and implement an institutional framework which ...[will allow to] open spaces for participation and public information to help create informed citizens, which in turn will guarantee a higher transparency in decision-making and more effective government policies and actions promoting the development of biotechnology." (CNDB, 2003)

<sup>53</sup> From that moment, any natural or legal person can study the contents of the application and formulate observations, and the administrative terms to interpose observations and consideration by the competent bodies are counted from the date of publication. The publication on the internet in the information system is intended for a more general dissemination.

<sup>54</sup> It has been pointed out that this Forum will not only guarantee the quality of the public debate on the development of biotechnologies in Chile, promoting the delivery of information, carrying out surveys and organizing plenary sessions and specific work groups, but it would also be consulted by the Committee for Biotechnology Regulations prior to the promulgation of new biotechnology standards, as a form of guaranteeing more transparency and a higher level of participation in the regulatory decisions.

about what information will be made public character in the future national biosafety system.

Therefore, it is important:

1. That each CNA consider that, once the Cartagena Protocol is ratified, a great part of the information submitted to the national system will be subsequently accessed from any country through the BCH's central web portal;
2. That each NCA should define which information to make public, which to submit to the system and which shall be confidential, withdrawn from public knowledge on the request of the applicant. Articles 20 and 21<sup>55</sup> of the Protocol offer one guideline on these categories of information, indicating which information has to be sent in by the Parties to the BCH, thus keeping it unrestricted.
3. That the public information contained in the national biosafety system is updated, not written in a overly technical language, presented in a simple and user-friendly way, including information on the applications for the authorization of GMOs submitted to the CNA, indicating which are being processed and which have already been resolved (approved or rejected), and including the lists of biotechnological events (GMOs) for human consumption which have been processed in the country, indicating approvals as well as rejections.

It is the majority opinion of the CNC of the UNEP-GEF Project that the consumers' rights to obtain information on foods containing biotechnological events are included within the precept of "access to information", and that food labels constitute a way of delivering this information.

In the CNC, no agreement was reached on this matter; among other things, the entrepreneurial sector considers that the labeling of GMO foods could represent an unnecessary trade barrier, and the Ministry of Foreign Relations (DIRECON) estimates that it is preferable to see how the labeling issue is solved at the international level before taking decisions which could affect the international commitments acquired by Chile. Contrary to the debate on labeling for sanitary reasons, the debate around GMO-labeling arise from the defense of diverging and irreconcilable interests and could reach a freezing point in the parliamentary review of the Bill of Law on the Biosafety of GMOs.

In virtue of the aforementioned points, the following recommendations represent a preview of the topic which will doubtless surface in the deliberations on the institution of consumer-oriented labeling regulations, based on the assumption that these rules and their treatment as a legal matter will be considered as convenient by Congress.

1. If a regulation on labeling is implemented by a biosafety law in order to inform the consumer on food products containing biotechnological events, it should include at least the following:
  - a. The legal requirement of a previous sanitary approval by the Ministry of Health for such events
  - b. The legal requirement that the information on the label has to be truthful, objective, clear and useful for the consumer, as well as supported by scientific and technical information
  - c. The definition of the important specifications for the labeling regulations, such as thresholds to determine whether a product classifies as "biotechnological" or not, and the systems of verification and accreditation of enterprises making sample analyses.
2. The Ministry in charge should carry out a participatory process to define what should be indicated on the labels of GMO products.

Finally, the following information represents the opinion of the National Coordinator of the UNEP-GEF Project:

3. There has to be clarity on what kind of food categories are exempt from labeling, for which it will be necessary to determine factors of proportion, processing and feasibility of the detection of events, as the picture is very different for combined foods, GMO ingredients, products derived from GMOs, additives and flavorings produced with GMOs.

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<sup>55</sup> Article 21, and in particular section 6, indicate the information that countries may NOT keep restricted: a) The name and address of the notifying person (applicant); b) a general description of the GMO or GMOs; c) a summary of the risk assessment (of the environmental area, always taking human health into account); and d) the methods and plans for a response in the case of an emergency.

## **..CHAPTER 8..**

# **DISSEMINATION OF AND AWARENESS-RAISING ON BIOTECHNOLOGY**

## DISSEMINATION OF AND AWARENESS-RAISING ON BIOTECHNOLOGY

### 8.1 - PUBLIC OPINION ON BIOTECHNOLOGY AND GMOs

#### 8.1.1 INTRODUCTION

As we have mentioned before, the opinion of Chilean society on biotechnology and GMOs cannot be described as positive; but then, it has not yet been extensively examined: only two studies have been made on this subject to this date.

The first one, carried out by Cambiotec-Chile during the year 2000 and the beginning of 2001 (Gil et al., 2001)<sup>56</sup>, made a survey among home-makers in 300 households of Santiago de Chile in four social classes and focused on the following aspects of biotechnology and GMO-derived foods: information sources, benefits and probable risks, regulatory entities, production, commercialization and consumption.

On the basis of this survey, it could be concluded that the knowledge of the population on biotechnology and GMO-foods is very low, although the Chilean consumer is interested in biotechnology and would like to know more on its benefits and risks (97% answered affirmatively). Its main sources of information on the quality of foods were radio and TV programs and the products' labels. 78% of the interviewees believed that the use of biotechnology affected society; 20% agreed with the use of biotechnology for any kind of application (although medical applications were regarded more positively than applications on food); 64% estimated that biotechnology should be prohibited in the production of food (60% believed that consuming GMO-foods could produce cancer); and only 25% were willing to consume GMO-food.

The socio-economic level of the surveyed population was related to the degree of misinformation on biotechnology and GMO-foods, which influenced their perception of potential risks. The survey also revealed that the public perceives that the State does not fulfill its regulatory role efficiently and, even if it does, it gives no importance to the communication of information.

Another study (Hernández, 2002)<sup>57</sup> carried out in the year 2002 by the Technical Cooperation Network on Plant Biotechnology (REDBIO), and financed by the FAO, for which 400 consumers were surveyed in Greater Santiago (during their food purchases in commercial establishments), indicated that 64 % do not know the meaning of the term "biotechnology"; that 57% trust official sources such as the Health Ministry, and that 75% believe that GMO-foods should be labeled. Generally, the public had the impression that the government did not fulfill its regulatory role very well, and that there was no coordination between the State, the academic world and the business sector. Like in the previous study, it could be determined that the information on biotechnology and GMO-derived foods was mainly obtained through the "propaganda" of the mass media (68%).

Definitely, both studies revealed an undeniable lack of information among consumers of Greater Santiago on biotechnology, its advantages, disadvantages and applications. To the point that this deficit would explain why Chile, in comparison with surveys in other countries, holds the second place after Japan in terms of negative public opinion on GMO-foods (73% reject it).

As a result, the authors pointed out the need for a communication campaign, based on scientific knowledge and presented in simple words, to inform the public on the benefits, risks and uncertainties of using biotechnology and GMO-foods.

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<sup>56</sup> This study was also published in December 2001 in *Rev. Ambiente y Desarrollo*, vol.17 n° 4. p52-58.

<sup>57</sup> <http://www.rlc.fao.org/prior/segalim/prodalim/prodveg/paper.htm>

### 8.1.2 OPINIONS IN THE CNC

Public opinion was a subject of discussion in various meetings of the CNC of the UNEP-GEF Project; on these occasions, fears and warnings on the convenience of addressing this issue through the Project were expressed. There were divergent opinions at the time of defining whether it was necessary or appropriate to carry out activities of dissemination on biosafety and/or biotechnology, and whether it was not better to first study public opinion on these topics.

A strong point of discrepancy was the question whether these activities, of whichever nature, should focus on biotechnology, biosafety or GMOs. Without trying to compare these concepts, it was recognized that citizens were highly uninformed on the three of them, so that their dissemination presented similar challenges. But there was definitely no consensus on which information it was important to make public, nor on how to collect the views of the people. Thus, instead of carrying out public surveys, whose objectives it was impossible to define within the CNC, the decision was finally made to generate a methodological proposal, described further on in this document, to address the evaluation of national public opinion in the future (focusing on biotechnology and, in its context, on GMOs) and the communication needs related with it.

#### *Civil Society*

The main opposition to the mentioned study came from the FSS, due to its dissatisfaction with the form and the participants proposed to develop the study, as well as with its report, since they considered that it was pro-biotechnology and focused on the benefits of GMOs. Nor did it agree with the decision to focus on biotechnology instead of on GMOs exclusively. Following is the FSS's comment on the public opinion on GMOs:

*Public opinion on GMOs is a field which has been considerably distorted. There always is a tendency to think, erroneously, that the public is ignorant and misinformed. The results of the studies on public opinion are the product of public campaigns informing on the risks of GMOs; they also reflect the lack of confidence in the government and its regulations.*

*It is necessary to inform the public on GMOs without confusing them with biotechnology, which is a broader field, delivering non-biased information on the risks of these crops and foods for the environment, biodiversity and health, and referring to the reduced number of studies on this subject.*

#### *Government of Chile*

There is no doubt that the study of the public opinion on biotechnology is a task the Government has to carry out to achieve the long-term objectives of its Biotechnology Policy, and that the public opinion on biosafety and GMOs is highly dependent on the level of the understanding of biotechnology. Without first knowing the population's views on this subject, the government can hardly identify the most appropriate mechanisms to include it into the country's social agenda, nor sensitize the general public on the real facts around GMOs. It is from this perspective that the Biotechnology Policy faces the challenges posed by public opinion and proposes actions to address some of them directly, and that the UNEP-GEF Project tries to be coherent with the governmental needs in this field.

### 8.1.3 CHALLENGES POSED BY THE PUBLIC OPINION

Through its work in 2004, the CNDB could identify a set of challenges for the public authorities and the entities linked to the areas of education and social communication on the matter of dissemination and awareness-raising on biotechnology. These challenges, presented in the table below, exclusively reflect the Government's vision on this issue.

## CHALLENGES POSED BY THE PUBLIC OPINION ON BIOTECHNOLOGY<sup>658</sup>

1. *In the first place, the public perception on biotechnology is closely linked to the system of risk assessment and management associated with the production and use of biotechnological products. There is a need to improve the efficiency of the national and biosafety system and the consumers' trust in it. This effort helps to achieve a comprehensive view and to generate critical and balanced public opinions. Once the consumers have the possibility to integrate risk assessment into their daily life, society will lose the fear of the new, which is one of the basic reasons of opposition to biotechnology.*

2. *A second challenge arises from the field of scientific research and technological development. Public opinion on biotechnology is also linked to the national R+D capacity and to the solidity of public institutions in this field. In other words, the perception is more positive when the national institutions (and particularly the public sector institutions) are the ones who to lead technological innovation and to assess risks, and not only multinational companies, and when not only experiences from other advanced countries are replicated. It is, thus, necessary to strengthen the national capacities for technological innovation and the technical capacities in the public sector and to support the cooperation between the public and private sector in this field, in order to increase the publics' confidence in national expertise. It is necessary to promote dynamic national enterprises as well as the bidirectional flow of know-how between enterprises, universities, research centers and the public sector.*

3. *In the third place, the public debate has to be aimed not only at today's biotechnological products, but also tomorrow's; i.e., it needs a future-oriented perspective in order to anticipate the technical advances as well as potential future challenges or inconveniences. These advances could radically modify the obtainment of biotechnological products, and thus diminish or eliminate some real or hypothetical risks currently linked to them.*

4. *The fourth challenge belongs to the field of information: citizens have to be informed with more effort than before. The public R+D sector must be more effective in trying to reach the different sectors. The scientific community must contribute a clear and truthful information on health and environment and on the benefits and precautions which have to be considered in each biotechnological application and in each product. The concerns of citizens and the socio-economic and cultural impacts must not be ignored or dismissed. It will be necessary to define and activate the mechanisms which allow scientists to participate in adequate and timely information processes.*

5. *Finally, the task of informing and educating is indeed indispensable, but neither its difficulties nor the necessary resources must be underestimated. Only a set of national policies including information and education and other actions which help to form opinions (such as the knowledge on the implications and benefits of food chains, transparency in the incentive policies for different technological sectors) can result in a correct public opinion on biotechnology. To develop this task of training and educating the general public at all levels, it is indispensable to have updated and trustworthy information on the advances of biotechnology policies as such, and the people's perception of them. Thus, it is extremely important to carry out qualitative and quantitative studies to obtain this information timely and truthfully. National decision-makers such as politicians, entrepreneurs, members of parliament and judges have to be taken into account in the information efforts. These segments of the public opinion must be the prioritized addressees of any activities of dissemination and education on biotechnology.*

### 8.1.4 INITIATIVES FOR DISSEMINATION AND AWARENESS-RAISING ON BIOTECHNOLOGY

The most significant initiative in the area of dissemination and public education on the matter of biotechnology stems from the Explora Program for the Dissemination and Evaluation of Science and Technology, subordinated to the CONICYT ([www.explora.cl](http://www.explora.cl)). It was created in 1995 (and is therefore unrelated to the UNEP-GEF Project) as a national and permanent initiative to contribute to the generation of an innovative and participatory attitude in the population, in particular among children and young people, towards scientific and technological innovations.

It is executed through different means, the most visible being periodical advertisement campaigns with

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<sup>58</sup> Extract of the Report to the Chairman of the National Committee for the Development of Biotechnology (CNDB, 2003)

numerous posters on public transportation means, as well as the annual Science and Technology fairs dedicated to a special scientific or technological theme, which draw a great number of young people (pupils and students). In 2004, the fair was dedicated exclusively on biotechnology in the Explora Program, which helped to highlight this theme enormously and to introduce it as a high-priority area of biological science for Chile.

However, as the Biotechnology Policy emphasizes, it is evident that at the time biotechnology R+D is fostered and the regulatory framework for biosafety is consolidated in order to turn biotechnology into a tool for national growth, it is also necessary to strengthen and stimulate existing public programs for scientific-technological dissemination and education, such as the Explora Program, the Interactive Mirador Museum, dissemination programs of the FIA and regional programs; it is pointed out that these have to address the multiple aspects of biotechnology and highlight its basic elements, tools and applications as well as its benefits and risks.

In this sense, the Government of Chile feels that the propositions of the Biotechnology Policy to strengthen programs which contribute to the dissemination and public education on biotechnology, or to include biotechnological themes into other programs for scientific-technological dissemination and education, coincide with the proposals for a potential future National Biosafety Framework, since in order to understand biosafety and GMOs, it is first necessary to build awareness on biotechnology and its applications.

However, this opinion is not shared by the FSS, a member of the CNC of the UNEP-GEF Program; this organization rejects the dissemination of the Explora Program, because it considers it entirely in favor of biotechnology and transgenesis, and criticizes the lack of public consultations. In change, it highlights the actions of *Greenpeace*, such as the campaigns of public dissemination and public surveys, as well as those of the *Network for a GMO-free Chile*, formed by more than 20 environmental, consumer and agricultural farmers' organizations. In the years 2004 and 2005, this NGO organized a national campaign to inform consumers on GMOs and on the need for labels on GMO-derived products, gathering around 10000 signatures in favor of the mandatory labeling of these foods.

## 8.2 - CONTRIBUTIONS OF THE UNEP-GEF PROJECT

The UNEP-GEF Project made various contributions to the dissemination and follow-up needs as to public opinion on biotechnology and biosafety; among others, the creation of a web site on biosafety and the generation of proposals on how to evaluate public opinion on these subjects. These inputs constitute punctual contributions, and never intended to satisfy all dissemination, education and sensitization needs implied by the incorporation of these themes into society, or to take responsibility for the corresponding provisions of the Biotechnology Policy. Its purposes were, basically, to take a highly specialized topic to the public arena and offer a series of inputs for the formulation of public policies in the fields of biotechnology, biosafety and conservation of the genetic heritage.

### (a) Web site

The objective was the preparation of information material on biosafety and its advances at the global as well as local level, and its presentation through a new web portal. As mentioned before, this site gathers all the results of the UNEP-GEF Project, and its web address is: [www.bioseguridadchile.cl](http://www.bioseguridadchile.cl)

The contents of the site have been developed with an impartial view and exposed in a simple language, which can be understood without the need for previous knowledge on the issue. Thus, the community is informed on biotechnology, GMOs, biosafety, the Chilean Government institutions involved, on-going initiatives, the Cartagena Protocol, citing the UNEP-GEF Project as one of various initiatives leading to a better management of the responsible use of GMOs.

It was decided not to give this site an institutional identity associated to the CONAMA, but a more independent character, for which reason it has its own logo as well as the URL [www.bioseguridadchile.cl](http://www.bioseguridadchile.cl), in spite of being hosted on the CONAMA server.

In addition, all written contents were submitted to a previous evaluation by the CNC of the UNEP-GEF Project, to ensure the fulfillment of the objectives of impartiality and education, and the absence of one or the other position on subjective issues which would result into unduly biased approaches.

For these reasons, the text of the website was approved by all the members of the CNC, with the exception of the FSS, an NGO which explicitly expressed its inconformity with the contents and focus of the program, because it considered that they did not adequately reflect its position on GMOs, nor the joint vision of the CNC of the UNEP-GEF Project. With the purpose of healing this divide, it was agreed that the web portal would include an explanatory note stating the FSS's inconformity and its arguments.

The site also contains all the technical documents and reports resulting from the studies which were carried out in the framework of the UNEP-GEF Project, in addition to the biosafety legislation in force, a news section, a calendar of interesting events, a glossary of terms and links to other interesting websites.

#### *(b) Information leaflet*

On the basis of the graphics and written material produced for the web portal, the UNEP-GEF Project, with the support of other sponsors, produced a simple and explanatory information leaflet destined to a broad public with little knowledge on GMOs, biotechnology or biosafety.

The intention behind this leaflet was merely to awaken the interest of people who are only marginally touched by the national discussion on biosafety and, maybe, are not so skillful in the use of the internet - people who have not yet formed an opinion on GMOs, nor intend to study specific facts about biosafety, but who might display a certain degree of curiosity towards this innovative issue.

Its contents offer a 12-page summary of the same themes dealt with in the web portal, inviting to visit the web portal for more information and using a more playful style of presentation and a 4-color design with images. Its publication was financially supported by CORFO because of the interest this institution has to promote a higher public knowledge on the more "daily" applications of biotechnology.

Its national distribution was made through the regional offices of CONAMA (present in 13 regions of the country), which used the leaflet for their own purposes and distributed it to the schools and municipalities with which they work regularly.

#### *(c) Thematic seminars*

At the end of 2004, the UNEP-GEF Project financed an international seminar of dissemination, dedicated exclusively to the Cartagena Protocol on Biosafety, in order to make it publicly known, including the advances and the experience acquired after one year of its international entry into force. The details and presentations of the seminar can be found at [www.bioseguridadchile.cl](http://www.bioseguridadchile.cl)

The idea of holding this seminar rose spontaneously at the request of the CNC of the UNEP-GEF Project, as a manifestation of its interest to know more about the contents and implications of this international agreement, vis-à-vis the possibility of its ratification in the future. An open encounter of this kind also responded to the mandate given to CONAMA by the Biotechnology Policy to foster a multi-sectorial discussion about the Cartagena Protocol, thus creating favorable conditions for the development of a stand on its ratification in the future.

The encounter, which had an eminently academic character and was sponsored by the University Diego Portales, took place with more than 100 people, and included lectures of experts from Mexico, the European Union and Argentina, who presented the forms in which their countries had approached the implementation of the Protocol and the growing market demands in practice. The event was also attended by renowned local experts and a member of parliament with knowledge on themes related to new technologies and their regulations.

The presentations contributed to highlight the primary material for the trade and exchange of biotechnological products, emphasizing to what degree the rights and obligations stipulated in the Cartagena Protocol, or in national or regional GMO-regulations, include economic considerations for those who entertained these trade relationships.

At the beginning of 2005, the UNEP-GEF Project also carried out an event with national experts linked to biotechnology, bioprospection, the conservation and investigation of native genetic resources, their public management and their funding.

The objective of this encounter was not only dissemination, but also the creation of an opportunity to share visions and projections on the relation between the country's biotechnological development and the conservation, use and valuation of native genetic resources, as a contribution to the potential National Biosafety Framework and the Plan of Action of the National Biodiversity Strategy, which CONAMA was developing those days to protect our genetic heritage.

Approximately 40 experts attended the meeting, which lasted an entire day; they were mainly scholars, but also representatives of governmental institutions with activities in R+D, conservation and sustainable use of genetic resources, project funding or definition of policies and regulations; they came from different regions of the country (north to south), and from Santiago.

#### *(d) Proposal to tackle public opinion on biotechnology*

A significant contribution to the UNEP-GEF Project was the development of a strategic and methodological proposal for the study and follow-up, over time, of the public opinion on the issue of biotechnology. This proposal, named "Methodological proposal for the follow-up on the public image of biotechnology in Chile" (Alcalá, 2005), is available at [www.bioseguridadchile.cl](http://www.bioseguridadchile.cl)

This proposal, addressed to the Ministry of the Economy as the coordinator of the Biotechnology Policy, was developed through the advice of a Task Group on Public Opinion, created with national and international experts, who were invited to a two-day-meeting in the city of Santiago to discuss the perception of citizens and provide the basis for the aforementioned proposal.

The mediated and interactive direction of the discussions within the Task Group, composed of a selected team of 12 recognized experts on biotechnology, social communication and social sciences, permitted a valuable and fruitful exchange of experience and the generation of proposals and recommendations for the evaluation of public opinion and the future education of the public.

Through the reflections in the group and from the findings of previous studies it could be determined that the trends<sup>59</sup> in the "public opinion" of Chile on biotechnology are in opposition to the political-institutional will to promote biotechnological development and could hamper it, if the predominant adverse position is founded on insufficient information and beliefs which diverge from scientific-technical principles.

Thus, the proposal tries to handle this situation by contributing to remove the discrepancy or disagreement between the public-institutional will and the current position of the civil society, which shapes a partially negative "image" of the biotechnological development, based on an insufficient level of information. The proposal is founded on a series of "modules", executable one by one and with a separate cost estimate for each.

If adopted, this proposal will allow authorities, and in particular the Ministry of the Economy, to carry out studies and develop methodologies and indicators to measure the evolution of public opinion on the challenges, opportunities and risks associated with biotechnology, using qualitative and quantitative methods. In addition, it will offer a tool to assess *ex post* the impact of the different measures of

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<sup>59</sup> These trends can be summarized as follows: (a) an important segment of public opinion has scarce or imprecise information on biotechnology and its specific uses, as well as of the functions of the authorities and the advances in regulatory matters; (b) Sources of media information, advertisements and labeling are used more than truly scientific or specialized publications or communications; (c) There is a strong general rejection of biotechnological applications on food, a better acceptance of industrial applications and an even more positive judgment in the fields of human and animal health; and (d) persons belonging to lower socio-economic strata and groups with less schooling in their majority manifest passionate rejection. (Alcalá, 2005)

dissemination implemented by the government (for example, programs for information dissemination) thereby facilitating the future adoption of public educational strategies and policies associated with the development of biotechnology, specifically GMOs.

### 8.3 - RECOMMENDATIONS ON DISSEMINATION AND PUBLIC OPINION<sup>60</sup>

It is the majority opinion of the CNC of the UNEP-GEF Project that it is important to draw citizens' attention, especially of pupils and teachers, on the social implications of biotechnology, informing on a range of biotechnological applications, not only on transgenesis.

To this end, it will be necessary to carry out the following actions:

1. The Ministry of the Economy, as the one in charge of Biotechnology Policies, should integrate specific biotechnology lines within the already existing programs and instruments of dissemination and exploiting the already existing didactic materials, maintaining a permanent interaction with the Ministry of Education, revising school programs and updating the training of teachers to elevate the level of knowledge on biotechnology.
2. Together with information on biotechnology, actions should be carried out to exchange experiences and sensitize the community towards the appreciation of genetic resources in all its dimensions (for example, in relation to their functions or the traditional knowledge, and not only with its economic use), considering that a higher sensitization on the importance of genetics and the concept of genetic heritage would contribute to a better appreciation by society of the benefits as well as risks of biotechnology.
3. All public or private institutions addressing the themes of biotechnology or biosafety on their web pages should include (in the way they deem most adequate) a "link" to the biosafety site created in the framework of the UNEP-GEF Project ([www.bioseguridadchile.cl](http://www.bioseguridadchile.cl)).
4. The administration of the biosafety web portal should lie in the hands of the institution or entity which, according to the potential future Law on Biosafety, will be in charge of the maintenance of the national system of information on biosafety. Alternatively, the site could be passed to the institution with the greatest interest in the dissemination of information on biosafety, i.e., the current Focal Point of the Cartagena Protocol.

It is the majority opinion of the CNC of the UNEP-GEF Project that before beginning dissemination of biotechnology for a higher sensitization of the public, it is necessary to carry out a systematic evaluation of their perception of this technology, which could be periodically repeated (5-10 years) in order to evaluate the reach of the dissemination.

In view of the aforementioned, the following recommendations are made:

1. The Ministry of the Economy should be officially presented with the proposal for an evaluation of the public perception on biotechnology, developed in the framework of the UNEP-GEF Project, so that the it may study the feasibility of allocating tax funds (for the Government period 2006-2010) and carrying it out in the medium term. (For this action, the change of Government in March 2006 will be highly important).
2. If it is not possible to take the mentioned proposal into account, any evaluation of public opinion on biotechnology should have a national scope and should include a replicable methodology, which allows for the subsequent disaggregating of the data to analyze specific population segments.
3. The Biotechnology Forum should have a high degree of influence on the decisions to incorporate biotechnology in the existing programs of scientific-technological dissemination.

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<sup>60</sup> FSS did not agree with the recommendations presented here.

## **..CHAPTER 9..**

# **RELEVANT ASPECTS FOR THE FUTURE RATIFICATION OF THE CARTAGENA PROTOCOL**

## RELEVANT ASPECTS FOR THE FUTURE RATIFICATION OF THE CARTAGENA PROTOCOL

As a useful criterion to determine our capacity and preparedness in face of the potential ratification of the Cartagena Protocol, those elements of the national system which could present weaknesses for the implementation of this international agreement were described in two already cited studies.

The relevant studies to understand the country's preparedness for the national application of the Cartagena Protocol are:

- 1.-"Assessment of the regulatory framework, institutional and trade obligations with respect to the biosafety protocol and the mechanisms for public participation in environmental decision-making" (CDA, 2004)
- 2.-"Assessment of the institutional capacities and needs of the national competent authorities and other entities related to Biosafety in connection with the Law on Biosafety and the Cartagena Protocol, " (BioEnlaces, 2005).

### 9.1 - REGULATORY ASPECTS

One of the cited studies also assessed the technical, analytical, administrative and human rights implications of putting into practice a new legislation in the matter of biosafety.

It would have been desirable to analyze, within the coordination instance which directed the UNEP-GEF Project, the Bill of Law on Biosafety of GMOs drafted by the Government, in the light of the requirements of the Cartagena Protocol. However, this did not take place. The opportunity of admitting sectorial opinions on the Bill of Law will arise at the time of submitting it to Congress or previously, through a public consultation.

For these reasons, in the present report no examination is made of the correspondence of the Bill of Law on GMO Biosafety with the Cartagena Protocol. However, general indications will be given on those aspects of the regulatory framework in force which are expected to be corrected or addressed by the bill of law in order to bring it into line with the Cartagena Protocol, whichever its final version.

The UNEP-GEF Project could only make a limited contribution on regulatory matters, including the ratification of the Cartagena Protocol. The connection between its normative proposal and the Cartagena Protocol is possibly limited to the observations made by those public services which participated in the drafting of the proposal (among them, CONAMA), and to the technical and legal studies whose objective it was, among others, to study the compatibility of certain elements of the valid national framework with the Cartagena Protocol.

However, a concurrence between the advances of the country and the goals of the CNC of the UNEP-GEF Project is the decision to legislate the safe use of biotechnology through a biosafety law. This important political decision will solve various normative faults detected by the studies of the UNEP-GEF Project, as well as by external experts. As a matter of fact, the need to legislate on biosafety for all phases of GMO-production and use and to clarify and strengthen institutional competences does not require more explanation than what has already been mentioned in this report.

It is widely known that the current regulatory framework on biosafety is insufficient, not only from the perspective of the possible future national implementation of the Cartagena Protocol, but also vis-à-vis the needs and projections of the country in this matter. It is, therefore, worthy that a Bill of Law on GMO-Biosafety<sup>61</sup> is already well-developed. If it is adopted, it could allow for the fulfillment of the requirements of the Cartagena Protocol, and specifically of its administrative components.

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<sup>61</sup>This appreciation reflects the opinion of the CNC of the UNEP-GEF Project, with the exception of the FSS, which does not consider this initiative as positive, as it was developed behind the general public's back and proposes an expansion of GMO crops. This NGO discards expressing any approval for this legislative proposal for the application of the Cartagena Protocol in the present report.

But while it is not promulgated, Chile will have to continue operating with the existing norms and deficiencies. This will be of no consequence for biosafety as long as the productive sectors which do not belong to the agricultural sector abstain, for now, from incorporating GMOs into their productive activities. At present, various types of GMOs can enter and be used in the country on the basis of general and/or sectorial regulatory frameworks related to living organisms, without specific biosafety requirements.

If the current regulatory framework is maintained, then a significant void in relation to the Cartagena Protocol will exist as to the transport of living organisms, and to any other activity outside the agricultural and livestock sector. The national legislation does not include the "crossborder movements" mentioned in the Cartagena Protocol; thus, the handling, packaging and documentation (identification) requirements in general are notoriously absent from our legislation. The same is true for the transport of living organisms through the national territory, whose regulation is limited to sanitary and phytosanitary requirements, without the obligation to identify them as GMOs, and without including the organisms for confined use.

The same is true for exports. The currently valid norms do not compel exporters to proceed according to the Advanced Informed Agreement of the Protocol (i.e., with a previous notification to the country of destiny and the sending of information on the corresponding risk assessment), nor to identify its shipments as GMOs<sup>62</sup>. For the current GMO-exports (only seeds), the seed companies themselves have taken the responsibility for these issues, as they are certified and segregated seeds which have been clearly studied and documented.

On the other hand, microorganisms, their confinement and biosafety during their transportation, use or release into the environment are not regulated in conformity with the safeguards and information required by the Cartagena Protocol. A limiting factor in this sense is that the currently valid legislation, contrary to the Protocol, does not distinguish nor submit to other regimes the microorganisms for confined use, microorganisms destined to the environment (i.e. for bioremediation, for example) and those for pharmaceutical use.

Only in the case of GMO-plants is there a partial compliance of the standards fixed by the Protocol. The institutionality and the competences to regulate agricultural GMOs certainly do exist, but the sphere of regulation is limited to the production of seeds for export. Thus, a good part of the agricultural, forestry or ornamental activities which can be developed with GMO-plants (considering that research on forest and fruit species is already taking place), including their internal commercialization, are not adequately regulated at present.

## 9.2 - ASPECTS OF ADMINISTRATION AND DECISION-MAKING

Chile's decision-making framework on the matter of GMOs is limited to living GMO-plants. This fault reflects the fact that Chile has not yet designated its Competent National Authorities, which is one of the first administrative tasks required by the Cartagena Protocol, including for Non-State Parties<sup>63</sup> and a sign of a consolidated institutionality in this field.

As to administrative processes for the notification, evaluation of and decision-making on GMOs, only Resolution N° 1523 of the SAG (GMO-plants for propagation) establishes procedures, terms, deadlines, forms of resolution (decisions based on risk assessment) and spaces for public participation which are fully in line with the Cartagena Protocol.

Resolution N° 3136 of the SAG (pharmaceuticals for veterinarian use containing GMOs) also correspond to the prescriptions of the Protocol, although to a lesser degree and in a very general way, requiring that the decision-making processes be based on a case-by-case risk assessment.

The methodology employed in the risk assessment of GMOs destined for release into the environment is in line with the methods and principles stipulated in Article 15 and Annex III of the Protocol; the only exception is section 1 of Annex III of the Protocol, which specifies that human health is one objective of risk

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<sup>62</sup> The current documentation requirements established by the authorities for any export of living organisms are phytosanitary or sanitary only and, contrary to the Protocol, are not applicable to organisms for confined use.

<sup>63</sup> especially those which have ratified the Convention on Biodiversity and subscribed to the Protocol, as is the case of Chile

assessment: the SAG does not include this aspect in its current analysis of GMO-seeds.

As to information management, the existing level is sufficient for the Cartagena Protocol, since at present the SAG and other public institutions such as the ISP, are in no conditions to comply with the BCH requirements of the Protocol<sup>64</sup>. This is true for information which should be available to the public (and is therefore excluded from the possibility of being declared restricted), as well as for the information which has to be submitted to the BCH and permanently updated, as an administrative task of the CNAs.

### 9.3 - NORMATIVE PROPOSALS IN PREPARATION

The authors of this report considered it appropriate to go into more detail on some aspects of the Cartagena Protocol which should be covered by the legislation on GMOs proposed by the Government, in order to maximize the harmonization between these two instruments.

#### 9.3.1 PROPOSAL FOR A TECHNICAL NORM ON FOOD

As to GMOs destined to the food industry, i.e. imports of LMO-commodities<sup>65</sup> according to the Protocol (non-processed foods), the current regulatory framework is far from complying with the dispositions of the Protocol. This increases the need to regulate some specific aspects, such as risk assessment, transportation, documentation for transboundary movements and local commercialization. The Ministry of Health has responded to this need by drafting a proposal for a technical norm to evaluate and authorize the national use of *biotechnological events* in human food.

Without a specific norm for this kind of food, Chile will hardly be able to comply with the requirements of Article 11 of the Protocol, which refer to the general availability of information, including documentation on transboundary movements (Article 18), more than to specific procedures, and allow the adoption of decisions on the basis of the regulatory framework of the importing country. At present, there is no legal obligation for importers of these products into Chile to previously notify the national authorities (Article 7), to make the risk assessment available (Article 11; Article 20), or to document whether the shipments entering the country contain LMOs or not (Article 18). Nor is there any practice, among the authorities, of informing on the decisions taken regarding the national use or import of these commodities (Article 11; Article 20).

If the technical norm proposed is promulgated, then the national authorities shall assume the responsibility to inform the other countries through the BCH, and thereby also the foreign producers and exporters, which norms and procedures are applicable in Chile on genetically modified commodities, which food events have been approved or rejected at the national level, for which commercial uses (animal or human consumption, or both), and with which restrictions, if any. As to locally produced GMO foods, the summaries of the risk assessments carried out in the country on the respective GMO shall be published on the internet.

The link between this technical norm and the authorization of GMOs for animal feed and for the release into the environment is also important. Thus, the most precautionary approach would be to obtain the approval of GMOs for consumption as human food, prior to authorizing agricultural production (release into the environment) and/or use for livestock. I.e., the corresponding authorizations should be given for both cases (human and animal food), before the GMOs are released into the environment. This point underlines the importance of the decisions to be taken by the Ministry of Health and then communicated to the BCH, in view of the future technical norm on biotechnological events and Article 11 of the Cartagena Protocol, respectively.

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<sup>64</sup> The SAG has the greatest software and hardware needs, as it requires the implementation of a system for the electronic storage and processing of data, in contrast with the aquacultural sector, which already possesses a model system for information management which also provides an adequate level of access to information to its users.

<sup>65</sup> LMOs destined to be directly used as human or animal food or to be processed in the food industry

### 9.3.2 DRAFT BILL OF LAW ON THE BIOSAFETY OF GMOs

Knowing that the country will decide on the ratification of the Cartagena Protocol in conformity with legislative proposal on biosafety drafted by the Executive Power, it seems logical to wait for this proposal to satisfy the requirements of the Protocol to the greatest possible extent. Since its character, scope and promulgation depend on the judgment of Parliament, it could still undergo some modifications.

Whichever is its final wording, it is sure that when a new law on the matter of biosafety is adopted, the authorities' attributions will increase, and so will their (technical, administrative and technological) capacities have to, in order for them to fulfill their functions, regardless of the final decision on the ratification of the Cartagena Protocol. It is evident that once the new GMO-regulation enters into force, the human and technical resources will have to be strengthened as well as the regional and customs capacities regarding biosafety, particularly the monitoring activities inside the responsible institutions.

Following is a list of some aspects of the Cartagena Protocol which are important to review at the time of legislating on biosafety:

**SCOPE:** It is convenient to make a difference, when legislating, between living modified organisms (LMOs) and genetically modified organisms (GMOs), which is a broader category. It also has to be remembered that the Cartagena Protocol makes an important exclusion of cross-border movements of pharmaceutical products for human use, which are covered by other international forums or agreements. Thus, the regulation of these LMOs remains a prerogative of the Parties.

**DEFINITIONS:** The legal definition of terms used by the Cartagena Protocol - terms like confined use, release into the environment and derived products - is of the highest importance, as it will determine the treatment for each category of GMO. The most reasonable thing to do is to consider any GMO which is not for *confined use* only as susceptible to be released into the environment. And that it shall be defined that *products derived from GMOs* are those exclusively destined to food or pharmaceutical use, in order to rationally delimit the scope of the provisions.

**REGULATED ACTIVITIES:** In addition to the more classical productive activities which could involve GMOs, the transit of GMOs through the national territory and the confined use of GMOs (for educational research and development purposes) should also be regarded by the national laws as GMO "activities". It has to be taken into account that the Cartagena Protocol excludes them from the procedure of the Advanced Informed Agreement and allows the Parties to determine its regulation. If this faculty is made use of, the approach to be adopted should obstruct these activities to a minimum, maybe exempting them from the more intricate authorization procedures and submitting them to a simplified system of prior notification. Equally, the export and import of GMOs (for commercial reasons or other) should be regulated, establishing for them, in conformity with Article 18 of the Protocol (sections 1 and 2),<sup>66</sup> minimum requirements of documentation and identification, as well as standards for packaging, handling and transportation, which including GMOs for confined use.

**DECISIÓN-MAKING:** To be as consistent as possible with the Advanced Informed Agreement to the Cartagena Protocol, the national legislation on biosafety should define a decision-making system based on: (i) the delivery of background information by the applicant; (ii) the subsequent confirmation of receipt; (iii) a risk analysis by the Competent National Authority(ies); and (iv) a case-by-case decision prior to the introduction into the country and release into the environment of the respective GMO. Thus at least it can be guaranteed that, in conformity with the Protocol and to reassure the general public, all GMOs for productive use are submitted to a risk evaluation prior to their authorization in Chile. Nor should the Chilean legislation exclude the possibility of revising already taken decisions *a posteriori* and in the light of new scientific evidence or new relevant background information, as contemplated in Article 12 of the Cartagena Protocol.

**INFORMACIÓN MANAGEMENT:** The generation of a National System of GMO information in the context of the law on biosafety is a welcome opportunity to make it compatible with the BCH of the Cartagena

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<sup>66</sup> Beyond the minimum text of Article 18 section 2, the kind of information which has to be delivered on any transboundary movement of GMOs, including transit, shall be defined by each country's legislation, although in the case of GMO-commodities, the details and specifications finally determined by the COP/MOP will be decisive.

Protocol. The information management model proposed by the BCH is considered a contribution to the processes of GMO-management, which require transparency, among other things. Definitely, the information system should become a management tool to access and process information electronically and speedily, and thus make communication and coordination inside the institutions and between them more effective. Likewise, the categories of information<sup>67</sup> employed should coincide with the classification promoted by the BCH. As to confidentiality, the requirements of the Cartagena Protocol are sufficiently clear and indicate the information that has to be published in the BCH and must not be kept confidential, in Article 20 and 21 respectively.

**INSPECTIONS AND CONTROL:** The critical factor here is not the legal correlation between the Cartagena Protocol and the possible future legislation on biosafety, but the institutional capacities required to comply with the new regulatory frameworks in the future - especially, in the case of the Protocol, in reference to involuntary (Article 17) and illegal (Article 25) crossborder movements. Both regulations imply monitoring and control activities and require a response capacity of the national authorities of the affected or responsible country. Finally, the biosafety legislation should include among its provisions, like the Protocol, the application of special measures for emergency situations or illegal activities, giving the authorities the competence to act, not only by imposing punitive measures, but also through immediate actions for the safeguarding of biodiversity and human health, covering border activities as well.

### 9.3.3 CONCLUSIONS

The Bill of Law on Biosafety of GMOs gives State institutions sufficient attributions for a future implementation of the Cartagena Protocol and, if promulgated, would provide a regulatory scenario that would be highly equivalent to the principles, focus and procedures of the Protocol<sup>68</sup>.

The same is true for the technical norm for the evaluation and authorization of biotechnological events used in human food. In both cases, its purposes are basically the same as the Protocol's (to prevent and control the potential risks of GMOs) and there is no discord between their administrative processes.

With the emphasis set on the consistence, between State Parties, of the procedures and regulatory approaches for transboundary movements of LMOs, and with important operative aspects<sup>69</sup> still undefined within the COP-MOP of the Protocol, Chile should follow the decisions of the COP-MOP and the evolution of the stipulations of the Protocol very closely, while the discussions on the Bill of Law on the Biosafety of GMOs and on the norms for genetically modified foods continue.

The recommendations on risk assessment, risk management and decision-making are of particular importance. A growing effort can be foreseen for the generation of instruments for the harmonization, essentially for the development of common principles and criteria, and patterns and guidelines to assess GMO-related risks. These will be endorsed and promoted by international organizations such as the FAO, OECD and OIE, as is occurring in the field of human health through the *Codex Alimentarius*. Chile should, therefore, consciously watch over the preservation of a high level of harmony between the application of its national framework and the guidelines resulting from the Cartagena Protocol.

## 9.4 - CHILE AS A NON-PARTY STATE TO THE CARTAGENA PROTOCOL

An argument which cannot be dismissed is the possibility that Chile, whether promulgating a new norm on biosafety or not, maintains its present position as a Non-State Party to the Cartagena Protocol. And that it will thus be confronted with GMO-trade with countries which are State Parties to the Protocol. Following is a list of some requirements which could be presented from countries with which Chile entertains trade relationships:

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<sup>67</sup> Two important categories of information are the summaries of the GMO-risk assessments carried out in the country (Article 20 section 3.c) and the national decisions on import, release into the environment, commercialization and any other national use of GMOs (Article 20, section 3.d). The former becomes relevant at the moment of making the bases transparent on which the national authorities take their decisions, and thus contribute to a mutual acceptance of data and the homologation of methodologies. The second is necessary to make explicit which GMOs have been approved in Chile, and for what purpose, as well as the reasons for either the denegation or authorization of the request.

<sup>68</sup> Of all the members of the CNC of the UNEP-GEF Project, the FSS was the only organization which disagreed with this judgment.

<sup>69</sup> such as the system of identification of LMO-commodities and the regime of responsibility and reparation, among others.

. It is probable that Chile will have to designate its CNAs and Focal Points and inform the Secretariat of the Cartagena Protocol about them through the BCH, so that other countries know which institutions are in charge of GMO-management in Chile.

. Countries importing from Chile or exporting to Chile should be informed through the BCH about which national norms have to be fulfilled for the authorized use of GMOs in the country.

. It is probable that the State Parties importing our products demand, from the Chilean authorities or private actors involved, compliance with the steps of the Advanced Informed Agreement, prior to the first transboundary movement of a GMO.

. They will equally demand the use of documentation identifying the GMOs transported, as well as asking for a guarantee that the information therein contained is trustworthy.

. Should Chile some day produce GMOs for its commercialization and exportation, the authorities of the State Parties in whose environment the respective GMO is supposed to be released and/or introduced would require to have knowledge of at least the environmental and/or sanitary risk assessments which have been carried out in Chile, prior to the first shipment of the GMO in question to the State Party of destiny.

The demands will vary according to the regulatory framework and norms in force in each country. But for compliance with the Protocol, it can be anticipated that the minimum requirements will be the fulfillment of the Advanced Informed Agreement to the first transboundary movement, a decision-making process based on risk assessment (which can be carried out in Chile or in a country of destiny), administrative terms and deadlines in conformity with those established by the Protocol and the need for a clear and official documentation accompanying the GMO-shipments and identifying them as such.

Evidently, this is a vision of the requirements of the Cartagena Protocol, but it should not be forgotten that, even if it is not a State Party to the Protocol, Chile shall have to comply with the provisions of the CBD, to which it is Party, on the matter of biosafety. In its Article 19 section 4, the CBD, whose text is a Law of the Republic of Chile, states the following:

Article 19 (4) of the CBD states: " 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".

These requirements are not unimportant but limited, as they refer exclusively to the delivery of unidirectional information in the exchange of GMOs between State Parties, when it includes GMOs destined to be released into the environment of one of the States. Chile will probably have to review the form in which it fulfills these specific demands, in the case the new biosafety legislation is not promulgated.

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