

Biosafety information management systems. A comparative analysis of the regulatory systems in Canada, Argentina, and Chile

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CamBioTec, a Canadian-Latin American Network promoting the safe and effective use of agricultural and environmental biotechnology, undertook an analysis of the current capacities of Argentina, Chile and Canada with respect to the management of information related to assessment and approval of products of modern biotechnology/genetically engineering. This report is based on data obtained during a number of interviews and institutional visits conducted during August 1998 and includes: an overview of current regulatory policy, identification of key human resources and authorities, analysis of information management capacity, recommendations for capacity building, and descriptions of relevant international initiatives. Canada has a regulatory system in place that is respected throughout the world for its ability to insure high-quality agricultural biotechnology products that meet international human and environmental health and safety standards. Argentina is recognized as leader among Latin American countries in the regulation of

biotechnology products. Chile is a well-known center of genetic diversity for a number of plant species but with very little in the way of biosafety regulation. Together these countries represent a broad spectrum of technical experience, regulatory policy, and agricultural interests.

In 1998, over 40 million acres of transgenic crops were grown around the globe. As these products are traded and pass from one country to the next, it is important to ensure that domestic regulator regimes are in place around the globe to ensure the safe use of these products. This report outlines the current capacities of Argentina, Chile and Canada with respect to the management of information related to assessment and approval of product of modern biotechnology/ genetically engineering. The data in this report is based on a number of interviews and institutional visits conducted during August 1998.

The regulatory systems of Canada, Argentina, and Chile are

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all at different stages of development. Canada has a system in place that is respected throughout the world for its ability to insure high-quality agricultural biotechnology products that meet international human and environmental health and safety standards. Argentina is recognized as leader among Latin American countries in the regulation of biotechnology products. And finally, Chile is a well-known center of genetic diversity for a number of plant species but with very little in the way of biosafety regulation. Together these countries represent a broad spectrum of technical experience, regulatory policy, and agricultural interests.

As with any information system, the key to success is always the people that use the system. In the case of a biosafety system these people are the regulatory authorities of the various government apartments involved in regulation of biotechnology products. Whether through in specific designation in their job description or through an evolution of their duties, each regulatory group tends to have one or two people that deal with biotechnology products on behalf of the group. This report identifies the key biotechnology contacts within these regulatory departments.

As the volumes of information required to process and track the development of biotechnology products increases, a greater need is placed on information management systems rather than on traditional paper files. Regulatory department in all three countries have relatively modern computer

systems often networked through LANs and access, though sometimes limited, to the Internet as a resource.

Recommendations for information system capacity building:

The key to successful technology transfer is based on technology pull rather than push. Canada has much to offer Southern cone partners in the development and implementation of domestic biosafety regulatory systems. Based on the analysis of the current capacity of all three countries, the following recommendation are made:

- Begin trilateral discussion of the Canadian and Argentine models to gain a better understanding of the regulatory development process in all three countries
- Develop an electronic network [email list serve] to connect regulators brought together through this technology transfer initiative.
- Develop a formal database of experts in the areas of biotechnology products and risk assessment for the benefit of both Canadian regulators and those in Latin America.
- Link information dissemination about product approvals and field trials with the current UNEP/OECD/UNIDO initiatives.

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1. Overview of Current Regulatory Policy

In 1998, over 40 million acres of transgenic crops were grown around the globe. As these products are traded and pass from one country to the next it is important to ensure that domestic regulator regimes are in place around the globe to ensure the safe use of these products. The regulatory systems of Canada, Argentina, and Chile are all at different stages of development. Canada has a system in place that is respected throughout the world for its ability to ensure high-quality agricultural biotechnology products that meet international human and environmental health and safety standards. Argentina is recognized as leader among Latin American countries in the regulation of biotechnology products. And finally, Chile is a well-known center of genetic diversity for a number of plant species, but with very little in the way of biosafety regulation. Together these countries represent a broad spectrum of technical experience, regulatory policy, and agricultural interests.

The regulatory systems of Canada and Argentina while developed independently are remarkably similar in structure. In developing biosafety regulations and establishing experienced regulators, Argentina should be considered to be about three years behind Canada. Chile, on the other hand, should be considered to be about where Canada was in 1988. Chilean departments have not really come together yet to address the need for a regulatory framework, the first step in regulatory development. The growing numbers of transgenic plant products in commercial use throughout the world make it crucial for all countries to have sufficient knowledge, experience and infrastructure to determine and implement assessment criteria appropriate for their environment.

1.1 Canada

The Canadian regulatory system for products of biotechnology is based on a product rather than process philosophy of regulation. The rationale for this approach is to provide for the assessment of all "novel" products introduced into Canada which may have a negative impact on human health, the environment, or the agricultural industry. As result, Canada has adopted a very broad definition of biotechnology, and focused regulations on novel traits rather than "genetic engineering".

"Biotechnology" means the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms;

Government of Canada, 1986

In December 1992, the federal Cabinet approved a framework for the regulation of products of biotechnology in Canada. This framework, produced by the Working Group on Safety & Regulations, provided federal

departments with 6 principles to guide them in the development of a regulatory system which:

1. *maintains Canada's high standards for the protection of the health of workers, the general public and the environment;*
2. *uses existing legislation and regulatory institutions to clarify responsibilities and avoid duplication;*
3. *continues to develop clear guidelines for evaluating products of biotechnology which are in harmony with national priorities and international standards;*
4. *provides for a sound scientific database on which to assess risk and evaluate products;*
5. *ensures both the development and enforcement of Canadian biotechnology regulations are open and include consultation; and*
6. *contributes to the prosperity and well being of Canadians by fostering a favourable climate for investment, development, innovation and adoption of sustainable Canadian biotechnology products and processes.*

Government of Canada, 1992

Point two of this framework is particularly important with respect to the authority and responsibility for biotechnology products within the federal government. Unlike countries such as Australia that have a "gene law", Canada chose to amend existing legislation and regulatory departments to accommodate these new products. The result is a number of different regulations with varying styles that have been developed based on specific product and usage requirements but ensure an equivalent level of safety from department to department. The only department to take on new responsibilities due to the introduction of biotechnology products is Environment Canada. Unlike, pharmaceuticals or plants, products such as industrial enzymes or organisms for bioremediation did not fall under traditional regulatory structures, so they are now captured under the Canadian Environmental Protection Act.

1.1.1 Technical Expertise

The first source of Canadian technical expertise for the assessment of a "novel" product lies within the regulatory departments. Evaluators within Federal departments take on significant technical responsibilities in the assessment process and in some cases are the only sources of technical expertise used in an approval. Not surprisingly, regulatory personnel are a vital repository of technical information on biosafety and risk assessment of biotechnology products. A second level of technical knowledge comes from other experts within the government that specialize in either risk assessment or biological research. Some evaluators use government laboratories and researchers to verify test data

provided in company submissions. These in-house experts may at times be asked to provide their scientific opinion on the evaluation of certain submissions.

The third level of technical expertise comes from external experts such as academic researchers. These individuals are recognized as leading authorities on specific organisms and are generally contacted on an "as needed" basis. Rather than establish a formal external advisory body to process applications, as is the case in some countries, the role of external advisors remains informal and case specific.

1.1.2 Regulations and Procedure

As indicated in the framework above, all new products of biotechnology are regulated under existing federal legislation. There were however, a number of amendments made to these acts to highlight the specific requirements for novel products of biotechnology. In addition, a number of guideline documents were produced to clarify what additional information may be required for a biotechnology product to comply with these regulations.

- i. statutory instruments amended to accommodate novel biotechnology products:
 - JUS-96-001-01 (SOR/DORS): Amendments to the Feeds Act -- Novel Feeds
 - JUS-96-002-01 (SOR/DORS): Amendments to the Fertilizers Act -- Novel Supplements
 - JUS-96-003-01 (SOR/DORS): Amendments to the Health of Animals Regulations -- Permits to Release Veterinary Biologics
 - JUS-96-004-01 (SOR/DORS): Amendments to the Seeds Regulations -- Release of Seed
 - JUS-97-022-01 (SOR/DORS): Regulations Amending The New Substances Notification Regulations
 - Novel Food Regulatory Proposal as Published in Canada Gazette Part I (August 26th 1995)
- ii. Regulatory directives, trade memorandums, and guidelines specific for novel biotechnology products:
 - Regulatory Directive Dir94-08: Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits
 - Regulatory Directive Dir95-01: Field Testing Plants with Novel Traits in Canada
 - Regulatory Directive Dir95-03: Guidelines for the Assessment of Livestock Feed from Plants with Novel Traits
 - Trade Memorandum T-4-118: Guidelines to Safety Assessments of Microorganisms in Fertilizers and Supplements Regulated under the Fertilizers Act
 - Trade Memorandum T-4-119: Explanatory Notes on the Information to be Submitted for Safety Assessments of Microbial Supplements
 - Canadian Food Inspection Agency - Veterinary Biologics - Biotechnology Guidelines

- Guidelines for the Notification and Testing of New Substances: Organisms - Pursuant to The New Substances Notification Regulations of the Canadian Environmental Protection Act
- Information Note: Reporting Substances that are Products of Microorganisms under the New Substances Notification Regulations
- Information Note 08-96: Notification of Post-transitional Biotechnology Products under the New Substances Notification Regulations
- Guidelines for the safety Assessment of Novel Foods (Sept 1994)

The procedures for the introduction of a new biotechnology product in Canada could best be explained by walking through the regulatory procedures for a specific type of product as below:

Sample: Regulatory steps in the Risk Assessment of Plants with Novel Traits

Step 1: Contained

Contained use of a plant is defined as use within a laboratory, growth chamber, or greenhouse. No oversight by Canadian Food Inspection Agency (CFIA) or environmental assessment is required for plants in contained use as they are expected to remain within these facilities and therefore pose no hazard to the environment. Similarly, no food/feed use for these product would be allowed without Health Canada/ CFIA approval. [Note: Food and/or feed must be obtained prior to commercialization, but may be sought at any stage of process.]. Import permits may be required if plant material for confined use is brought from outside the country.

Prior to Step 2:

Before a confined field trial can take place, the CFIA must undertake an environmental assessment. Details on evaluation criteria and data formats can be found in the reference document:

Field Testing Plants with Novel Traits in Canada

If authorized, continue to step 2.

Step 2: Confined Field Trials

Confined Field Trial refers to a small test plot of plants that are grown in an open field with measures taken to ensure: reproductive isolation, restrictions on post-harvest land use, site monitoring, and control and disposition of seed, plants and progeny. As above, no food/feed use for these product would be allowed without Health Canada/ CFIA approval. [Note: Food and/or feed use must be obtained prior to commercialization, but may be sought at any stage of this process.] Again, an import permit may be required if plant

material for confined use is brought from outside the country.

Prior to Step 3:

Before an unconfined field trial can take place, the CFIA must undertake an environmental assessment. This is a more detailed assessment than would be required for a confined use permit. Details on evaluation criteria and data formats can be found in the reference documents:

Assessment Criteria for Determining Environmental Safety of PNTs and subsequent guidelines

If authorized, continue to step 3.

Step 3: Unconfined Release

Plants that have received an unconfined release permit can then be grown in large quantities for variety registration trials or seed multiplication. There is no requirement for reproductive isolation or restrictions on post-harvest land use, however, monitoring for adverse effects continues. Once again, no food/feed use for these product would be allowed without Health Canada/ CFIA approval. [Note: Food and/or feed must be obtained prior to commercialization, but may be sought at any stage of process.]. Import permits may be required if plant material for unconfined use is brought from outside the country.

Prior to Step 4:

At this step Health Canada or CFIA must undertake a Food or feed safety assessment. Details on evaluation criteria and data formats can be found in the reference documents:

Health Canada - Novel Food Guidelines or Feeds Act (CFIA)

If authorized, continue to step 4.

Step 4: Commercialization

The final step, where applicable, is variety registration signifying permission for commercial release of the product. Food/Feed or industrial use permits are issued at this step. Even after commercial approval adverse effect monitoring continues.

1.2 Argentina

The Argentine regulatory system for products of biotechnology is philosophically different than the system established in Canada. Rather than focussing on novel products, Argentine regulations focus on the biosafety of products developed through the process of genetic engineering. As a result the regulatory system is based on the following definition of "genetically modified organisms".

<p><i>"Genetically Modified Organisms" means organisms in which any of the genes or other genetic material have been modified by means of the following techniques:</i></p> <ul style="list-style-type: none"> <i>the insertion by any method into a virus, bacterial plasmid or other vector system of a nucleic acid molecule, which has been produced by any method outside that virus, bacterial plasmid or other vector system, as to produce a new combination of genetic material which is capable of being inserted into an organism in which that combination does not occur naturally and within which it will be heritable genetic material;</i> <i>the insertion into an organism, by micro-injection, macro-injection, micro-encapsulation or other direct means, of heritable genetic material prepared outside that organism;</i> <i>where they involve the use of recombinant DNA molecules in in vitro fertilization that implies the genetic transformation of an eukaryotic cell.</i> <p style="text-align: right;"><i>Government of Argentina, 1992</i></p>
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In 1991 the Secretary of Agriculture, Livestock and Fisheries created the Comisión Nacional Asesora de Biotecnología Agropecuaria (CONABIA) (The National Advisory Committee on Agricultural Biosafety) as a mechanism for consultation and technical support on the design and management of regulations concerning the biosafety of the introduction and environmental release of transgenic material. The CONABIA is made up of representatives of both public and private sectors engaged in agricultural biotechnology.

Public Sector Representation	Private Sector Representation
<ul style="list-style-type: none"> • SENASA- (National Service of Health and Quality of Agri-foods [Animal and Plant branches]) • INASE- (National Institute of Seeds) 	<ul style="list-style-type: none"> • ASA- (Association of Argentine Seeders) • Foro Argentino de Biotecnología (Argentina Forum of Biotechnology) • CAPROVE- (Argentine Chamber of Veterinary)

<ul style="list-style-type: none"> • Secretariat of Public Health • Secretariat of Natural Resources and Sustainable Development • National institutes of research <ul style="list-style-type: none"> • INTA- (National Institute of Agricultural Technology) • CONICET- (National Council of Scientific and Technical Research) • University of Buenos Aires 	<p>Products)</p> <ul style="list-style-type: none"> • CASAFE (Chamber of Agricultural Health and Fertilizers) • Argentine Society of Ecology.
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The Department of Agricultural Production under the National Department of Agriculture and Forestry Production and Economics from the Undersecretariat of Agriculture, Livestock and Forest Production acts as secretariat to the CONABIA.

1.2.1 Regulations and Procedures

While the philosophy underlying the Argentine regulations for assessments of GMOs is fundamentally different than Canadian regulations, the product approval procedures are remarkably similar to those outlined in the "Regulatory steps in the Risk Assessment of Plants with Novel Traits" are utilized for GMOs in Argentina. The main differences in the two systems are:

- Argentina exerts regulatory oversight on products for contained use (same data required for contained or confined trial) where Canada does not exert oversight until Confined use is requested.
- Canada asks for more detailed information in the field trial applications
- Unconfined release requirements in both countries are remarkable similar. (Note: Unconfined status in Argentina is called flexibilization)

Apart from these differences the systems are remarkably similar. The same types of approvals (environmental assessment, feeds, human health, and variety registration) are required in both countries and are based on very similar information requirements. CONABIA provides the biosafety element for each of the approvals. The specific regulations involved in the approval process are as follows.

- i. New statutory instruments, specific for GMOs:
 - Creation of the CONABIA, Resolutions # 124/91, 669/93 and 328/97 of the SAGYP.
 - Requirements for the environmental releases of GMOs, Resolutions # 656/92, 837/93 and 289/97 of the SAGYP.
- ii. Statutory instruments, non specific for GMOs:
 - Decree-Law regulating the Health Defense of Agricultural Production, # 6704/66 and its amendments.
 - Law regulating Seeds and Phytogenetic Constructions, # 20247/73 and its regulatory order.

- Law regulating Veterinary Products, Manufacturing and Commercialization Inspection # 13636/49.

1.3 Chile

The Chilean regulatory system for products of biotechnology is still in its infancy. The regulatory system for field trials is operating under sanitary and phytosanitary regulations for importation of plant material. Thus, the law requires field trials of imported transgenic products only. There's no system in place for the regulation of transgenic products developed domestically and no system for approval of products for commercial use. This means that there are no commercial approved transgenic products available to the Chilean consumer. A few plant products have received approval for large scale growing, but are restricted to multiplication of seed and re-export for use elsewhere; none of these products are available to Chilean consumers.

1.3.1 Technical Expertise

In November 1993 the "Advisory Committee on the Release of Transgenic Organisms (CALT)" was created to provide technical support to the Agricultural and Livestock Service (SAG) with regard to the introduction and environmental release of transgenic material. The CALT members are specialists appointed by the Minister of Agriculture as permanent officials representing the Ministry of Agriculture, Ministry of Health, agricultural research centres and Universities. The Advisory board does not have any private sector representation.

CALT Representation
<ul style="list-style-type: none"> • Ministry of Agriculture, Agricultural and Livestock Service (SAG) • INIA- (National Agricultural Research Institute) • CONICYT- (National Commission on Scientific and Technical Research) • University of Chile • Catholic University • Austral University • Institute of Public Health

The Department of Plant Protection under the National Agricultural and Livestock Service acts as secretariat to the CALT.

1.3.2 Regulations and Procedures

The procedures for control of agricultural products in Chile are somewhat different than those in Canada. Chilean regulators are very focused on preserving the unique indigenous species found in the distinct ecosystem zones that divide the country. The primary role of the Agricultural and Livestock Service (SAG) is the protection of the zones through quarantine procedures. As a result, the regulatory system is very focused on the threat of invasive foreign species. The regulations under which Chile is currently regulating GMOs are limited in their authority to products of import. Transgenic plants produced at INIA, a government research facility, have been voluntarily submitted to CALT for review. Chilean regulators seem to be taking "a wait and see approach" before developing domestic regulations hoping to benefit from international initiatives such as the UN Biosafety Protocol. These regulations currently in place are as follows:

- i. statutory instruments, specific for GMOs:
 - Resolution of exemption 1927/93 of the SAG

- ii. statutory instruments, non specific for GMOs:
 - Decree-Law 3554/81

2. Identification of Key Human Resources and Authorities

As with any information system, the key to success is always the people that use the system. In the case of a biosafety information system, users of the system are the regulatory authorities of the various government departments involved in regulation of biotechnology products. Whether through specific designation in their job description or through an evolution of their duties, each regulatory group in all of the countries studied tend to have one or two people that deal with biotechnology products on behalf of the group. The following is a breakdown of the different regulatory departments and the key biotechnology contacts within those departments.

2.1 Canada

Governmental agencies involved in the regulation of agricultural biotechnology products

Agricultural and Livestock Biosafety	<ul style="list-style-type: none"> • Canadian Food Inspection Agency (CFIA). Animal Health • Health Canada, Health Protection Branch, Office of Food Biotechnology
Human Health	<ul style="list-style-type: none"> • Health Canada, Health Protection Branch, Office of Food Biotechnology.
Seeds Certification	<ul style="list-style-type: none"> • Canadian Food Inspection Agency (CFIA). Animal Health
Agrochemical	<ul style="list-style-type: none"> • Pest Management Regulatory Agency (PMRA)

National coordinating bodies for biotechnology regulations

- National Biotechnology Strategy, Biotechnology Coordinating Group, Subgroup on Safety and Regulation

Within the *Canadian Food Inspection Agency* there are four groups responsible for evaluations: Seeds, Feeds, Fertilizers, Health of Animals. Coordinated interaction with each of these groups of evaluators can be achieved through the Biotechnology Strategies and Coordination Office, Associate Director, Margaret Kenny

Ms. Margaret Kenny
 Associate Director
 Canadian Food Inspection Agency
 59 Camelot Drive
 Nepean, ON K1A OY9
 Tel: 952-8000
 Fax: 228-6604
 Email: mkenny@em.agr.ca

The primary biotechnology contact for each group in CFIA is listed below (next page).

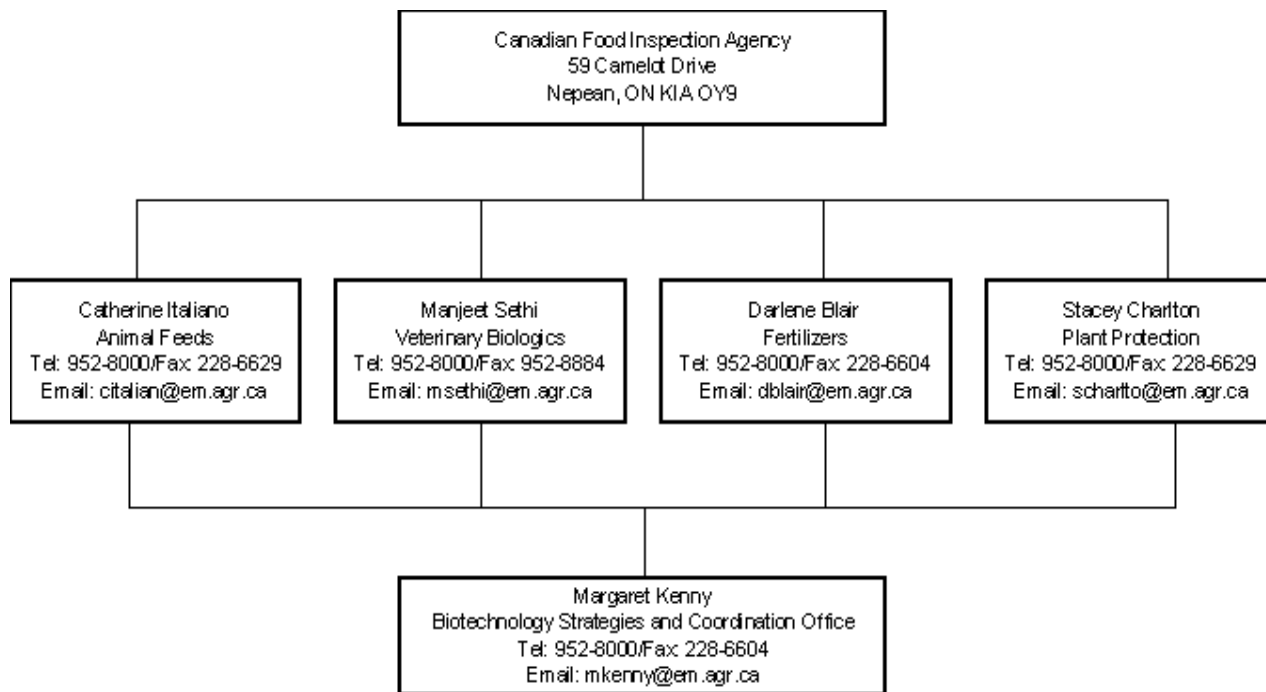
Within *Environment Canada* regulatory authority over biotechnology products falls New Substances Notification Division:

Import and Manufacture of New Biotechnology Substances - CEPA

Dr. Nigel A. Skipper
 Head, Biotechnology Section
 Environment Canada
 Commercial Chemicals Evaluation Branch
 14th Floor, Place Vincent Massey
 Ottawa, ON K1A 0H3
 Canada
 Tel: 953-1678
 Fax: 819-953-7155
 Email: Nigel.Skipper@ec.gc.ca

Within *Health Canada* there are two groups that have responsibility for Biotechnology products; each authorized

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under separate acts of parliament. The first is the *Office of Food Biotechnology*, under the *Food and Drugs Act*, that coordinated evaluations of novel food products with other groups in Health Canada responsible for nutritional and toxicological assessments. The second group deals with health related aspects of environmental releases under the *Canadian Environmental Protection Act* (primarily microorganisms).

Novel Foods

Ms. Karen E. McIntyre
 Head, Office of Food Biotechnology
 Health Canada, Research Centre
 Health Protection Branch
 Evaluation Division
 Sir Frederick Banting Res. Centre, 4th F
 Tunney's Pasture
 Ottawa, ON K1A 0L2
 Canada
 Tel: 952-7322
 Fax: 952-6400
 Email: karen_mcintyre@inet.hwc.ca

Import and Manufacture of New Biotechnology Substances - CEPA

Allan Godfrey
 Health Canada
 Biotechnology Section
 Environmental Health Centre Tunney's Pasture
 Ottawa, Ontario
 Canada
 K1A 0L2

Tel: 957-9114
 Email: allan_godfrey@inet.hwc.ca

Within the ***Pest Management Regulatory Agency*** there are again multiple groups each of which evaluate different aspects of a submission. These activities are coordinated through the Alternatives Strategies and Regulatory Affairs group:

Pest Control Products

Mr. John D. Smith
 Senior Project Manager
 Pest Management Regulatory Agency
 Alternatives Strategies and Regulatory Affairs
 Sir Charles Tupper Building
 2250 Riverside Drive
 Ottawa, ON K1A 0K9
 Canada
 Tel: 736-3670
 Fax: 736-3659
 Email: JSmith@pmra.hwc.ca

2.2 Argentina

Governmental agencies involved in the regulation of agricultural biotechnology products:

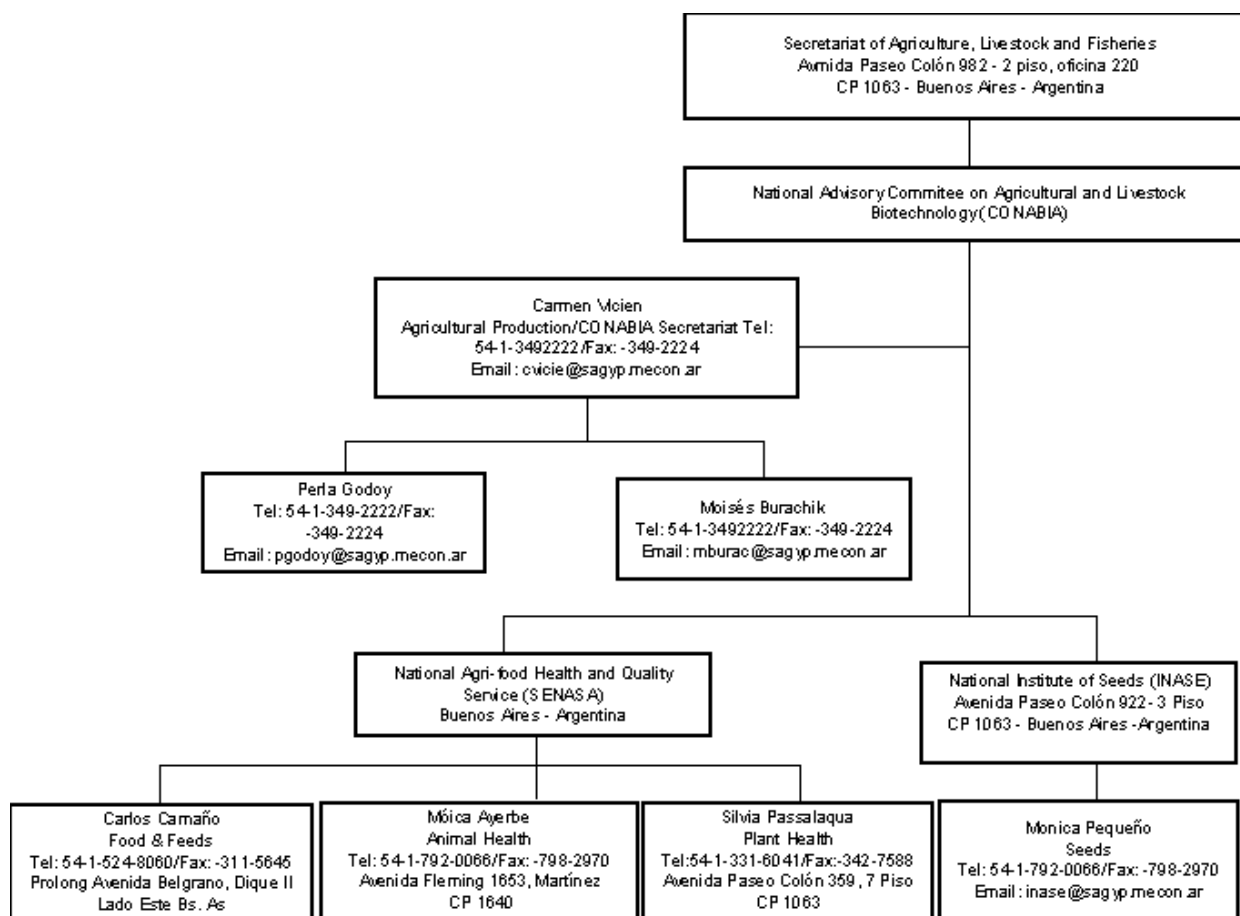
Agricultural and Livestock Biosafety	<ul style="list-style-type: none"> • Secretariat of Agriculture, Livestock and Fisheries (SAGPyA) • Argentine Institute of Plant Health and Quality (IASCAV) • National Agri-food Health and Quality Service (SENASA).
Human Health	<ul style="list-style-type: none"> • Secretariat of Health, National Committee on Biotechnology and Health (CONBySA), Subcommittee on Food.
Seeds Certification	<ul style="list-style-type: none"> • National Institute of Seeds (INASE).
Agrochemical	<ul style="list-style-type: none"> • Argentine Institute of Plant Health and Quality (IASCAV).

National coordinating bodies for biotechnology regulations

- National Advisory Committee on Agricultural and Livestock Biotechnology (CONABIA)
- National Committee on Biotechnology and Health (CONBySA), Subcommittee on Food.

Coordination of CONABIA within SAGPyA, and therefore primary assessment of GMOs, is the responsibility of the Agricultural Production Directorate headed by Carmen Vicien. The staff within this directorate can coordinate the evaluators within the various agencies under the secretary of agriculture (SENSA, INASE...)

Carmen Vicien
 Directora de Producción Agrícola, SAGPYA
 Avenida Paseo Colón 982 – 2º Piso Oficina 220
 CP 1063 – Buenos Aries – Argentina
 Tel: 54-1-349-2222
 Fax: 54-1-349-2224
 E-mail: cvicie@sagyp.mecon.ar
 The various evaluator contacts are listed below.



2.3 Chile

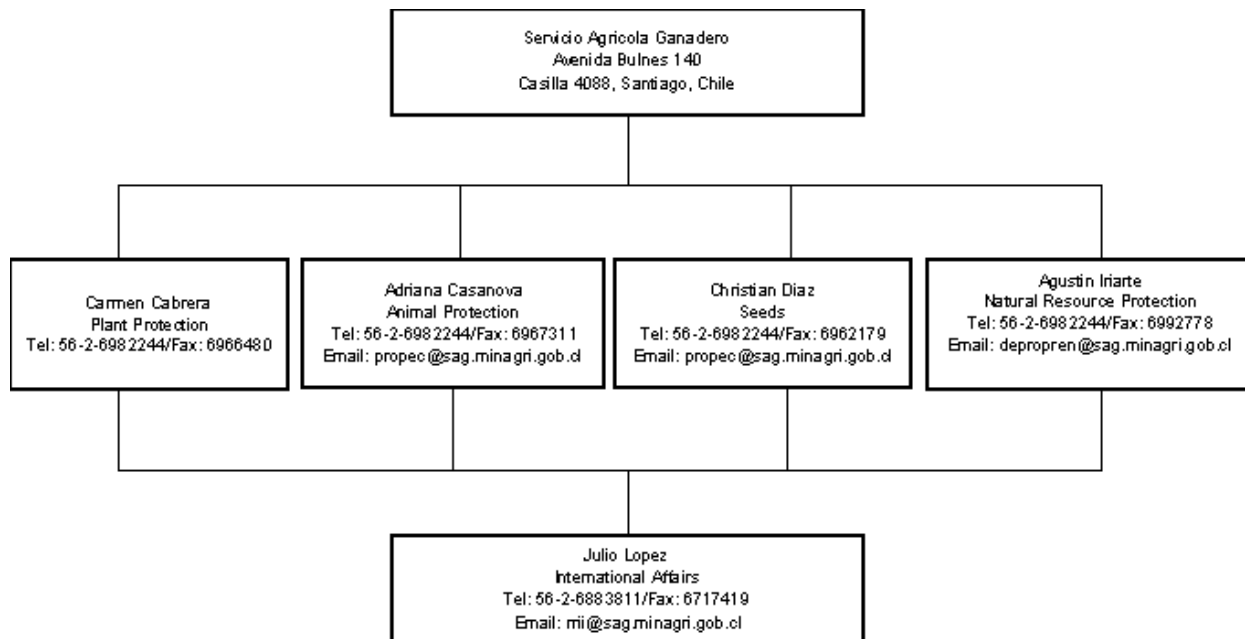
Governmental agencies involved in the regulation of agricultural biotechnology products

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Agricultural and Livestock Biosafety	<ul style="list-style-type: none"> Ministry of Agriculture, Agricultural and Livestock Service (SAG), Department of Agricultural Protection, Subdepartment of Agricultural Defense
Human Health	<ul style="list-style-type: none"> Ministry of Health, Subdepartment of Bromatology, Institute of Public Health.
Seeds Certification	<ul style="list-style-type: none"> SAG, Technical Department of Seeds.
Agrochemical	<ul style="list-style-type: none"> SAG, Department of Agricultural Protection, Subdepartment of Agricultural Defense. Ministry of Health.

National coordinating body for biotechnology regulations

- Advisory Committee on the Release of Transgenic Organisms (CALT) Within the Agricultural and Livestock Service (SAG) the key Biotechnology contacts would be:



At this time, the international affairs department has volunteered to coordinate the various groups in SAG with respect to biosafety capacity building.

Julio Lopez
International Affairs
Tel: 56-2-6883811
Fax: 56-2-6717419
E-mail: rrii@sag.minagri.gob.cl

Within the Ministry of Health initial contacts should be made through:

Luis Navarrete Muñoz
Director
Public Health Institute
Ministry of Health
Marathon 1000
Santiago, Chile
Tel: 56-2-2391105

3. Analysis of Information Management Capacity

In analyzing the information management capacity of the various government departments it is important to keep in mind that the volumes and urgency of information dictate system requirements. The key to developing an appropriate system for each situation is to thoroughly understand the current information needs and hopefully anticipate near-term and long-term information requirements.

As the volumes of information required to process and track the development of biotechnology products increase, a greater need is placed on information management systems rather than on traditional paper files. In this regard, Canada is at a significant advantage relative to many other countries, in that we have an advanced and well-used telecommunications and computer infrastructure. Tools such as high-speed Internet connections are readily available and used almost universally throughout both government and businesses. Canadians also enjoy the benefit of seamless integration into the U.S. network.

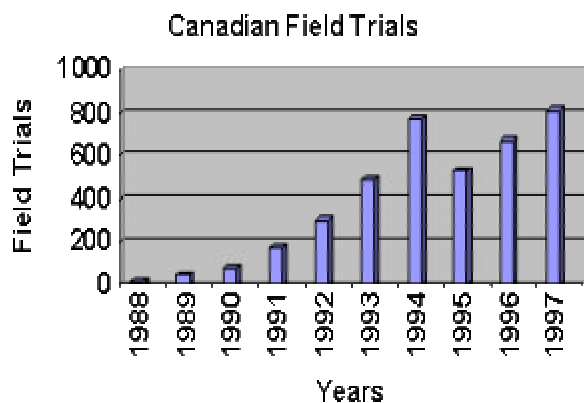
Countries such as Argentina and Chile have relatively modern computer systems often networked through LANs. External linkages tend to be slow due to limited bandwidth for telecommunications connections such as to the Internet. For example, a Latin American research Institute of 300 people would typically share a 64 Kbps connection, where a Canadian office of 12 people sharing that same bandwidth would likely be considering an upgrade. As well, Latin American countries tend not to have developed a sufficient number of domestic network nodes and as a result Internet service providers (ISPs) often have only a single high-speed connection to the Internet through a provider in the United States. This means that a message being sent across the street in Chile to a computer that is using a different ISP must be routed through the United States. Similarly, when that single connection fails, those users are isolated from the rest of the Internet until repairs are made.

Within the regulatory agencies studied, Internet access is often restricted to only a few machines within each organization. Often people are required to log onto specific workstation in order to check their e-mail [often not routed through the LAN to the computer on their desk]. As a result, communications via Internet do not tend to have the same immediate response rate as is generally found here in Canada. The basic hardware and software tools are available to ensure effective information management with the regulatory groups of both Argentina and Chile. What are lacking are applications designed to specifically handle these products.

3.1 Canada

Canada's various regulatory departments differ in the types of information they need as well as in the volume of information they wish to process. In the regulation of

transgenic plants the Plant Protection Branch of the Canadian Food Inspection Agency (CFIA) deals with the bulk of this information. This reason for this is simply that they are the first department to look at regulatory submissions for new products (i.e. field trials are usually conducted before food or feed assessments) and they often receive multiple field trial submissions before a final environmental assessment is done. Thus while Health Canada had rendered about 40 Novel Food decision, CFIA has approved about 4000 field trials. Not surprisingly, the Plant Protect Branch has had to develop a fairly advanced information tracking and retrieval system. An in-house database was developed to track field trial submissions, field inspections, environmental assessment submissions, and approvals. This database is currently running on a FileMaker pro platform and is available within CFIA via their LAN. The Plant Protection Branch has already received budget approval to develop in Internet interface to their database for both publicly accessible information as well as a secure system for field personnel to access the database via the World Wide Web.



Other regulatory groups such as Health Canada's Food Biotechnology Office and Environment Canada's New Substances Notifications group are not currently dealing with significant enough volumes of information to have forced them to create such an elaborate tracking and monitoring system. Beyond tracking and monitoring, all regulatory departments utilize databases of one form or another for classification and retrieval of scientific reports relevant to the assessment procedure. As well, wide availability of the Internet has provided a valuable tool to regulators searching scientific literature. One regulatory group commissioned the development of a pathogen database, but in hindsight felt the use of "off-the-shelf" databases was more cost-effective. When questioned, most regulators felt that the most useful source for searching scientific literature was still the Commonwealth Agriculture Bureau Database on CD-ROM (now available online) or personal contact with known experts.

Use of the World Wide Web as a tool for providing information has been use by all federal departments

involved in biosafety regulation. The amounts and types of information posted by these groups vary based on the information generated by the department and the need to present the public with information. All of the sites listed below provide links to regulations and guidelines produced by the department. The CFIA site is particularly useful in that it also provides lists of approved products, decision documents, and regulatory directives on the biology of commonly studied organisms.

CFIA – (<http://www.cfia-acia.agr.ca/english/ppc/biotech/bsco.html>)

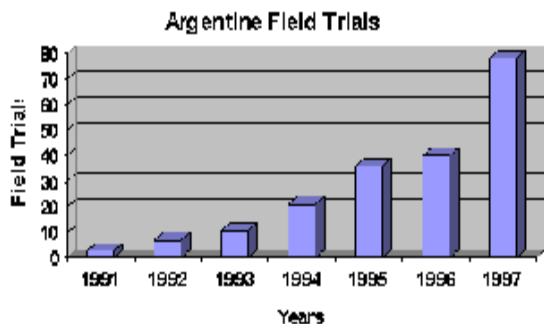
Environment Canada – (<http://www2.ec.gc.ca/cceb1/eng/biohome.html>)

Health Canada [Novel Food] – (<http://www.hc-sc.gc.ca/main/hc/web/datahpb/datafood/english/>)

For the most part, Canadian regulatory agencies have done an excellent job of managing the information related to products of biotechnology. The one area in which there is room for improvement is the tracking of personal contacts. Every regulatory uses personal contact with experts to assist in their assessments, and when a regulator leaves the department, the contact with those experts also leaves. In future, attempts should be made to prevent this loss of corporate memory during staff changes by developing a database of experts.

3.2 Argentina

Secretariat of Agriculture, Livestock and Fisheries (SAGPyA) has done a very good job developing information systems to suit their current needs. The number of field trials in Argentina has been steadily growing since 1991. In 1997, SAGPyA processed 78 field trial submissions up from 40 the year before, prompting the department to begin development on a database to track applications and field trials. The database was developed in-house to run on a stand-alone PC using a FoxPro [x base] platform. Thus far, the system is not yet been the tested due to a lack of human resources to enter and test the data.



SAGPyA has also produced a WebSite that prominently displays information on CONABIA including information on regulations, field releases, and agricultural biosafety issues.

(<http://www.sagyp.mecon.ar/HOME/English.htm>).

All information is provided in both English and Spanish and is presented in a clear and well-organized format. Now that Argentina has five biotechnology products approved for commercial use, it would be useful to list these products on the WebSite.

Internet access is somewhat restricted in that it is only available from certain machines, bandwidth is shared across the organization providing slower access times, and the firewalls can create up to 24-hour delays in downloading of some information. Thus, Internet searches are more time consuming and less efficient for collecting biosafety information from countries such as Argentina. Traditional library database searches and personal contacts tend to be a better use of time. With regard to personal contacts, e-mail is available to all regulators in Argentina though often not at the workstation that they regularly use. This could result in some delays in response to e-mail requests from Canada.

During site visits regulators in Argentina were found to be well informed about biosafety issues should be commended on their efforts to keep up to date on scientific research related to their regulatory duties. While Canada may have processed a large volume of field trial applications, the variety of products examined by Argentina is comparable.

3.3 Chile

Tracking and monitoring of information in Chile is not an immediate concern because of the small volume of information. CALT the national advisory body on environmental releases of transgenic organisms currently reviews 15 to 20 applications annually. Since there is no system for approving these products for "commercial use" field trials are limited to products for multiplication and re-export. It is expected that once a regulatory system is put in place, information volumes will increase and a tracking system will have to be implemented.

The ministry of agriculture has established a WebSite providing information on all different groups within this ministry including SAG (regulatory agency) and INIA (research agency).

(<http://www.minagri.gob.cl/>)

The WebSite is available in Spanish only and information on SAG is limited to a basic organizational overview. There's no information currently available about regulation of any products. INIA on the other hand, has what appears to be a fairly well managed network including an Intranet information system. Both INIA and CONICYT have offered to provide resources to upgrade and train SAG personnel to help develop their WebSite.

As in Argentina, Internet access is somewhat restricted. In SAG for example, e-mail is assigned to groups within the agency and rather than individuals. As well, not all machines have access to the Internet, and limited bandwidth

is shared across the organization. Thus, for the personnel at SAG internet does not appear to be widely used for gathering or disseminating information, but this may change once the regulatory demands on the agency increase.

4. Recommendations for Capacity Building

The experience of Canadian regulators in the development of regulations, assessment of products, and management of information, can greatly assist Southern Cone regulators in increasing their capacity to deal with these new products. Based on interactions with the regulatory departments discussed in this document, the following recommendations are made:

4.1 Argentina

The Argentine regulatory system for products of biotechnology is already fairly well developed and well suited to the current volume of products being processed by this country. The regulators have done an excellent job of setting up a system that protects human health and the environment, while assuring that approval and commercialization of new products occur in a timely and efficient manner. The primary role for Canadians in the evolution of regulatory system will be to

1. help the Argentines modify their system to accommodate the growing number of applications they are asked to handle; and
2. provide personal contacts with relevant experts to promote an exchange of technical information.

Last year CONABIA, the national advisory body, reviewed 78 applications for field trials. This is up almost one hundred percent from the year before. As a result, SAGPyA was forced to increase their staff and start preliminary screening of applications in-house. It is clear that this trend will continue over the next few years and SAGPyA will be expected to rely more and more on decisions from their regulators rather than CONABIA. During site visits, the SAGPyA staff displayed good technical knowledge and experience could handle greater responsibility in the approval process. These staff members will benefit greatly from interactions with Canadian regulators in seeing how large volumes information are handle. It is expected that over the next few years the role of CONABIA will be forced to change as the demands on committee members increases and experience with the products and in-house expertise grows. It may eventually be decided that certain types of approvals or combinations of organisms and transformation could be handled competently by SAGPyA staff rather than requiring a decision from CONABIA.

4.2 Chile

The Chilean regulatory system for products of biotechnology is still in its infancy. The regulatory system for field trials is operating under sanitary and phyto-

sanitary regulations for importation of plant material. There's no system in place for the approval of products for commercial use. At present, products can be grown only for multiplication of seed and re-export. In addition, the regulators do not yet have the experience or familiarity with the products they are asked to evaluate. The role for Canadians in the evolution of the Chilean regulatory system is twofold. Primarily, the Chileans need to establish the policy and regulatory framework for the assessment of these products. In addition, access to technical expertise is required. With respect to the development of a regulatory and policy framework, the Chileans should be exposed to as many approaches to regulation as possible. Meeting with Chilean regulators revealed that they are more concerned at this time with environmental protection and conservation of genetic resources than using biotechnology to increase agricultural production. The philosophical approach to regulation by SAG appears to be closer to the approach of Environment Canada rather than that of CFIA. Therefore, it is recommended recommend that any Chilean regulators be exposed to both regulatory groups.

The technical needs of the Chileans are very different from those of the Argentines. In fact, the need for an expanded technical advisory body is significant. The lack of in-house experts should be augmented, at least in the short-term, by a greater use of the advisory body (CALT). This group should be expanded to include individuals with industrial expertise and formalized procedures for review of applications should be established. The Chileans may benefit greatly from interactions with the Argentine regulators to discuss their development and use of CONABIA and how they dealt with issues such as representation and confidential business information. If possible, the Chilean visits to Canada should be coordinated to coincide with those of their Argentine counterparts.

4.3 Interactions with Canada

The key to successful technology, knowledge or resource transfer is based on "information pull" rather than "push". If Canada is to have a significant impact on the way countries such as Argentina and Chile regulate products of biotechnology, there must exist the right attitude and desire for collaboration. Partners must first recognize that there is a need for what Canada can offer to them, and second engage champions to integrate this knowledge into domestic regulatory systems. In the case of Argentina, both of these requirements have been satisfied. The case of Chile, the attitude towards products of biotechnology is one of suspicion. To date, commercial products of biotechnology have not focused on priority areas for the Chilean agricultural industry or consumers and thus are seen to be forced on them by foreign multinationals. Domestic development of products of biotechnology has already begun and once this is recognized, attitudes will likely change.

Insofar as policy development is concerned, there is value

in providing models for countries such as Chile to use as reference. But ultimately, policy and regulatory development is a domestic issue. It is hoped that through discussion of the Canadian and Argentine models and particularly in sharing how and why these models have been developed to their current form, a better understanding of the regulatory process will be achieved in all three countries and open the doors to regulatory harmonization.

With regard to technical cooperation, both Chile and Argentina have advisory bodies designed to augment the technical knowledge of their regulators. It is expected that these advisory bodies will continue to play a vital role in the regulatory process for the next several years, particularly with regard to their understanding of unique domestic situations that cannot be provided from Canada. However, as regulators gain more experience with these products and conduct more of the assessments in-house, networks of personal contacts will become more important. It is recommended that an electronic network [email list serve] be established to connect regulators brought together through this technology transfer initiative. In addition, an effort should be made to develop a formal database of experts in the areas of biotechnology products and risk assessment for the benefit of both Canadian regulators and those in Latin America. This database should be made available to as many regulators as possible, and include experts from all over the world.

Finally, an effort should be made to link information dissemination about product approvals and field trials with current OECD / UNEP initiatives such as BioTrack and the Global Environment Facility Biosafety Enabling Pilot Project. At this time, information about product approvals is still not available in any sort of regularly updated clearinghouse mechanism. However, should these international organizations decide to establish and/or maintain a global database or internet based search system, Canada, Argentina and Chile should be prepared to participate and possibly prototype such an initiative.

5. Relevant International Initiatives

Since biotechnology products are being rapidly adopted around the world there is an increasing need to ensure consistent safety standards are put in place to protect human health and the environment from any potential adverse effects of these products. To date, there are only three international organizations (OECD, UNIDO, and UNEP) that have, or plan to, invest significant resources into biosafety information systems. Recent pressures due to increasing global trade in these products and the UN Biosafety protocol negotiations have encouraged cooperation between these organizations.

5.1 OECD

5.1.1 Programme on the Harmonization of Regulatory Oversight in Biotechnology

The OECD *Programme on the Harmonization of Regulatory Oversight in Biotechnology* is an initiative designed to ensure that environmental health and safety aspects are properly evaluated, while avoiding non-tariff trade barriers to products of biotechnology. The majority of OECD member countries have (or are developing) a system of regulatory oversight for the products of modern biotechnology which are intended for release into the environment. The Programme is expected to play a coordinating role for regulatory department in member countries.

There are three main areas of work:

1. The development of Consensus Documents, on specific scientific issues related to biotechnology,
2. Outreach activities, including the development and maintenance of Biotrack Online, that makes information on the Harmonization programme available to anyone interested, and
3. General Issues associated with harmonization of biotechnology regulation.

Outreach Activities - Information Dissemination

BioTrack is an online database used to track regulator developments and field trials of transgenic plant products in OECD member countries. BioTrack Online currently includes:

- information related to major legislative developments in OECD Member countries (including details of the relevant regulatory authorities);
- an online database (including a search facility) of field trials of transgenic organisms in OECD Member countries; and
- links to other related World Wide Web sites.

Further development of BioTrack Online is planning to focus on information related to the regulatory oversight of products of biotechnology which is used by governments and industry in preparing notifications/assessments.

There will be co-operative development of OECD's BioTrack Online with UNIDO's Biosafety Information Network and Advisory Service (BINAS). The first step in 1996 was the construction of a joint BioTrack/Binas page (BIOBIN) on the World Wide Web. Currently, this is an aid to users to navigate between the two sites. However, during 1997-1999, BIOBIN will be developed further in an effort to contribute towards a global information system related to regulatory issues and harmonization.

A second project is a joint global survey with UNEP on *Regulatory Oversight on the Commercialization of Agricultural Products Derived through Modern Biotechnology*. Questionnaires have been forwarded to approximately 180 countries. The national responses will

be documented and used to compare current regulatory systems. This information will also be used by UNEP for the implementation of the UNEP International Technical Guidelines on Biotechnology.

Contact for OECD's Secretariat

OECD Environment Directorate, Environmental Health and Safety Division

Mailing address: 2, André-Pascal 75775 Paris Cedex 16, France
FAX: ** 33 1 45 24 16 75
E-mail: ehscont@OECD.org

5.2 UNIDO

5.2.1 Biosafety Information Network and Advisory Service (BINAS)

In 1992, UNIDO decided to develop an in-house capability to foster biosafety by providing developing countries with the science-based and informational tools needed to attain an adequate oversight capability in biotechnology. This resulted in the establishment of the Biosafety Information Network and Advisory Service (BINAS), a bioinformatics resource drawing largely upon the expertise and experience of the International Centre for Genetic Engineering and Biotechnology. Today the stated objective of BINAS is to assist member States in developing regulations for biotechnology.

Available on the Internet since December 1994, BINAS databases have provided biosafety data from sources worldwide. The database spectrum will soon be expanded to include technology-impact assessments and intellectual property rights. At the request of Governments in Eastern Europe, BINAS convened an expert group meeting to consider the feasibility of establishing a regional biotechnology forum mandated to work towards the harmonization of biotechnology oversight in the region. The meeting led to further requests for assistance to BINAS by Government authorities in the participating countries

and a BINAS expert has already visited Bulgaria to advise officials involved in developing biotechnology regulations. A similar regional initiative, involving the ASEAN countries, is currently being considered.

5.2.2 Genetically Modified Organisms: A Guide to Biosafety

This book Jointly produced by UNIDO and the Commonwealth Agriculture Bureau International is aimed at scientists and administrators with the intention of focusing on the major issues underlying the safety of biotechnology and how these affect policies for its regulation. Large arrays of biotechnology applications are reviewed with emphasis on risk assessment procedures. In this context, the book analyses potential adverse effects on health and the environment, and pays due attention to mitigation procedures.

Pages: 224
ISBN 0-85198-972-1
Language: E
Date: 1995

Contacts:

UNIDO Public Information –

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Street: Wagramer Strasse 5, A-1220 Vienna, Austria.
Telephone: (+43 1) 211-31, Fax: (+43 1) 232 156
E-mail: unido-pinfo@unido.org

5.3 UNEP

5.3.1 Convention on Biological Diversity

The UN Convention on Biological Diversity is the first UNEP initiative to focus on the issue of biotechnology and more specifically biosafety. The Convention signed in 1992 laid out provision for the development of a biosafety protocol.

Article 19. Handling of Biotechnology and Distribution of its Benefits

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

4. 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.

Article 8. In-situ Conservation

Each Contracting Party shall, as far as possible and as appropriate:

(g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;

Convention on Biological Diversity, 1992

5.3.2 Biosafety Protocol

The protocol, which is currently under negotiation, is intended to, along with other complementary regional and international instruments, hopes to offer an effective framework for regional and international cooperation aimed

at enhancing the transfer of, and ensuring safety in, biotechnology. Unfortunately this has not been evident thus far. The protocol has included an article specifically on the exchange of information related to biosafety and movement of products of biotechnology.

ARTICLE 19 - INFORMATION SHARING/BIOSAFETY CLEARING-HOUSE/ [BIOSAFETY DATABASE]

The Parties shall facilitate the collection and exchange of [publicly available] [scientific, technical, environmental and legal] information on, and experience with, LMOs to enable Parties to make informed decisions related to biosafety, taking into account the special needs of developing countries and the countries with economies in transition, through a [Biosafety Clearing-house] [Biosafety Database]. ...

Consolidated Text: Fifth meeting of the Protocol Working Group, Aug. 1998

5.3.3 Global Environment Facility pilot biosafety enabling project

In November 1997, the Council of the Global Environment Facility (GEF) approved a \$2.744 million UNEP/GEF pilot biosafety enabling project. The aim of the project was to provide assistance to developing countries and countries with economies in transition in formulating national biosafety frameworks for the implementation of the UNEP International Technical Guidelines for Safety in Biotechnology, and the future implementation of any agreements on biosafety. Given that it was not yet possible to have a full understanding of the kinds of assistance that countries might need in addressing biosafety issues and the future implementation of biosafety agreements, the usefulness of the project lies in assisting Governments to undertake an initial assessment of the state-of-play in their countries on matters of biosafety.

This effort is to be accompanied by a global awareness-raising initiative on biotechnology-related biosafety aspects, given the central importance of those issues for the Convention on Biological Diversity and the potential longer-term operational implications for the Global Environment Facility. In implementing the project, UNEP has agreed work closely with, and seek advice from, relevant United Nations bodies, governmental and non-governmental organizations, the biotechnology industry, the Secretariat of the Convention and regional institutions. The project managers have planned a series of regional workshops for this.

Contacts

Convention on Biological Diversity Secretariat:
World Trade Centre
393 St Jacques Street, Office 300
Montréal, Québec
Canada H2Y 1N9
(Montreal Metro Stop is "Square Victoria")
Tel: +1-514-288-2220
Fax: +1-514-288-6588
Email: secretariat@biodiv.org

The ideas and the content of this report belong to the author and are not responsibility of CIDA.

Web Sites related with Biosafety

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Argentina

- Comité Nacional Asesor en Biotecnología Agropecuaria- CONABIA
<http://siiap.sagyp.mecon.ar/http-hsi/english/conabia/frameing.htm>

Australia

- Australia's Genetic Manipulation Advisory Committee
<http://www.science.gov.au/gmac/gmachome.htm>
 - Gene Technology Information Unit
<http://geneinfo.hightide.net.au/>

Belgium

- The Belgian Biosafety Server
<http://biosafety.ihe.be/>

Brazil

- National Technical Biosafety Commission (CTNBio)
<http://www.mct.gov.br/ctnbiotec/Default.htm>
 - Biosafety Information system
<http://www.fiocruz.br/cict/oquee/estrut/dect/bis/bis.html>
 - Biosafety Journal, Bioline Publications
<http://www.bdt.org.br/bioline/by>
- Information Resource for the Release of Organisms to the Environment
<http://www.bdt.org.br/bdt/irro-l/>
 - BIN21, Biodiversity Information Network
<http://www.bdt.org.br/bin21/>

- Tropical database

<http://www.bdt.org.br/bdt/>

- Legislation Public Policies-CNPq
<http://www.cnpq.br/prossiga/rei/politicas-publicas/legis.html>

Canada

- Canadian Food Inspection Agency, Office of Biotechnology

<http://www.cfia-acia.agr.ca/english/toc.html>

<http://www.cfia-acia.agr.ca/english/ppc/biotech/bsco.html>

- Environment Canada - New Substances and Biotechnology

<http://www2.ec.gc.ca/cceb1/eng/nsbphome.htm>

- Health Canada's - Novel Foods

HTTP://www.hc-sc.gc.ca/datahpb/datafood/english/main_e.htm

- Food Biotechnology Communications Network - FBCN

<HTTP://www.foodbiotech.org/>

- Interesting Biosafety Links – University of Ottawa

<http://web.uvic.ca/ohs/biolinks.html>

- Info Biotech Canada – NRC

<HTTP://www.ibr.nrc.ca/ibr/home.html>

- Plant Biotechnology Institute – NRC

<http://www.pbi.nrc.ca/pbi.html>

Germany

- Publications on safety of novel food, German Federal Research Centre for Nutrition

<http://www.dainet.de/bfe/homee.htm>

- Robert Koch-Institut (Department of Genetics and Gene Technology)

http://www.rki.de/GENTEC/GENENG/GENTEC_E.HTM

- Biosafety Pages - The Plant Pathology Internet Guide Book (PPIGB), Institute for Plant Diseases, University of Bonn.

<http://www.ifgb.uni-hannover.de/extern/ppigb/ppigb.htm>

Hungary

- Agricultural Biotechnology Center, Biosafety Homepage

<http://www.abc.hu/hbh.html>

Japan

- Ministry of Agriculture, Forestry and Fisheries (Innovative Technology Division)
<http://ss.s.affrc.go.jp/docs/sentan/>
 - Tsukuba Univ. - Regulation & Field Trials of GMOs News
<http://www.biol.tsukuba.ac.jp/~macer/index.html>
<http://www.biol.tsukuba.ac.jp/~macer/NBBGMOs.html>
 - Current Status of Transgenic Crop Plants in Japan, MAFF
<http://ss.s.affrc.go.jp/docs/sentan/eguide/evelop.htm>

Netherlands

- Biosafety in the Netherlands
<http://www.minvrom.nl/milieu/ggo/>

New Zealand

- Food Administration – Ministry of Health
HTTP://www.moh.govt.nz/moh.nsf/wpg_Index/News+and+Issues-Index

Switzerland

- BATS - Biosafety Research and Assessment of Technology Impacts, of the Swiss Priority Program on Biotechnology
Http://www.bats.ch/index_e.html

United Kingdom

- Advisory Committee on Releases to the Environment (ACRE), UK Department of the Environment (DoE)
<http://www.shef.ac.uk/~doe/>
 - Institute of Food, Science & Technology - IFST
<HTTP://www.easynet.co.uk/ifst/>
 - The UK Department of Trade and Industry BioGuide
<http://dtiinfo1.dti.gov.uk/bioguide/bioguide.htm>
 - Biotechnology in our Food Chain – John Innes Centre
<http://www.jic.bbsrc.ac.uk/exhibitions/bio-future/index.htm>
- Ministry of Agriculture, Fisheries and Food, UK – World Wide Web site
<Http://www.maff.gov.uk/>

United States

- **USDA: Biotechnology and Scientific Services (BSS)- the United States Department of Agriculture (Animal Plant Health Inspection Service)**
[Http://www.aphis.usda.gov/biotech/](http://www.aphis.usda.gov/biotech/)

- **Biotechnology Information Center (the National Agricultural Library of the US Department of Agriculture)**
<http://www.nal.usda.gov/bic/>

- **US EPA, Office of Pollution Prevention and Toxics TSCA Biotechnology Program**
<http://www.epa.gov/internet/oppts/>
<http://www.epa.gov/opptintr/biotech/>

- **FDA : Center for Food Safety and Applied Nutrition (CFSAN)**
<http://vm.cfsan.fda.gov/~lrd/biotechm.html>

- **Information Systems for Biotechnology, a joint project of Virginia Tech and USDA**
<http://nbiap.biochem.vt.edu/>

- **Agricultural Genome Information Server, sponsored by the U.S. Department of Agriculture, Agricultural Research Service**
<http://probe.nalusda.gov:8000/>

- **International Food Information Council Foundation - Food Safety and Nutrition Information**
<HTTP://ificinfo.health.org/infofsn.htm>

- **The American Biological Safety Association**
<http://www.absa.org/>

- **CDC Biosafety Information**
<http://www.cdc.gov/od/ohs/biosfty/biosfty.htm>
<http://www.cdc.gov/health/diseases.htm>

European Commission

- **Information on Biotechnology, Directorate-General XII: Science, Research and Development**
<http://www.europa.eu.int/comm/dg12/biot1.html>

- **Deliberate field trials notified under part B of Directive 90/220/EEC, from the European Commission, Joint Research Centre**
<http://food.jrc.it/gmo>

International Organizations

- **UNIDO's Biosafety Information Network and Advisory Service (BINAS)**

<http://binas.unido.or.at/binas/>

- BIOBIN, Joint UNIDO-OECD Biosafety resource
<http://www.oecd.org/ehs/biobin/>
- OECD's "BioTrack Online" – Harmonization of Regulatory Oversight in Biotechnology
<http://www.oecd.org/ehs/service.htm>
- International Centre for Genetic Engineering and Biotechnology (ICGEB), Biosafety Pages
<http://www.icgeb.trieste.it/biosafety/>
- UNEP's International Register on Biosafety
<http://who.unep.ch/biodiv/>
- Technical Co-operation Network on Plant Biotechnology in Latin America and the Caribbean (REDBIO/FAO)
<http://www.cnpt.embrapa.br/redbio/>
- UN Biosafety Protocol Negotiations, UNEP Convention on Biological Diversity
<Http://www.biodiv.org/biosafe/index.html>
 - AgBiotechNet, CABI Publishing
<http://agbio.cabweb.org/ABTAGBIO.HTM>
- IICA-PROCISUR Sistema De Informacoes De Recursos Geneticos Do Cone Sul
<http://www.cenargen.embrapa.br/~sirgsur/>