(The following section is taken from "Biosafety regulation: A review of international approaches. April 2003. The World Bank. Agriculture and Rural development department. Report No. 26028." http://www.worldbank.org)

Regulation of Genetically Engineered Plants and Foods: Country-Specific Examples

The following case studies are provided as examples of biosafety policies and practices that have been challenged with the assessment and approval of one or more genetically engineered plants. These studies exemplify the key issues that should be considered during conceptualization and implementation of a national biosafety regulatory system.

IMPLEMENTING BIOSAFETY REGULATIONS

Statutory vs. Non-statutory Instruments

Case by case, the flexibility afforded by implementing voluntary guidelines must be weighed against potential limitations in monitoring and enforcement powers, including the impact of public perception. Despite their limitations, voluntary guidelines have proven very useful as countries develop biosafety systems. The case studies below illustrate two examples in which non-statutory measures have been used to ensure biosafety.

Argentina

Argentina is the second largest producer of transgenic crops, with 11.8 million ha (22 percent of the global area of transgenic crops) under cultivation in 2001, mainly transgenic herbicide-tolerant soybean and herbicide-tolerant and insect-resistant maize.[1] Approvals for the environmental release of genetically modified organisms (GMOs) and their use in human food or livestock feeds are conducted under regulations administered by the Secretary of Agriculture, Livestock, Fisheries and Food (SAGPyA) and SENASA (National Service of Health and Quality Agrifood). In 1991 SAGPyA created the Comision Nacional Asesora de Biotecnologia Agropecuaria (The National Advisory Committee on Agricultural Biosafety, or CONABIA) as a mechanism to provide advice on the technical and biosafety requirements for environmental releases, human food, and livestock feed uses of genetically engineered plant and animal materials.[2] CONABIA's membership is composed of both public and private sector representatives with a wide range of expertise in agricultural biotechnology. Members are selected according to a transparent process (SAGyPA Disposition No 004/00) and are approved by SAGPyA. Argentine regulations concerning the environmental release of GMOs were developed by CONABIA and are enforced by SAGPyA.

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[1] James, "Global Review of Commercialized Transgenic Crops."

[2] Comisión Nacionál Asessora de Biotecnologia Agropecuaria (CONABIA) (National Advisory Committee on Agricultural Biotechnology), 2000, <siiap.sagyp.mecon.ar/programas/conabia_ingles/FRAMEING.htm>.

The regulatory framework for biosafety encompasses the contained use, deliberate release (that is, confined field trials), and commercialization of GMOs. The regulatory requirements for GMOs are based in guidelines in the form of non-legislative resolutions that are integrated in the overall regulatory system that governs the release of products in the agricultural sector. Under this framework, specific guidelines were developed to establish conditions under which environmental releases of transgenic materials may be conducted and the resulting data reviewed by CONABIA (Resolutions SAGyPA No 656/92, No 837/93, and No 289/97). Although the system is not considered voluntary, there is no specific law that makes the resolutions legally binding.

Other regulations

In addition to the environmental release of GMOs, SENASA administers the safety evaluation of foods and food ingredients containing or composed of GMOs (SAGPyA No 511/98). Feed and food evaluation standards are defined by SENASA, and the Secretary is responsible for their enforcement. In addition to the scientific assessment of risk performed by CONABIA and SENASA, all products are subject to an economic analysis by the National Office of Agrifood Markets within SAGPyA, which studies the potential impact of the approval on domestic and international markets.

Products of biotechnology must comply with existing regulations related to plant protection (Decree Law of Agricultural Production Health Defense No 6704/66 and its amendments), seeds registration (Seed and Phytogenetic Creations Law No 20.247/73), and animal health (Law of Veterinarian Products Supervision of Their Elaboration and Creation No 13.636/49).

Egypt

The mandate for biosafety regulation in Egypt is shared among several government ministries and agencies: Ministry of Agriculture and Land Reclamation (MARL); Ministry of Health; Ministry of Trade and Supply; the Egyptian Organization for Standardization and Quality Control; and the Ministry of the Environment.

Ministry of Agriculture and Land Reclamation. Egypt's biosafety regulatory system was initiated in 1993 with the drafting of biosafety guidelines for the use, handling, transfer, and testing of GMOs in laboratories, greenhouses, and field experiments, which were published in draft form in 1994. To formalize the biosafety system, the Ministry of Agriculture and Land Reclamation (MARL) issued two decrees in 1995: the first to establish a National Biosafety Committee (NBC) and the second to adopt biosafety guidelines for Egypt.[3] The biosafety guidelines are not legally binding.

[3] M. A. Madkour, A. S. El Nawawy, and P. L. Traynor, "Analysis of a National Biosafety System: Regulatory Policies and Procedures in Egypt," ISNAR Country Report 62, International Service for National Agricultural Research, The Hague, 2000.

Other Regulations

Law No. 53 of 1966 provides MARL with the statutory responsibility for seed activities in Egypt. MARL Decree No. 82/1998 established policy and provided guidance on the procedures and protocols for the release of crop varieties developed by the Agricultural Research Centre. Conventional and transgenic varieties are handled in the same way: variety identification is standardized and conforms to international standards issued by the International Union for the Protection of New Varieties of Plants (UPOV). Performance testes are also conducted.

Decree No. 242/1997 by the Ministry of Health prohibits the import of genetically engineered foods unless their safety has been established. The decree also requires that imported seeds carry a certificate confirming that the seeds were not derived from untested genetically engineered plants. Genetically engineered plants and seeds can be imported if they have been assessed for safety and approved in the country of origin.

Article 151 of the Egyptian Constitution states that any international convention that Egypt ratifies will become Egyptian law.

Statutory Options

The following case studies are examples of different approaches that have been taken in developing biosafety regulations. These studies also exemplify how these approaches blend with other regulations for foods, the import and export of commodities, and the movement of conventional plants across borders. Australia and South Africa are examples in which new legislation was developed specifically to deal with gene technology and genetically modified organisms, whereas in the United States and Canada, biosafety was addressed through modifying existing laws.

Australia

Until 2001, the regulation of biotechnology and its products in Australia was coordinated under five different systems[4]: the Australia New Zealand Food Authority (ANZFA), the Therapeutic Goods Administration (TGA), the National Registration Authority (NRA), the National Occupational Health and Safety Commission (NOHSC), and the Australian Quarantine and Inspection Service (AQIS).

From 1987 through June 21, 2001, the Genetic Manipulation Advisory Committee (GMAC), which was housed within the Interim Office of the Gene Technology Regulator (IOGTR) of the TGA, was the non-statutory body responsible for overseeing the research, development, and use of novel genetic manipulation techniques in Australia, and the environmental release of GMOs. GMAC was concerned with any operation that

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[4] Interim Office of the Gene Technology Regulator (IOGTR), Information Sheet (IOGTR), Fact Sheet 3: "About the GMAC," Office of the Gene Technology Regulator, Commonwealth Department of Health and Aged Care, Canberra, 1999.

resulted in or used organisms of novel genotype produced by genetic manipulation that fell under its scope of review. GMAC had defined its scope as:

> any experiment involving the construction and or propagation of viroids, viruses, cells or organisms of novel genotype produced by genetic manipulation which are either unlikely to occur in nature, or likely to pose a hazard to public health or to the environment.

While compliance with GMAC's voluntary scheme was high, limitations were identified, including:

- The voluntary system of compliance with GMAC guidelines was not designed to provide for product regulatory approvals, because its original focus was the oversight of research.

- It had no legal provisions to ensure compliance by auditing or monitoring practices, nor to ensure that punitive actions were taken in the event of noncompliance.

- The existing product regulatory system was not designed with GMOs in mind; as a result, there were gaps and deficiencies within the framework.

- There were no established standards or rules for risk assessment or management.

- The voluntary system was not sufficiently transparent nor did it include adequate public consultation, which lacks compromised public confidence in its effectiveness.

In response to these inadequacies, the States, Territories, and the Commonwealth of Australia collaborated to develop a nationally consistent regulatory system for GMOs. This system was developed through extensive consultations with relevant government agencies, academic and private sector developers, consumer and environmental groups, primary producers, industry, and the public. The end product is the Gene Technology (GT) Act[5], which received Royal Assent on December 21, 2000 and came into force in June 2001. The act does the following:

- Establishes a statutory officer, the Gene Technology Regulator, to administer the legislation and make decisions under the legislation
- Establishes three key committees (the Gene Technology Technical Advisory Committee, the Gene Technology Ethics Committee, and the Gene Technology Community Consultative Group) to provide scientific, ethical, and policy advice
- Regulates all "dealings," that is, research, manufacture, production, commercial release, and import, with live, viable organisms that have been modified by

[5] Office of the Gene Technology Regulator (OGTR), Gene Technology Act, 2000, Canberra, 2001. <http://law.agps.gov.au/cgibin/download.pl?/scale/data/pasteact/3/3428>.

techniques of gene technology, including the progeny of such GMOs that also share a genetically modified trait
- Establishes a scheme to assess the risks to human health and the environment associated with various dealings with GMOs, including opportunities for extensive public input
- Provides for monitoring and enforcement of the legislation
- Creates a centralized, publicly available database of all GMOs and genetically engineered products approved in Australia (the Record of GMO and genetically engineered product dealings).

The provisions of the Gene Technology Act are "in addition to, and not in substitution for, the requirements of any other law of the Commonwealth (whether passed or made before or after the commencement of the Act)."

Other Regulations

Under the Australian Constitution, the responsibility for regulating the safety of food produced for consumption within Australia is vested in the States and Territories. As a result, Australia has a complex and varied food regulatory system, encompassing several agencies and types of legislation across three levels of government. A 1998 review of food regulation found approximately 150 acts and associated regulations related to food or agrifood businesses in Australia that were administered by several Commonwealth agencies, over 40 State and Territory agencies, and over 700 local governments.

National food standards are developed by ANZFA and are adopted by the States and Territories by reference and without amendment after being agreed by a majority of members of the Australia New Zealand Food Standards Council (ANZFSC). The council is comprised of Commonwealth, State, Territory and New Zealand health ministers. In July 1998, ANZFA established *Standard A18-Food Produced Using Gene Technology*[6], which came into force on May 13, 1999. Under this standard, the sale of food produced using gene technology is prohibited unless the food is included in the table to clause 2 of the standard. The standard requires that a pre-market safety assessment be conducted on all foods produced using gene technology. However, the standard provides an exemption for foods currently on the market provided that an application was accepted by ANZFA on or before April 30, 1999; that the food is lawfully permitted in a country other than Australia or New Zealand; and that ANZFSC has not become aware of evidence that the food poses a significant risk to public health and safety.

South Africa

In 1978 the South African Genetic Experimentation Committee (SAGENE) was formed to encourage recombinant DNA research, provide guidelines for responsible management of recombinant microorganisms, approve and classify research centers and projects, and

[6] Australia New Zealand Food Authority (ANZFA), Standard A18: Food Produced Using Gene Technology, 1999, Canberra <http://www.anzfa.gov.au/documents/gen37_99.asp>.

arrange advanced training for scientists[7]. The terms of reference for SAGENE were changed in 1989 to make the committee South Africa's national advisory body for the environmental release of GMOs. As a non-statutory committee, SAGENE promulgated the following guidelines beginning with the laboratory guidelines in the early 1980s, and then comprehensively in 1996:

- Guidelines and Notification Procedures for Laboratory Containment of Genetically Modified Organisms, which describe essential and recommended practices for genetic manipulation in the laboratory.
- Guidelines for the Categorization of Genetic Manipulation Experiments, which apply to cloning in prokaryotic and lower eukaryotic organisms, and to the genetic manipulation of plant cells. They provide guidance on assessing the risk to human health and safety and to environmental safety, when working with experimental GMOs, and were designed to conform to South Africa's Occupational Health and Safety Act, 1993 (Act. No. 85 of 1993).
- Guidelines and Notification Procedures for the Large-scale Use of Genetically Manipulated Organisms, which describe the factors to be considered in the risk assessment of the large-scale use of GMOs and the notification protocol for informing SAGENE of large-scale work. Large-scale use refers to "the use or growth of GMOs in a pilot plant or commercial manufacturing facility on a scale of 10 liters or more."
- Guidelines for the Trial Release of Genetically Modified Plants in the Republic of South Africa, which provide recommendations for the risk assessment and monitoring of genetically modified plants cultivated in experimental field trials. The guidelines require applicants to adhere to the Environmental Conservation Act, 73 of 1989 and the principles and requirements of the Integrated Environmental Management Procedure of the Department of Environmental Affairs and Tourism.

Initially, South Africa's National Department of Agriculture managed the experimental use and subsequent commercial release of GMOs using interim guidelines under amendment of the Agricultural Pest Act, 1983 (Act No. 36 of 1983). SAGENE reviewed all applications for experimental trials and environmental release of GMOs and made recommendations to the government in this regard[8]. The interim system issued permits for GMO activities under the Plant Pest Act, but was compulsory only for imported genetically engineered seeds and plant material. Application for permits to conduct greenhouse and field trials with genetically engineered plant material was voluntary (M. Koch, personal communication). For this reason, in combination with the fact that regulation of GMOs was becoming a more controversial issue, South Africa elected to produce a new legal instrument specifically to regulate GMOs. In 1997 the Genetically Modified Organism Act was passed. The act was developed to

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[7] Z. M. Ofir, "Biotechnology in the New South Africa," Biotechnology and Development Monitor 20 (1994): 1415.

[8] M. Koch, "Public Awareness Information on Genetically Modified Food," Africabio <http://www.africabio.com/news/old/article22.html>.

- Provide for measures to promote the responsible development, production, use, and application of genetically modified organisms
- Ensure that all activities involving the use of genetically modified organisms (including importation, production, release, and distribution) shall be carried out in such as way to limit possible harmful consequences to the environment
- Give attention to the prevention of accidents and the effective management of waste
- Establish common measures to evaluate and reduce the potential risks arising from activities involving the use of genetically modified organisms
- Lay down the necessary requirements and criteria for risk assessments
- Establish a council for genetically modified organisms
- Ensure that genetically modified organisms are appropriate and do not present a hazard to the environment
- Establish appropriate notification procedures for specific activities involving the use of genetically modified organisms and provide for matters connected therewith.

The act, which came into force in 1999 with the publication of regulations, created:

- An Executive Council (EC). This independent decision-making body will make decisions on all applications for work with GMOs. The Council is made up of representatives from six government departments and, when making its decisions, will take into account issues such as socioeconomics, trade, labor and safety to humans and the environment.

- A Scientific Advisory Committee. This body of scientists will review the human and environmental safety of GMOs and advise the Council of its findings.

- Registrar and Inspectorate. The Registrar will administer the GMO Act on behalf of the Minster of Agriculture, will issue permits at the request of the EC, and will use the Inspectorate to monitor and inspect local work with GMOs.

Other Regulations

All imports and exports of agricultural materials require a permit issued under the Agricultural Pest Act, 1983. In addition, if the item to be imported is a GMO, a permit for import or export is required under the GMO Act.

The safety of all foods, including foods derived from biotechnology, is regulated under the Foodstuffs, Cosmetic and Disinfectants Act, 1972 (Act No. 54).

United States

Three United States departments share responsibility for regulating agricultural biotechnology: Department of Agriculture (USDA), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA).

USDA-APHIS. The USDA's Animal and Plant Health Inspection Service (APHIS) is the lead agency for the regulation of genetically engineered plants, including the experimental evaluation of these products in confined field trials. In 1993 USDA finalized a regulation under the Federal Plant Protection Act (PPA) (formerly the Federal Plant Pest Act) that described a petition process for determining whether particular plants would no longer be regulated and, therefore, could be commercially planted[9,10]. A regulated article is defined as any organism that has been altered or produced through genetic engineering if the donor organism, recipient organism, or vector or vector agent belong to any genera or taxa designated as, or believed to be, a plant pest[11]. APHIS also can designate any product of genetic engineering a regulated article if the article is deemed to be a plant pest. For a crop to achieve nonregulated status, USDA prepares "environmental assessment" and "determination of nonregulated status" documents that address a number of safety concerns, including impacts on agriculturally beneficial organisms and the potential to become a plant pest.

APHIS' authority to regulate genetically engineered plants stems from the fact that, to date, these plants have been products of Agrobacterium tumefaciens (a bacterial pest causing crown gall disease in plants), mediated transformation, and/or contain regulatory sequences derived from a plant pest (cauliflower mosaic virus 35S promoter). Although APHIS' regulations for genetically engineered plants apply only to plant pests, the agency's broad discretionary authority provides it with sufficient latitude that any transgenic plant could be considered a plant pest and so fall within its mandate.

EPA. The Environmental Protection Agency is responsible for regulating pesticides in the United States, including pesticidal substances produced through biotechnology. Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the EPA ensures that pesticides meet federal safety standards. The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that the EPA determine safe levels of pesticide residues in food. In 1994 the EPA published proposed regulations describing policies for pesticidal substances expressed in transgenic plants under FIFRA and FFDCA. In 2001 this rule was finalized along with two others that clarify which plant-incorporated protectants are exempt.[12,13,14] A plant-incorporated protectant is a pesticidal substance that is produced

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[9] United States Department of Agriculture (USDA), "Introduction of Organisms and Products Altered or Produced through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," 7 CFR 340, 1993 <http://www.aphis.usda.gov/bbep/bp/7cfr340.html>.

[10] United States Department of Agriculture (USDA), "Genetically Engineered Organisms and Products: Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status," Federal Register 58: 17044-59. <http://www.aphis.usda.gov/bbep/bp/393rule.txt>.

[11] A plant pest is defined as any living stage of invertebrate animals, bacteria, fungi, parasitic plants, or viruses; or any organisms, agents, or substances that can directly or indirectly damage or cause injury to plants or parts thereof.

[12] Environmental Protection Agency (EPA), Regulations under the Federal Insecticide, Fungicide and Rodenticide Act for Plant- Incorporated Protectants (formerly Plant Pesticides), 40 CFR Parts 152 and 174, Federal Register 66 (2001): 37772817.

[13] EPA, "Exemption for the Requirement of a Tolerance under the Federal Food, Drug and Cosmetic Act for Residues of Nucleic Acids that Are Part of Plant-Incorporated Protectants (formerly Plant Pesticides), 40 CFR Part 174, Federal Register 66 (2001):
3781730.

and used by the living plant, typically to protect the plant from pests, such as insects, viruses, and fungi.

Other Regulations

The FDA is responsible for assuring that foods derived through genetic engineering are as safe as their traditional counterparts. Under the FFDCA, the FDA has the authority to require pre-market review and approval in cases in which protection of public health is required, such as when a substance is added intentionally to a food and there are questions about its safety. FDA also has post-market authority to remove a food product from commerce and sanction those marketing the food if it poses a risk to public health.

In the United States, the complex array of criminal and civil sanctions, including tort and contractual remedies, available to governments and private parties provides food producers and manufacturers with every incentive to bring safe, wholesome foods to market.

In 1992 the FDA published in the Federal Register a Statement of Policy on its approach to the regulation of foods derived from genetically engineered plants[15]. The purpose of this policy was to provide a risk-based "decision tree" to guide plant breeders and food manufacturers through issues critical to ensuring the safety, nutritional value, and wholesomeness of new foods. Under this "standard of care," which applies equally to new foods produced through traditional breeding as well as biotechnology, FDA also provided guidance on regulatory issues such as cases in which an introduced substance is not generally recognized as safe and would require pre-market approval as a food additive, and for which special labeling would be required under FFDCA. Food producers are not required to seek FDA pre- market approval or apply a special label for a new variety of food if it is substantially equivalent to existing varieties already on the market.

In January 2001, the FDA published a proposed rule for mandatory pre-market notification for genetically engineered foods. Under this rule, the FDA will require the submission of data and information about genetically engineered foods destined for human or livestock consumption 120 days prior to the commercial distribution of such foods. This means that when the proposed rule is finalized, the FDA will move from its current voluntary system to a mandatory system for the regulatory oversight of genetically engineered foods and livestock feeds.

Before commercialization, genetically engineered plants/organisms also must conform to standards set by state and federal marketing statutes such as state seed certification laws,

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[14] EPA, "Exemption for the Requirement of a Tolerance under the Federal Food, Drug and Cosmetic Act for Residues Derived through Conventional Breeding from Sexually Compatible Plants of Plant-Incorporated Protectants (formerly Plant Pesticides),
40 CFR Part 174, Federal Register 66 (2001): 3783054.

[15] May 29, 1992, 57 FR 22984.

the Toxic Substances Control Act, and the Federal Plant Protection Act. There are no national requirements for variety registration of new crops.

Canada

In Canada, the regulation of agricultural biotechnology products is coordinated between the Canadian Food Inspection Agency (CFIA), Health Canada, and Environment Canada. In all cases, these agencies have used existing acts to incorporate new or amend existing regulations.

CFIA. The CFIA is responsible for regulating the importation (Plant Protection Act), environmental release (Seeds Act), variety registration (Seeds Act), and use in livestock feeds (Feeds Act) of plants with novel traits (PNTs), including transgenic plants. PNTs are plant varieties/genotypes that are not considered substantially equivalent, in terms of their specific use and safety both for environment and for human health, to plants of the same species, with regard to weediness potential, gene flow, plant pest potential, impact on non-target organisms, and impact on biodiversity. PNTs may be produced by conventional breeding, mutagenesis or, more commonly, by recombinant DNA techniques.[16]

The first confined field trial of a PNT in Canada was authorized in 1988 in accordance with voluntary guidelines that were published in 1995 as Regulatory Directive 95-01: Field Testing Plants with Novel Traits in Canada. These guidelines have been amended three times since, most recently in 2000[17]. Information guidelines for the environmental risk assessment of PNTs were published in 1994 as Regulatory Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits. In 1996 the Canadian government amended the Seeds Act and Regulations[18] with the promulgation of Part V, Release of Seed, which was further amended in 2000. These regulations allow for the testing of PNTs in field trials under confined conditions, and prescribe the requirements for mandatory environmental and human health safety assessment prior to authorization for unconfined environmental release.

Other Regulations

The importation into Canada of PNTs, including transgenic plants, and any products derived from them requires a permit issued under the Plant Protection Act. Typically, permits are issued with specific conditions to limit the movement or use of the PNTs after entering Canada.

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[16] Canadian Food Inspection Agency (CFIA), Regulations Amending the Seeds Regulations, Canada Gazette 134 (2000): 3294-99.
[17] CFIA, Directive 2000-07: Guidelines for the Environmental Release of Plants with Novel Traits within Confined Field Trials in Canada.
[18] Agriculture and Agri-Food Canada (AAFC), JUS-96-004-01 (SOR/DORS): Amendments to the Seeds Regulations-Release of Seed, <http://www.inspection.gc.ca/english/plaveg/pbo/96004e.shtml>.

Health Canada is responsible for the assessing the safety of all food products, including novel food products under the Novel Food Regulations of the Food and Drugs Act, which were promulgated in October 1999[19]. Under these regulations, a manufacturer or importer of a novel food must notify Health Canada 45 days prior to the sale or advertising for sale of these products. The department undertakes to respond within 45 days should additional safety information of a scientific nature be required, and will notify the manufacturer within 90 days of receipt of such information as to whether it is sufficient. Until the Novel Food Regulations came into force in 1999, the safety assessment of novel foods was based on voluntary compliance with the "Guidelines for the Safety Assessment of Novel Foods."[20]

Under the Canadian Environmental Protection Act (CEPA), Environment Canada is responsible for administering the New Substances Notification Regulations and for performing environmental risk assessments of CEPA-defined toxic substances, including organisms and microorganisms that may have been derived through biotechnology.

POSITIONING SOCIOECONOMIC CONSIDERATIONS WITHIN BIOSAFETY REGULATION

The examples that follow are meant to illustrate some different approaches that have been used to address the issue of incorporating (or not) socioeconomic concerns in regulatory decision-making.

Argentina

In 1991 the Argentine Secretary of Agriculture, Livestock, Fisheries and Food (SAGPyA) created the Comision Nacional Asesora de Biotecnologia Agropecuaria (The National Advisory Committee on Agricultural Biosafety, or CONABIA) as a mechanism to provide advice on the technical and biosafety requirements to be met in environmental releases, human food, and livestock feed uses of genetically engineered plant and animal materials. Additional regulations, administered by the National Service for Agrifood Safety and Quality (SENASA), apply to safety evaluations of foods and food ingredients containing or composed of genetically modified organisms (see section 0 for a complete description of the Argentine system).

In addition to the scientific assessment of risk performed by CONABIA and SENASA, all products are subject to an economic analysis by the National Directorate of Agrifood Markets within SAGPyA, which studies the potential impact of the approval on domestic and international markets. This consideration of economic consequences is one example of addressing a particular type of socioeconomic concern within a product approval system.

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[19] Health Canada, Schedule No. 948: Novel Foods Regulations, 1999 <http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/sch948e.pdf>.

[20] Health Canada, Guidelines for the Safety Assessment of Novel Foods, 1994 <http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/novele.pdf>.

South Africa

South Africa's Genetically Modified Organism Act, which was implemented in 1999, controls the production, importation, distribution, and environmental release of genetically modified organisms (GMOs), including LMOs[21]. Prior to the coming into force of this legislation, these activities were subject to a series of voluntary guidelines published by the South African Committee for Genetic Experimentation (see section above on implementing biosafety regulations in South Africa).

The new act creates two new structures that serve to separate the risk management decision-making and scientific risk assessment processes. The Executive Council, which is comprised of up to eight persons, including one representative from each of six government departments, is responsible for advising on authorizations. In so doing, the Council also will take into account socioeconomic issues relating to labor and trade impacts. A separate scientific body, the Scientific Advisory Committee, is responsible for performing risk assessment reviews of potential environmental risks associated with the release of GMOs into the environment. Their findings and advice are provided as input to the Executive Council for formulation of a final recommendation to the Minister.

In this example, separating the activities of risk assessment from risk management has provided a mechanism for including non-science issues in the decision-making process without prejudicing the science-based evaluation process.

Canada

The authority for reviewing the environmental and livestock feed safety of plants with novel traits, including genetically engineered plants and their products, and for authorizing their release or use in commerce, resides with Canadian Food Inspection Agency under the Seeds Act and Regulations, and the Feeds Act and Regulations. Canadian regulators employ an evidence-based approach to risk assessment that considers only the additional scientifically defensible risks associated with a particular product, without consideration of possible benefits. In Canada, the scientific risk assessment largely "determines" the regulatory decision, and there are no opportunities to consider broader socioeconomic issues.

Within the context of the Canadian Biotechnology Strategy, the federal government established the Canadian Biotechnology Advisory Committee (CBAC) as an independent expert advisory body with a mandate to provide advice to government on broad policy issues associated with the ethical, social, regulatory, economic, scientific, environmental, and health aspects of biotechnology. [22] CBAC's 1998 interim report on improving the regulation of genetically modified foods in Canada examined the question of related social and ethical concerns but did not make specific recommendations other than ones

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[21] South African Genetically Modified Organism Act, No. 15, Government Gazette 383 (18029) (23 May 1997).

[22] Industry Canada, "The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process," Ottawa <http://strategis.ic.gc.ca/cbs>.

aimed at strengthening environmental stewardship[23]. These included introducing a stronger ecosystem perspective in environmental risk assessments and funding a research program to examine long-term impacts. Future advice in this area, particularly with respect to the development of a public "acceptability framework," may shape the direction of national policy and the federal framework for regulating biotechnology products.

United Kingdom

Since 1990, under Directive 90/220/EEC, the United Kingdom and other European Union member states have had a harmonized approach to considering applications for the environmental release of GMOs. This directive, which applied to the release and marketing of all GMOs except the marketing of products derived from them (for example, novel foods, or human or veterinary medicines), was replaced by a new framework under Directive 2001/18/EC, which took effect on April 17, 2001. Member states had until October 17, 2002 to bring into force national measures to comply with the new Directive's provisions. These provisions focus primarily on harmonizing principles of environmental risk assessment; managing potential long-term cumulative effects on the environment and wildlife; post-market monitoring; and improving transparency, openness and public consultation. With respect to ethical and socioeconomic issues, the new directive does not include these as specific factors to be taken into account. However, it does provide for consulting ethical committees on matters of a general nature and for periodic reporting on the socioeconomic implications of environmental releases of GMOs.

In June 2000, the UK government established the Agriculture and Environment Biotechnology Commission (AEBC) to provide independent strategic advice on biotechnology developments and related implications for agriculture and the environment. This committee is similar in structure and mandate to Canada's CBAC, except that the remit of the latter includes the entire spectrum of biotechnology applications and issues, not solely those specific to agriculture. Among its other roles, the AEBC will advise the UK Government on the ethical and social implications arising from agricultural biotechnology developments and their public acceptability.

REGULATORY STRUCTURES, SECURING SCIENTIFIC ADVICE, INSPECTION, AND ENFORCEMENT

Locating the Risk Assessment Function

The following case studies are examples of countries that have chosen to locate the risk assessment function with expert advisory committees (UK) or with scientists and professionals working within government departments and agencies (Canada, U.S.).

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[23] Canadian Biotechnology Advisory Committee, "Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada: Interim Report to the Government of Canada Biotechnology Ministerial Coordinating Committee," Ottawa, 1998 <http://www.cbac-cccb.ca>.

United Kingdom

Within the UK, the Advisory Committee on Releases to the Environment (ACRE) is an independent statutory advisory committee, appointed by the Secretary of State for the Environment, which reviews applications for field trials or general (commercial) releases of GMOs under parts B and C of Directive 90/220/EEC (now Directive 2001/18/EC). Originally convened as an advisory body in 1990, ACRE was re-appointed as a statutory committee under the Environmental Protection Act 1990, which requires Ministers to seek advice from ACRE on all applications for the environmental release of GMOs. The committee represents a broad-based source of scientific expertise in agronomy, ecology, entomology, microbiology, molecular biology, plant breeding, rural development, virology, and weed ecology. It has no specific representation from the social sciences or from stakeholder groups such as industry or environmental pressure groups.[24]

Canada and the United States

In contrast, the biosafety risk assessment of transgenic plants in the United States involves only government evaluators within the Biotechnology Permits Branch of USDAAPHIS. A similar arrangement exists within the Plant Biosafety Office of the Canadian Food Inspection Agency (CFIA). In these countries, the incorporation of external scientific expertise, in the form of expert panels or committees, is not a general requirement but nonetheless has been accommodated ad hoc. Two examples include the CFIA consultations with the Bt Corn Coalition (1998) to establish mandatory insect resistance management plans, and a USDAAPHIS expert panel consultation (1997) on the risks associated with incorporating plant viral genes into transgenic plants.[25,26] Other examples of standing committees include the US EPA Scientific Advisory Panel and Health Canada's Scientific Advisory Panel. In these countries, ad hoc committees and advisory panels provide advice on the formulation of government policy and/or regulations, or advice on specific issues, such as the allergenic potential of Cry9C protein[27]. Unlike committees such as ACRE, these bodies do not participate in the evaluation of specific applications or petitions.

HORIZONTAL ISSUES

Integrating Biosafety Regulation in National Policies and Strategies

The following are examples of national strategies that include guiding principles and

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[24] Advisory Committee on Releases to the Environment, Department of the Environment, Transport and the Regions, Annual Report 7, (2000) <http://www.defra.gov.uk/environment/acre/pubs.htm>.

[25] Canadian Food Inspection Agency, Plant Health and Production Division, Plant Biosafety Office, Insect Resistance Management of Bt Corn in Canada, 1998 <http://www.inspection.gc.ca/english/plaveg/ pbo/bt/btcormai1e.shtml>.

[26] USDA-APHIS, Summary of Public Meeting on Virus-Resistant Transgenic Plants, 5 Aug. 1997 <http://www.aphis.usda.gov/biotech/virus/virussum.html>. Advisory Panel (SAP) Meeting, Washington, D.C., 28 Nov. 2000.

[27] U.S. EPA, "Assessment of the Scientific Information Concerning StarLink Corn," SAP Report 2000-06, FIFRA Scientific

coordinating structures for implementing national biosafety systems. In addition, each provides for the creation of an advisory committee to serve as a focal point to initiate public dialogue and address cross-cutting issues related to the ethical, legal, and social implications of biotechnology.

Australia

The development of Australia's National Biotechnology Strategy was begun in 1999 with the establishment of the Commonwealth Biotechnology Ministerial Council to coordinate government biotechnology activity. At the same time, government established the Biotechnology Consultative Group (BIOCOG), a panel of experts from industry and the scientific and research community, to provide it with independent advice. Overall, the goals of the strategy are to capitalize on existing advantages in biotechnology, achieve sustainable industrial growth, strengthen coordination of government activities at the Commonwealth and State levels, develop a catalytic role for government, and provide a basis for ongoing consultation and strategy development.

As a result of a series of consultations and assessments, Australia's strategy identified six key themes, two of which - biotechnology in the community and ensuring effective regulation - are relevant to biosafety. The remaining themes focused on the economic and trade aspects of biotechnology. A key thrust of the theme on biotechnology and the community was to establish a dialogue with Australians that would serve to increase awareness of biotechnology, its applications, and the regulations in place to safeguard the environment and health; to address ethical and socioeconomic concerns; to examine community health benefits arising from biotechnology; and to examine the role of biotechnology in sustainability and natural resource management issues.

The strategy also forms a broad policy platform that describes the Australian approach to biotechnology regulation. It establishes the role of the Office of the Gene Technology Regulator as the principal body responsible for biosafety and articulates as an overarching goal the need to ensure that potential risks from the introduction of GMOs are accurately assessed and effectively managed. Furthermore, the strategy defines the principles on which environment risk assessment should be based and identifies specific objectives. These include the establishment of a framework and scientific methodology for risk assessment, the identification of priorities for an environmental risk assessment program, improvement of the scientific knowledge base, monitoring for unforeseen consequences, and monitoring regulatory effectiveness.

Canada

Biotechnology has been the object of special attention within the Canadian federal government for at least 20 years. In 1979 Ministry of State for Science and Technology (MOSST) published the report, "Biotechnology in Canada," and the joint industry university task force report, "Biotechnology: A Development Plan for Canada," was presented to the MOSST Minister in February 1981. These early reports ultimately led to

the creation of a National Biotechnology Strategy (NBS) in 1983 to encourage research and development, investment, and market acceptance, of this new technology.

In 1990 a review of the NBS recommended an increased focus on the regulatory issues affecting biotechnology and the development of those technologies that would bring new products to market more rapidly. After a significant public consultation, the federal government announced its coordinated regulatory framework for products of biotechnology on January 11, 1993. The objectives of this framework were to maintain Canada's high standards for the protection of human health and the environment; use existing legislation and regulatory institutions; develop clear guidelines for evaluating products that are in harmony with national and international standards; provide a sound scientific basis for risk assessment and product evaluation; ensure that both the development and enforcement of regulations are open and include consultation; and contribute to the prosperity and well-being of Canadians.

Partly in response to changing budgetary imperatives, a review of the objectives of the NBS was conducted during 1996/97, leading to a renewed Canadian Biotechnology Strategy (CBS) in 1998[28]. The new CBS was based on the principles of promoting sustainable development, competitiveness, public health, innovation, transparency, and scientific excellence. Among the 10 key themes identified by the strategy are 3 that relate directly to biosafety: building public confidence, expanding the science base to support regulations, and regulating to protect human health and the environment. With respect to the regulatory framework, the strategy emphasizes efficiency and effectiveness, international harmonization, transparency, and human technical and scientific capacity.

South Africa

South Africa's National Biotechnology Strategy is emerging, a first draft having been prepared in June 2001. The South African experience illustrates that the formulation of national policy need not occur prior to the development of biosafety regulation, as was the case for Canada, but can occur at any time. Biosafety regulation is achieved under the Genetically Modified Organism Act 1997, which was implemented in 1999, and prior to that was governed by voluntary guidelines published by the South African Committee for Genetic Experimentation. The government recognized the need to develop a coordinating policy to stimulate innovation and human resource development and encourage research and development investment in South Africa, while preserving the environment. These motivations are similar to those expressed by other countries that have developed similar strategic policies. Of relevance to this discussion, the South African strategy aims to increase public understanding of biotechnology by improving communication of risks and benefits, communicating as a single voice across government departments, and including biotechnology issues (ethical, social, environmental) within school curricula.

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[28] Industry Canada, "The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process," Ottawa <http://strategis.ic.gc.ca/cbs>.

Transparency and Public Engagement

Australia

In many respects, the Australian approach to regulating GMOs and products derived from them, such as novel foods, is a model of transparency and public involvement. The Office of the Gene Technology Regulator (OGTR), which administers Australia's new Gene Technology Act 2000, is responsible for reviewing and approving the deliberate environmental release of GMOs, either in experimental field trials or as commercial plantings. Commercial plantings are distinguished from field trials in that they do not have provisions for reproductive isolation; however, OGTR reserves the right to place conditions or restrictions on their conduct. Irrespective of whether the release is an experiment trial or a commercial planting, OGTR engages in two rounds of public notification and request for comment. These practices are the same as those previously followed under the voluntary system of guidelines administered by the Genetic Manipulation Advisory Committee[29]. Upon receipt of applications for intentional release, OGTR publishes notices in the Commonwealth of Australia Government Notices Gazette, as well as national and regional newspapers, and its own website (http://www.ogtr.gov.au). These notifications also serve as a request for public comment. Similar notifications, including the publication of risk assessment reports and opportunities for public input, are provided for proposed decisions on the environmental release of GMOs.

The Australia New Zealand Food Authority (ANZFA), which is responsible for the regulation of novel foods under Standard A-18Food Produced Using Gene Technology in the Australian Food Standards Code, engages in similar public consultation processes. In soliciting public comment, ANZFA publishes a draft risk analysis report that provides a background to the application; highlights the issues addressed during the risk assessment; summarizes public comment submitted in response to the notification of application; and deals with legitimate issues raised in public comments[30].

United States

Under the Coordinated Framework, three agencies share responsibility for regulating biotechnology.[31] The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) is the lead agency with respect to the environmental review and deregulation of transgenic plants, while the U.S. Environmental Protection Agency (EPA) is responsible for the registration of plant-incorporated protectants (for example, plant-expressed toxins derived from Bacillus

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[29] Genetic Manipulation Advisory Committee, Public Information Sheets on deliberate release proposals, including field trials and general releases, that have been assessed by GMAC <http://www.health.gov.au/ogtr/volsys/infosheets.htm>.

[30] Australia New Zealand Food Authority, Recent Standards Development: Applications <http://www.anzfa.gov.au/foodstandards/recentstandardsdevelopment/index.cfm>.

[31] The Coordinated Framework for Regulation of Biotechnology Products, Federal Register 51: 23303 (26 June 1986).

thuringiensis). Since 1992, the U.S. Food and Drug Administration (FDA) has been operating under a policy for regulating bioengineered foods that took the position that these foods should not be subject to additional regulation solely because they were produced using modern biotechnology. In that context, FDA has worked with developers through a system of voluntary consultation and review prior to the commercial introduction of these products.[32]

U.S. law requires that all petitions for a determination of non-regulated status, or applications for registration of a plant-incorporated protectant, be published in the Federal Register prior to any regulatory decision. In the case of APHIS petitions, this notification includes a synopsis of the petition (that is, general characteristics of the transgenic plant) and explains the role of other regulatory bodies (EPA and FDA), and the process for submitting comments and obtaining more information, including a copy of the petition, less any confidential business information. Following its assessment, and if it determines that the plant poses no significant risk to other plants in the environment and is as safe to use as more traditional varieties, APHIS publishes a "determination of non-regulated status" in the Federal Register. This notice advises the public of the availability of all written comments received, APHIS' environmental assessment, and the Finding of No Significant Impact (FONSI) for the article. This statutory requirement for public notification and request for comment does not apply in the case of confined experimental field trials of transgenic plants; however, APHIS does periodically publish a notice in the Federal Register indicating the availability of a listing of current field trials. Public notification and opportunities for public input have not been a part of FDA's voluntary consultation process with industry prior to the introduction of new foods. This situation is poised to change with the proposal by FDA of a new rule requiring that all new foods derived from biotechnology be subject to mandatory review prior to marketing[33]. The new rule proposes to increase transparency by providing for pre-market publication of a notification prepared by the developer that would describe the new food and the related safety data. While addressing the criticism that the existing system lacks openness, the proposed rule does not go so far as to allow opportunities for public comment during the consultation period. In March 2001, the FDA published the results of the 51 voluntary industry consultations regarding bioengineered foods that have occurred since 1994[34].86 The publication of this information, which previously was available only by request under the Freedom of Information Act (FOIA), provides further evidence that FDA is seeking to improve regulatory transparency.

European Union

The revision to Directive 90/220/EEC governing the environmental release of GMOs,

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[32] FDA, Center for Food Safety and Applied Nutrition (CFSAN), "Guidance on Consultation Procedures: Foods Derived from New Plant Varieties" <http://vm.cfsan.fda.gov/~lrd/consulpr.html>.

[33] FDA, CFSAN, "Pre-market Notice Concerning Bioengineered Foods, Federal Register 66 (12): 470638, Docket No. 00N-1396 (18 Jan. 2001).

[34] FDA, CFSAN, "List of Completed Consultations on Bioengineered Foods" <http://www.cfsan.fda.gov/~lrd/biocon.html>.

which took effect on April 17, 2001 (Directive 2001/18/EC), makes new provisions for increased transparency and public involvement. These changes establish a mandatory requirement for public notification and some form of consultation with the public or special interest groups prior to the conduct of experimental or farm-scale trials (for example, environmental releases under Part B). The new directive does not specify the exact form or scope of consultation other than to require that it include a "reasonable time period." The new directive also contains requirements for seeking public input on applications for Part C releases (for example, marketing consents), and any proposed changes of policy with respect to categories of Part B releases or the information requirements for Part C applications. While respecting the principle of protecting confidential business information, the new directive specifically excludes from such protection information pertaining to a general description of the GMO; name and address of the notifier; purpose of the release; location of the release; methods and plans for monitoring of the GMO; and the environmental risk assessment.

To make the decision-making process more predictable and transparent, the new Directive also establishes, for the first time, clear deadlines for each stage of the regulatory process. The directive also sets a maximum term for new Part C marketing consents of 10 years and requires that all existing consent holders reapply for an extension by October 2006.

International and Regional Harmonization

Canada U.S. Bilateral on Agriculture Biotechnology

In recent years, Canada and the United States have engaged in bilateral discussions on harmonizing their approach to the risk assessment of transgenic plants. These efforts have aimed at establishing a shared set of criteria in the areas of molecular characterization and environmental risk assessments that each country will use to review submissions for regulatory approval.

In 1998 officials from the Biotechnology Permits Branch (USDAAPHIS), the Plant Biotechnology Office (CFIA), and the Office of Food Biotechnology (Health Canada) met to compare and harmonize, when possible, the information requirements and standards for submissions dealing with the molecular genetic characterization of transgenic plants[35]. The two countries reached substantial agreement in detailing the essential elements of molecular characterization data required to be submitted by a petitioner and to be used by the agencies for decision-making. They also reached agreement on quality standards for submitted information in the form of checklists for reviewers. It was anticipated that these efforts will facilitate cooperation and information-sharing between the agencies as well as expedite the review process.

Although slight differences remain between the two countries' requirements, for the most part, petitioners are able to submit very similar data packages on their molecular

[35] CFIA, "Canada and United States Bilateral on Agricultural Biotechnology," Ottawa. <http://www.inspection.gc.ca/english/plaveg/pbo/usda/usda01e.shtml>.

characterization to both regulatory agencies. The clarification of data requirements and standards provided petitioners with a better understanding of the agencies' needs, enabling petitioners to adjust their research programs to meet these standards.

During 2001, Canada and the United States finalized their discussions on harmonizing the evaluative criteria for environment risk assessments. These harmonized criteria, published in 2002, more clearly explain the detailed information requirements related to assessing potential risks of outcrossing, weediness, and impacts on non-target organisms.[36]

Both countries also are engaged in separate bilateral discussions with the European Union on similar risk assessment harmonization issues related to the molecular characterization of transgenic plants.

(see Table 1 for a Summary of characteristics of regulatory frameworks)

[36] CFIA, "Environmental Characterization Data for Transgenic Plants Intended for Unconfined Release," Ottawa. <http://www.inspection.gc.ca/english/plaveg/pbo/appenannex2e.shtml>.

Table 1 Summary of characteristics of regulatory frameworks

Characteristic of regulatory framework	Argentina	Australia	Canada	Egypt	Japan	S.Africa	UK (EU)	USA
Conceptual approach	**"X" indicates conformity with 1st alternative in each dichotomous comparison**							
-Regulatory oversight triggered by the process of genetic engineering (recombinant DNA technology) vs. product attribute	X	X		X	X	X	X	X[a]
-Regulatory decision making requires political involvement vs. occurs solely within competent authority	X	X		X		X	X	
Implementing biosafety regulation								
-Statutory instruments are employed vs. voluntary guidelines		X	X		X	X	X	X[b]
-New laws were passed to specifically address gene technology vs. existing statutes used		X			X	X	X	
-Decision-making process includes consideration of economic and/or social factors vs are based primarily based on science assessment	X[c]				X[d]			
-Scientific risk assessment by an expert committee vs. by evaluators within the public service	X	X[e]		X		X	X	
-Mandatory requirement for post-market validation testing or monitoring vs. no, or limited, monitoring						X[f]		
Horizontal issues								
-Biosafety regulation under the umbrella of an overarching national biotechnology policy vs. no national strategy		X	X			X		
-Mandatory requirement for public notification of decisions vs. no legal requirement for notification		X					X[g]	X
-Mandatory requirement for public comment prior to decisions vs. no legal requirement		X					X	X

Notes:

a. Applies to USDA-APHIS and U.S. EPA. To date, U.S. FDA policy has been that bioengineered foods are not inherently more risky than other foods so has engaged in voluntary consultation only.

b. Exception is U.S. FDA voluntary consultation process with developers.

c. In addition to the scientific assessment of risk performed by CONABIA and SENASA, all products are subject to an economic analysis by the National Directorate of Agrifood Markets within SAGPyA, which studies the potential impact of the approval on domestic and international markets.

d. The Executive Council, which advises the minister on approvals, also will take into account socioeconomic issues relating to labor and trade impacts.

e. Mixed approach in which food safety assessments are conducted by evaluators within the ANFZA but environmental considerations are considered by an expert committee.

f. The recent revision to Directive 90/220/EEC (Directive 2001/18/EC) proposes a statutory period of mandatory post-market monitoring. The period will be agreed at the point of giving commercial approval; at the end of the review period, a decision to renew the commercialization approval will be made based on any monitoring evidence.

g. Recent revision to Directive 90/220/EEC (Directive 2001/18/EC) governing the environmental release of GMOs, which took effect in Oct. 2002, makes new provisions for increased transparency and public involvement.