USDA Foreign Agricultural Service
GAIN Report
Global Agriculture Information Network
Template Version 2.09

Required Report - public distribution

Date: 7/15/2008

GAIN Report Number: CI8013

Chile

Biotechnology

Santiago

2008

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Report Highlights:
Monsanto is planning to increase the 2,000 hectares of soybean planted in 2007 to 10,000 hectares for 2008. SAG has approved the field trials.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Santiago [CI1]
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Executive Summary

Chile has a long history of field trials with transgenic seeds. However, to date, no product has been approved for domestic commercialization. All transgenic seeds imported for multiplication must be produced under strict field controls and re-exported. Thus, the general farming community does not benefit from this technology, even though Chilean consumers eat genetically engineered products imported from other countries. The reason for this de facto ban is that Chile is concerned it could lose its Asian and European markets (collectively more than 50 percent of exports) if it openly adopts this technology.

The Bachelet administration appears to be moving cautiously on biotechnology, there is not pressure from this administration on moving forward with the legislation even if there are three different initiatives in Congress and the Chilean consumers don't benefit from this technology.

Over the past years there has been many attempts to legislate on biotechnology, perhaps former president Lagos who created a national commission to study the issue initiated the biggest one, the framework that resulted from this commission was never introduced in Congress. The most aggressive attempt was the introduction of a bill to label all products containing genetically engineered ingredients. On June 19th 2006 the Chamber of Deputies voted 94-1 in favor of mandatory labeling, the bill moved to the Senate and is now an agenda in the Health Committee. On September 2006 a group of Senators from different sectors introduced a more ambitious bill into the Agricultural Committee as an attempt to regulate not only the labeling issue but also all aspect relating the production, consumption and commercialization of GMO products, this framework is expected to be voted in the Committee this year.

Chile requires that all transgenic events used in food must be registered and explicitly approved by the Ministry of Health. Despite of our previous believes, companies like Monsanto and others are submitting their event registration.

In terms of commercial interests, Chile could be a consumer of transgenic sugar beets, corn, alfalfa, and soybeans (if the salmon industry were to lift its self-imposed ban on the use of biotech feeds), to name a few crops. Although not widely publicized, Chile has begun to do landmark research in “orphan” crops (non-bulk commodities), such as salmon, pine, stone fruit, apples, and grapes. As part of the government’s efforts to increase research and development using funds received from copper mining royalties, Conicyt/FIA/Corfo manage the funds and establish consortiums to do biotech research.

As with many developing countries, the majority of research funds come from the public sector. This year the Government announced a number of programs and affiliations with different universities in the U.S., Australia, Canada to favor technology transfer and postgraduate degrees with the purpose of increasing research and develop the country.

However, the agricultural export sector also remains concerned about the trade implications of this technology. They view the issue from the perspective of how will the uses of transgenic affect Chile’s “natural” image. They argue that currently there are few benefits for the products in which Chile has a competitive advantage (horticultural crops, salmon and forestry). As Chile is an agricultural export based economy, with agricultural exports accounting for 15% of GDP, these reservations have prompted Chile to take a cautionary approach on biotech issues and play a muted role in international fora such as APEC, MERCOSUR, and OAS, as well as UN and WTO organizations such as FAO, CODEX, and the International Plant Protection Convention (IPPC). Chile signed the Cartagena Protocol on Biosafety, but has not ratified it yet. Nor has Chile established an adventitious presence level

for imports yet. However, with a strong regulatory system and a greater investment in the technology, Chile could become an important developing country spokesman in the above-mentioned venues.

Section II. Biotechnology Trade and Production

a) Does Chile commercially produce any biotechnology crops? Chile does not produce any crops for sale domestically. However, Chile has produced transgenic seeds under strict field controls for re-export for more than a decade, during 2007, and for the first time Chile planted two thousand hectares of soybean and is expected to increase that number to ten thousands during 2008, this is a project run by Monsanto. See Section VI. Reference Materials, Appendix A. Table of Approved Biotechnology Products.

b) Are there any biotechnology crops under development in your country that will be on the market in the coming year? Appendix A shows the field trials and seeds being propagated in Chile. Additional research is being conducted on such crops as citrus, stone fruits, grape vines, pine, and salmon. However, none of these crops are scheduled for commercial release domestically within the next year.

c) Does the country import biotechnology crops/products? Yes. See Appendix A. The main crops are corn, soybeans, canola, tomatoes and sugar beets. Chile also imports processed food products containing transgenic ingredients from many countries including Canada, the US, Brazil, Mexico, Argentina, and the European Union.

d) Is Chile a food aid recipient or likely to be a food aid recipient in the near future? No

e) Does Chile produce any biotechnology crops that were developed outside of the United States and have not passed through the US regulatory system? Crops from other countries have been approved for field trials in Chile, however the events have been approved in the United States as well.

Section III

a) . Responsible Government Ministries and their role.

See the list in Section VI for the contact information for each office:

- The Agricultural Livestock Service (SAG), Ministry of Agriculture is responsible for analyzing applications to conduct field trials or grow and market transgenic. Through both a document review process and consultations with technical experts (CELT-Advisory Council on the Release of Transgenic), SAG performs the environmental risk assessment. The application includes a complete description of the botanical, agro economic, and molecular aspects of the different components of the new cultivars, including studies evaluating possible environmental interactions and methods of controlling possible gene flow.

- The Ministry of Health sets the rules governing food safety, including labeling requirements and approves ingredients for human consumption. In January 2000, the food law was modified to require a case-by-case analysis to authorize transgenic products for human consumption. Events have to be approved by the Ministry before entering the country, at this moment Monsanto has submitted a number of events following the procedure set by the Ministry, the process of approval considers a fast track when FDA has approved the events. Currently mandatory labeling of transgenic foods/ingredients is required when the product is substantially different from the conventional product.

- The Regional Ministry of Health offices (SEREMIS SALUD) provides import approvals for foods, based on the regulations established by the Ministry of Health. Currently there is no official adventitious presence level. This office is the responsible to enforce the approval of the events or the labeling if/when Congress adopts a new labeling requirement.

- CONAMA (Environmental Commission) represents Chile at the Biosafety Protocol meetings, participates in the National Biotechnology Commission, and is on the National Committee on Biosecurity Matters. However, they are not specifically authorized under the current regulatory structure to do environmental impact assessments for transgenic products.

- The Agricultural Research Institute (INIA), creates, adapts and transfers scientific know-how and technology to the agricultural community via its centers, libraries, and laboratories. Currently, they are the lead government agency in the area of practical research in biotech crops in Chile.

- The National Commission for Technology and Scientific Research (CONICYT) defines science and technology policy; promotes and finances science and technology research programs and projects; promotes international cooperation and increases public awareness and understanding of the benefits that accrue to the country as a result of its investment in scientific and technological research.

- The Foundation for Agricultural Innovation (FIA) is part of the Ministry of Agriculture and finances programs that incorporate innovative production processes or creative industrial or marketing methods in agriculture, livestock, forestry, and aquaculture. They have funded projects and training in the area of biotechnology.

ii. Role and membership of Biosafety Committee (if any).

Chile signed the Cartagena Protocol on Biosafety, but has not ratified it yet. On November 30, 2000, a National Committee for Biosecurity Matters was established. CONAMA is on this committee and has represented Chile at the international Biosafety Committee meetings. In general, though, Chile has not taken any lead positions in international venues pending adoption of its national biotechnology framework law.

iii. Assessment of political factors that may influence regulatory decisions related to agricultural biotechnology.

Chile is an export based economy, with agricultural exports accounting for 15% of GDP. The agricultural export sector has voiced some concerns about the trade implications of this technology. They view the issue from the perspective of how will the uses of transgenic affect Chile's "natural" image. They argue that currently there are few benefits for the products in which Chile has a competitive advantage (horticultural crops, salmon and forestry). These reservations have prompted Chile to take a cautionary approach on biotech issues and play a muted role in international fora such as APEC, MERCOSUR, and OAS, as well as UN and WTO organizations such as FAO, CODEX, and the International Plant Protection Convention (IPPC).

On June 19, 2006 the Chamber of deputies voted almost unanimously to adopt mandatory labeling. The detection threshold for biotech content is 1% and should be label as "Genetically Modified Product". The bill is now with the Senate Health Committee. On September 2006 a new framework was introduced to the Senate, sponsored by Senator from different sector, government and opposition, this bill is now in the Agricultural Committee and it is expected to be voted during this year. What makes it different than other attempts to regulate on the matter is that was drafted by senators of different sectors and that it deals

with all aspects related to agricultural biotechnology, commercialization, production, consumption and not only with the labeling issue as the ones introduced before.

Finally, select NGOs have called for GMO free zones in the country. This was deemed unconstitutional. However, a few Congressmen in response to these special interest groups are researching how voluntary zones might be created.

b) List biotechnology crops that have been approved for:

i. Food, processing, and feed – none

ii. Environment – See Appendix A, which shows crops approved solely for multiplication and re-export.

c) Does Chile allow field-testing of biotechnology crops? Yes, currently strictly for re-export.

d) Please note the treatment of stacked events.

If all the genes have been approved individually by SAG they go through an expedited process. They still have to be approved as a new event, but the process is simplified.
If the genes have not been approved individually or one of them has not yet been approved, the stacked event is considered to be a whole new event, and it must go through a full review.

e) What is Chile's policy on coexistence between biotechnology and non-biotechnology crops? Are there rules in place or proposed on coexistence?

There currently are no specific rules on the subject of coexistence, but Resolution 1523 of 2001 introduced a traceability system and documentation requirements for all seeds and the fields where they are planted. As part of the process for every field trial approval, biosafety measures are established, such as physical isolation from sexually compatible species and post harvest management. The draft framework bill is expected to specifically address this issue, but is unclear what modification may be made to this document under the new Bachelet Administration. She is not opposed to biotechnology, and many of her ministers are openly proponents of the technology, however, she has not taken a public stance on the issue to date. The Ministry of Agriculture has hosted several open forums on this topic, with panelists ranging from agronomists, economists, regulators, activists and trade and legal experts. The question of liability has been openly vetted in these meetings, although the final draft language is not available yet.

f) Does the country require labeling for packaged foods or feeds?
For human consumption, mandatory labeling currently is required for products and/or ingredients that are substantially different from their conventional counterparts. There are no labeling requirements for crops, as currently there are no crops approved for domestic commercialization.

g) Has Chile signed or ratified the Biosafety Protocol?

Yes, Chile signed the Biosafety Protocol but has not ratified it yet.

h) Biotechnology-related trade barriers.

Currently there is a Ministry of Health requirement that all transgenic events be reviewed by the Ministry of Health, registered and explicitly approved prior to allowing their use in domestic and imported foods could result on a trade barrier if the producers of the event have no interest on register or submitting their information in Chile.

In terms of commercial interests, Chile could be a significant consumer of transgenic soybeans, but the salmon industry has chosen to impose a de facto ban on the use of biotech feeds, due to their concerns that European and Japanese consumers might reject the product. While these types of industry imposed constraints clearly adversely affect trade, they are not formal technical barriers to trade.

i) Is there pending legislation with the potential to affect exports?

As previously mentioned, there is a mandatory labeling proposal approved by the Chamber of Deputies is currently being debated by the Senate Health Committee. If adopted with a 1% threshold detection level for biotech ingredients many domestic and international products could be affected.

The new daft of biotechnology framework introduced on the Agricultural Committee of the Senate does not include mandatory labeling, but we do not know the direction it can take when is being discuss by other committees of the Senate or when it goes back to the Chamber of Deputies.

j) Are there 'technology fees' for commercially planted crops? No

Section IV. Marketing Issues

a) Market acceptance issues for producers, importers, retailers and consumers.

Currently there are no high visibility advocates of this technology. The scientific/academic community and parts of the agricultural community (corn and sugar beet farmers) are proponents of allowing genetically engineered products to be marketed domestically, but have not been very vocal in their support. At the same time, Chile's traditional export sectors (wine, salmon, and fresh fruits) remain concerned about the effect adoption of this technology might have on their markets in Europe and Japan. These sectors are doing research in genome mapping and, in the case of the salmon industry, research in transgenic vaccinations, but they also have distanced themselves from being perceived as in favor of genetically engineered products. Consumer understanding of the issue is uninformed, with exposure mainly being to alarming reports from special interest groups. Neither importers nor retailers have taken a stance on the issue.

b) Relevant studies on the marketing of biotechnology products.

INIA has a series of relevant publications and books that can be purchase from their library. You can find a list at the following website: http://www.inia.cl/biotecnologia/

Bioplanet, contains extensive information on national and international biotech developments.
http://www.bioplanet.net/index.htm

Fundación Chile, a non-governmental research organization, conducts biotech studies.

http://www.fundacionchile.cl

Fundacion Ciencias para la Vida, private company dedicated to create a link between the biotechnology and the private sector

http://www.cienciavida.cl

Centro de Biotecnologia Universidad de Concepcion

http://www.centrobiotecnologia.cl

This site has information on "Agricultural Biotechnology Cooperation in Latin America and the Caribbean "
http://www.redbio.org/

This site has Biotechnology information for the Chilean industry
http://www.sofofa.cl/sofofa/index.aspx?channel=3732

Biotechnology as a tool for development and well-being
http://www.acti.cl/publicaciones/biotecnologia.htm

This site provides information to the industry and also to general public

http://www.chilepotenciaalimentaria.cl/?cat=8

Section V. Capacity Building and Outreach

a) U.S. Government or USDA funded capacity building or outreach activities.

Past biotechnology activities in Chile include:

Post is organizing a Biotechnology Workshop oriented to law makers during the month of September.
Funded the participation of seven Chilean participants to different APEC Agricultural Biotechnology activities in Peru, Bolivia and Australia.
Funded the participation of Dr. Ralph Scorza as speaker at the Red Bio Agricultural biotechnology Conference organized in Viña del Mar, Chile in October, 2007.
Organized a biotechnology/IPR seminar with the participation of high level government officials and agencies, June 7,2007, that included the participation of Clive James (ISAA) and Karen Hauda (U.S. Patent and Trade Mark Office) as main speakers. Sponsor the participation of the one member of the Chilean delegation to the APEC High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB) held in Canberra, Australia, 2007. Embassy Science Fellowship program with the participation of a USDA/ARS scientist for two months in Chile from May-July 2006. Ministry of Agriculture Official was sent to a training course in the Philippines in June 2006 on Commercializing biotech crops. The U.S. Government participated in the Tenth APEC Research, Development and Extension of Agricultural Biotechnology (RDEAB) hosted by Chile in November 2005, we organized a reverse CODEL to the U.S. to be learn about the U.S. regulatory System for Biotech products in July 2005; We sponsored a Chilean expert to attend the APEC Seminar: "Creating a Positive Investment Environment for Agricultural Biotechnology", in Malaysia in Dec 04; we organized a panel of experts to address the Chilean Agriculture and Health Committees in Oct 04; we sent the President of the Small Farmers

Cooperative Confederation to a farmer-to-farmer training program in Honduras in Aug-Sept 04; we sponsored two participants to attend the Michigan State biotechnology short course in August 2004; we hosted a visit to the U.S. of a team of Ministry of Health officials tasked with gathering information about other countries biotech regulations in Mar-Apr 04; we coordinated between the Einstein Institute for Science, Health and the Courts (EINSHAC) and the Chilean Judicial Institute to provide technical training to the judiciary regarding biotechnology in civil, criminal and family cases in Mar 04; we organized the HLPDAB in Chile, in Feb 04 and funded the participation of 22 representatives from APEC emerging markets to attend, as well as nine speakers.

b) Country specific needs or strategies for Chile.

The objective of the above-mentioned activities was to promote science based regulation for biotech foods, especially in the case of food labeling, and to generate Chilean support in international standard setting bodies for reasonable requirements. The programs also were intended to build long-term regulatory acceptance for future biotech food crops using science bases principals to conduct risk assessments and to foster the adoption of common documentation for trade in bulk commodities under the Biosafety Protocol.

Also an effort was made to facilitate/refine/build mechanisms for enhancing public/private collaboration in biotechnology. Work in this area should continue. By improving the communication between the Chilean agricultural export community and the R&D facilities and by streamlining the tech transfer process within Chile, the development and adoption of biotech crops of economic interest to Chile could be increased and consequently so probably would be Chile's participation in the international dialogue on how biotech crops are handled globally.

Finally, and probably the most important focus should be on educating the public and Congress. Activities targeting journalist, Congress and general public through the schools could help form the debate on labeling and general acceptance of genetically engineered products. Specially, a train the trainer workshop would be helpful to help the regulators educate and inform the public about biotechnology. Finally, the Ministry of Health and the Public Health Institute have requested technical training for their laboratory officials. They received a grant from the European Union to build a lab and need technical information on how the U.S. uses its laboratories to comply with its international commitments.

Section VI. Reference Materials

Contact Information for Government Agencies:

Servicio Agrícola Ganadero - SAG (Agricultural Livestock Service)
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FIA (Foundation for Agricultural Innovation)
Fundación para La Innovación Agraria – FIA
Director Ejecutivo: Rodrigo Vega Alarcon

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Apendix A

List of event approved for field trial 2007-2008

Requested by	Specie	Event	Genetic Modification
MONSANTO	SOYBEAM	PV-GMPQ-HT 6305	Modification on the composition of the oil in the seed and tolerance to glifosate
MONSANTO	SOYBEAM	PV-GMAP5779	Yield increase

MONSANTO	SOYBEAM	PV-GMPQ-HT 6302	Modification on the composition of the oil in the seed and tolerance to glifosate
MONSANTO	SOYBEAM	PV-GMPQ-HT 6304	Modification on the composition of the oil in the seed and tolerance to glifosate
MONSANTO	SOYBEAM	PV-GMPQ-HT 6306	Modification on the composition of the oil in the seed and tolerance to glifosate
MONSANTO	CANOLA	PV-BNHT-5212	Tolerance to Glifosate
MONSANTO	CANOLA	PV-BNHT-6311	Tolerance to Glifosate
MONSANTO	CANOLA	PV-BNHT-2672	Tolerance to Glifosate
MONSANTO	SOYBEAM	PV-GMPQ-HT-6303	Modification on the composition of the oil in the seed and tolerance to glifosate
MONSANTO	SOYBEAM	PV-GMPQ296	Increase oil in the seed
MONSANTO	CORN	PV-ZMIR7233	Resistance to coleopterons
MONSANTO	CORN	PV-ZMIR7234	Resistance to coleopterons
MONSANTO	CORN	PV-ZMAP1043	Tolerance to Glifosate
MONSANTO	CORN	PV-ZMAP4341	Resistance to draught
MONSANTO	CORN	PV-ZMAP3292	Resistance to draught
MONSANTO	CORN	PV-ZMAP3284	Resistance to draught

GREENSEED	CORN	P006	Resistance to draught
GREENSEED	CORN	P007	Resistance to draught
PIONEER	CORN	PHP27401	Tolerance to Glufosinate and modification on the oil content
PIONEER	CORN	PHP27347	Tolerance to Glufosinate and modification on the oil content
PIONEER	CORN	PHP29806	Tolerance to Glufosinate and modification on the oil content
PIONEER	CORN	PHP28289	Tolerance to Glufosinate and modification on the oil content
PIONEER	CORN	PHP28278	Tolerance to Glufosinate and modification on the oil content
PIONEER	CORN	PHP28189	Tolerance to Glufosinate and modification on the oil content
PIONEER	CORN	PHP28156	Tolerance to Glufosinate and modification on the oil content
PIONEER	CORN	PHP29994	Tolerance to Glufosinate and modification on the oil content
PIONEER	CORN	PHP30048	Tolerance to Glufosinate and modification on the oil content
PIONEER	CORN	PHP29722	Tolerance to Glufosinate and modification on the oil content
PIONEER	CORN	PHP27643	Tolerance to Glufosinate and modification on the oil content
PIONEER	CORN	PHP29528	Tolerance to Glufosinate and modification on the oil content
PIONEER	CORN	PHP29021 X PHP8999 X PHP17662	Tolerance to herbicides and resistance to insects

PIONEER	CORN	PHP29021 X PHP8999	Tolerance to herbicides and resistance to insects
PIONEER	CORN	PHP29021	Tolerance to herbicide
PIONEER	CORN	PHP29012X PHP8999 X PHP17662	Tolerance to herbicides and resistance to insects
PIONEER	CORN	PHP29012X PHP8999	Tolerance to herbicides and resistance to insects
PIONEER	CORN	PHP29012	Tolerance to herbicide
PIONEER	CORN	PHP27118	Tolerance to herbicides and resistance to insects
PIONEER	CORN	PHP29064 X PHP8999	Tolerance to Glufosinate, increase yield and resistance to insects
PIONEER	CORN	PHP29063 X PHP8999	Tolerance to Glufosinate, increase yield and resistance to insects
PIONEER	CORN	PHP29062 X PHP8999	Tolerance to Glufosinate, increase yield and resistance to insects
PIONEER	CORN	PHP89002 X PHP8999	Tolerance to Glufosinate, increase yield and resistance to insects
PIONEER	CORN	PHP28651 X PHP8999	Tolerance to Glufosinate, increase yield and resistance to insects
PIONEER	CORN	PHP23180 X PHP8999	Tolerance to Glufosinate, increase yield and resistance to insects
PIONEER	CORN	PHP23180	Tolerance to Glufosinate, increase yield
PIONEER	CORN	PHP29004 X PHP8999	Tolerance to Glufosinate, increase yield and resistance to insects
PIONEER	CORN	PHP29005 X PHP8999	Tolerance to Glufosinate, increase yield and resistance to insects
PIONEER	CORN	PHP 29003 X PHP8999	Tolerance to Glufosinate, increase yield and resistance to insects

PIONEER	CORN	PHP29065 X PHP8999	Tolerance to Glufosinate, increase yield and resistance to insects
PIONEER	CORN	PHP24597 X PHP8999 X PVZMGT32	Altered fertility, resistance to insects and tolerance to herbicides
PIONEER	CORN	MIR162	Resistance to insects
HYTECH	CANOLA	MS8	Tolerance to ammoniac glufosinato
MANSUR	SOYBEAM	PSF10	Tolerance to herbicides
MANSUR	SOYBEAM	TG GM12	Increase yield
MANSUR	SOYBEAM	TG GM13	Increase yield
MANSUR	SOYBEAM	TG GM16	Increase yield
MANSUR	SOYBEAM	TG GM18	Increase yield
MANSUR	SOYBEAM	TG GM19	Increase yield
GREENSEED	CORN	BT11 X P3149	Resistance to lepidopterous and resistance to draught
MASSAI	SOYBEAM	PV-GMPQ296 X MON89788	Increase oil on the seed and tolerante to glifosate
TUNICHE	SOYBEAM	PV-GMPQ296 X MON89788	Increase oil on the seed and tolerante to glifosate
TUNICHE	SOYBEAM	PV-GMPQ296	Increase oil in the seed

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