

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT
POLICY

Required Report - public distribution

Date: 8/4/2014

GAIN Report Number: CI1409

Chile

Agricultural Biotechnology Annual

Agricultural Situation in Chile - 2014

Approved By:

James Butterworth, Agricultural Attaché

Prepared By:

Nelson Ramirez, Agricultural Specialist

Report Highlights:

Although events occurred over the past year that looked like Chile might move on its biotechnology framework, in the end, Chile is in the same place as it was last year.

SECTION II. EXECUTIVE SUMMARY:

In March 2014 Michelle Bachelet returned to the presidency of Chile. She had been president 2006-2010, but Chile's law prohibits its president from serving consecutive terms. Sebastian Piñera served as president in between her two terms. In May 2013, under the Piñera administration, Chile's Congress approved the text of the International Union for the Protection of New Varieties of Plants (UPOV 91). The implementing regulations, however, were not developed and therefore they were not signed by then president Piñera before he left office. The new, second Bachelet Administration withdrew the law from Congress, which was somewhat unexpected because it was her first administration that sent the project to Congress initially. The new Administration is reviewing the regulations before it resubmits them to the legislative process. It is not clear how long this review might take.

Under the current Chilean regulations, Chilean farmers can only propagate transgenic seeds for export. When used in food products, the Ministry of Health requires that all events be registered. The product must be labeled only if substantially different from the conventional counterpart.

Over eight years ago anti-biotech groups submitted two anti-biotech bills to the Chilean Congress that, if ever implemented, supposedly would regulate biotechnology. One requires mandatory labeling and the other would create a biotechnology regulatory framework. Congress has yet to move forward on either of these bills.

The Piñera Administration, especially the Minister of Agriculture, was seen as enthusiastic to push forward on reviewing the regulations that are stuck in Congress so that Chilean farmers may benefit from this technology. Nevertheless, that did not happen.

Commercially, Chile could be a producer of transgenic sugar beets, corn, and alfalfa. If Chile's salmon industry ever were to lift its self-imposed ban on the use of biotech feeds, soybeans could be added to that list. Although not widely publicized, Chile has begun to do landmark research in "orphan" crops (non-bulk commodities), such as salmon, pine trees, stone fruit, apples, and grapes. As part of the government's efforts to increase research and development using funds received from copper mining royalties, the Ministries of Education, Agriculture and Economy have established consortiums for biotech research.

As with many developing countries, the majority of research funds come from the public sector. In 2009 the Government of Chile (GOC) announced a number of programs and affiliations with different universities in the United States, Australia, and Canada to favor technology transfer and postgraduate degrees for the purpose of increasing research and development.

SECTION II. PLANT AND ANIMAL BIOTECHNOLOGY:

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) **PRODUCT DEVELOPMENT:** There are no genetically engineered plants or crops being developed in Chile that could be commercialized in the next five years.

b) **COMMERCIAL PRODUCTION:** Chile has propagated genetically engineered seeds; mainly corn and soybean, under strict field controls for re-export for more than a decade. Chile currently ranks fifth among countries exporting seeds worldwide, and ranks first in exports of genetically engineered seeds in the southern hemisphere. (ANPROS 2013).

In the season of 2012/2013 the total area of genetically engineered seed in the country was 35,507 hectares of which 82 percent were of corn seeds (29,244 ha), 12 percent of canola seed (4,351 ha) and 6 percent to soybean seed (1,907 ha). Other transgenic seeds reproduced in the country were sugar beet seed, tomato, and green mustard, which in total accounted for less than 0.0015 percent of the total area of transgenic seed (SAG, 2013). Exports accounted for US\$238 million. (ANPROS 2013)

c) **EXPORTS:** genetically engineered seeds reproduced in Chile are exported primarily to the United States and Canada. The export documentation details the types of seeds and genetically engineered events.

d) **IMPORTS:** Chile imports processed products that contain genetically engineered ingredients and genetically engineered seeds for reproduction and re-export. Chile imports genetically engineered corn and soy animal feed from Brazil and Argentina as well as the United States.

e) **FOOD AID RECIPIENT COUNTRIES:** Chile is a major agricultural export country and does not need food aid.

PART B: POLICY

a) **REGULATORY FRAMEWORK:**

i. Responsible Government Ministries: Chile does not have a biotechnology framework in place. Only the reproduction of seeds for re-export is allowed under strict control from the Agricultural and Livestock Service (SAG) of the Ministry of Agriculture. SAG's Resolution 1523 from 2001 regulates this process, which includes field multiplication, harvest, export production, safeguard measures, byproducts, and waste. The necessary forms to introduce genetically engineered seeds to Chile can be found in Appendix 1.

The registration, approvals of events for human consumption and the labeling of genetically engineered products only if they are substantially different to the conventional product is under the

Ministry of Health. Decree 115 through the Administrative Technical Norm number 83 entitles the Public Health Institute (PHI) of this Ministry to determine the evaluation on the differences and similarities of the genetically engineered product with the conventional one and to determine if they can be approved in the country. PHI also needs to determine toxicity, allergenicity and long term effects of the events; if the events have been previously authorized by FDA the process is shorter.

ii. Role of the Biosafety Committee/Authority: Chile signed but has not ratified the Cartagena Protocol on Biosafety. Chile has not established an adventitious presence level for imports.

iii. Assessment of Political Factors: The new Administration has not specifically raised the topic of regulation of plant biotechnology. Current indications are that the status quo will be maintained.

iv. Distinctions between Food and Feed Regulations: There are some differences between the regulatory treatment of the approval for food, feed, processing, and environmental release. Food products that contain genetically engineered ingredients can be imported without any problems, as is feed. Imports of seeds for environmental release, however, are only allowed for seed reproduction that will be re-exported. This is done under SAG's strict supervision.

v. Pertinent and Pending Legislation: There are three pieces of legislation pending (languishing) in Chile's Congress that could potentially restrict U.S. exports to Chile, but they haven't moved in years. They are: 1) a mandatory labeling requirement (Boletin 3818-11/2005); 2) the Biotech Framework (Boletin 4690-01/2006); and, 3) a ten year moratoria (Boletin 8507-11/2012).

vi. Timelines for Approvals: The President determines the urgency of matters brought before Congress. No urgency has been assigned to any of the pieces of legislation mentioned on the previous points and thus it is unlikely that Congress will move on them in the foreseeable future.

b) APPROVALS: Again, only the reproduction of seeds to be re-exported is allowed in Chile. Field trials are allowed but are treated the same way, i.e., under SAG's (Chilean APHIS) strict controls, please refer to i. Responsible Government Ministries of section a) ; there are no crops authorized to be commercialized in Chile. Unfortunately, FAS Chile could not obtain the official information on the authorized crops this year because SAG declared it sensitive.

c) FIELD TESTING: Chile allows field trials for new events which are treated the same as the production of seeds. FAS Chile could not obtain the official information on the authorized crops this year because SAG declared it sensitive.

d) STACKED EVENTS: The Ministry of Agriculture treats stacked events in field trials and reproduction of seeds as if it was a single new event. The Ministry of Health, on the other hand, regulates the imports of food products and it requires all events to be registered in the Chile. If they have been registered before with the U.S. Food and Drug Administration (FDA), the process is faster. On stacked events they require the registrations of all events. Please refer to i. Responsible Government Ministries of section a) for more details.

e) ADDITIONAL REQUIRMENTS: No additional registration is required beyond approval and prior

to use.

f) **COEXISTENCE:** Currently there are no specific rules for coexistence. 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.

g) **LABELING:** The Ministry of Health only requires labeling of the product when the genetically engineered-derived ingredient/product is different than the conventional one.

h) **TRADE BARRIERS:** Unless and until the discussion on the framework to regulate biotechnology-related issues is finalized and implemented, FAS Chile cannot say that there are any trade barriers. It will be clearer once the discussion begins, since the labeling issue is very sensitive.

i) **INTELLECTUAL PROPERTY RIGHTS (IPR):** Congress approved the ratification of UPOV 91, which the Constitutional Court did, and it is waiting for the President's signature. Despite it being a requirement in the 2004 U.S.-Chile Free Trade Agreement, due to the sensitivity of the issue, the new Administration withdrew the regulation to review it and there is no known time frame for its introduction or modification,

j) **CARTAGENA PROTOCOL RATIFICATION:** Chile has signed but not ratified the Cartagena Protocol on Biosafety. The GOC has given no indication of ratifying the Protocol in the near future. In July 2014, FAS Chile attended a video conference in Santiago about the Cartagena Protocol that the Inter-American Institute for Agricultural Cooperation (IICA) organized in preparation for the 12th Conference of the Parties to be held the second semester of 2014 in Korea. The video conference presented the model used by Mexico, the United States, and Canada in handling, transporting, packaging, and identifying grain shipments as an implementing tool to Article 18.2 of the Protocol.

k) **INTERNATIONAL TREATIES/FORA:** Given Chile is an agricultural export-based economy, with agricultural exports accounting for 15 percent of GDP, it has taken a cautious approach to biotech issues and has play a muted role in international for a, such as APEC, MERCOSUR, and OAS, as well as UN and WTO organizations such as FAO, CODEX, and the International Plant Protection Convention (IPPC).

l) **RELATED ISSUES:** Regarding climate change and food security, there is some research being done in Chile. Some of this research is being conducted by the Chilean universities. Also, U.S. companies with operations in Chile are working on drought resistant products, especially corn. Due to the fact that is impossible to release in Chile any of the products of this research for commercial use, these products are taken back to the United States.

m) **MONITORING AND TESTING:** There is no official monitoring or testing program for genetically engineered products.

n) **LOW-LEVEL PRESENCE POLICY (LLP):** The Chilean Congress is considering by has not approved a LLP policy. It is part of Chile's broader biotech legislation package.

PART C: MARKETING

a) **MARKET ACCEPTANCE:** Chile's agricultural export sector remains concerned that the use of transgenics might harm Chile's "natural" image and argues that currently there are few benefits for the products for which Chile has a competitive advantage, including horticultural crops, salmon, and forestry.

b) **PUBLIC/PRIVATE OPINIONS:** There are many organizations in Chile both for and against this technology and both groups with their respective followers. The groups against this technology have succeeded in instilling fear in the general public's mind about the safety of genetically engineered products. The groups in favor of this technology have had considerable difficulty in offsetting these fears and misperceptions. The more highly educated Chileans, however, believe this technology can benefit Chile. FAS Chile believes that the users should have a bigger role in putting pressure on their representatives to move the regulations in Congress, as they are the ones that see the benefits and are suffering from not being able to use it.

c) **MARKETING STUDIES:** There are no studies on the marketing of genetically engineered plants and plant products in Chile.

PART D: CAPACITY BUILDING AND OUTREACH – RECENT TWO YEARS

a) **ACTIVITIES:** U.S. Government or U.S. Department of Agriculture (USDA) funded capacity building or outreach activities.

In 2012, using State Department funds, FAS Chile collaborated with the International Life Sciences Institute (ILSI) to have targeted environmental risk and regulatory workshop with the Ministries of Environment and Agriculture in Santiago.

In 2011, FAS Chile in collaboration with Asia Biobusiness, IICA and the Chilean Ministry of Agriculture organized a two-day Risk Communication Workshop that had the participation of all the Ministries that will have to address the public to clarify misleading information, or just speak about biotechnology in general. The Minister of Agriculture opened the workshop and supported the event.

In 2010, FAS Chile and the State Department organized a seminar focused on how agricultural biotechnology can help the region address climate change issues. FAS Chile included Argentina and Peru to make it a regional activity. Two speakers from the United States participated of this seminar.

FAS Chile requested a speaker from the Environmental Protection Agency (EPA) to participate at a UN-Cepal sponsored Carbon Footprint Workshop in September to be held in Chile.

For FAS Chile's earlier agricultural biotechnology capacity-building and outreach activities, see [FAS Chile's 2013 GAIN report CII309](#)

b) STRATEGIES AND NEEDS:

FAS Chile's strategies on biotechnology since about 2006 have focused on the regulatory aspect of the issue and providing science-based information.

The main objective regarding regulation is to have Chile adopt a framework that is science-based and that does not impose trade barriers. To accomplish this goal, FAS Chile has taken congressmen to the United State so they can get knowledge *in situ* of the U.S. regulatory process of biotechnology. They met with all the regulatory agencies, NGOs, and growers to get a better understanding of the benefits of this technology so they can draft science-based regulations in Chile. One of the participants of the group was one of senators that drafted the framework that is being discussed in Congress. That draft that was shared with FAS Chile and other USDA agencies and the Department of State before it was introduced to Congress in 2006.

FAS Chile's strategy will continue to encourage and assist Chile to adopt a science-based regulatory framework. This is the key to beginning trade.

FAS Chile has organized and will continue to organize biotechnology seminars with universities and researchers with the participation of U.S. scientists and speakers. FAS Chile believes that the more information it provides, the better the public will be informed, and the public's fears about biotech products eventually will be eliminated.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

Cloning is an animal biotechnology that developers frequently utilize in conjunction with other animal biotechnologies, such as genetic engineering, and therefore included in this report.

PART E: PRODUCTION AND TRADE

a) **PRODUCT DEVELOPMENT:** No genetically engineered or cloned animals are being used or imported into Chile.

b) **COMMERCIAL PRODUCTION:** Not applicable

c) **EXPORTS:** Not applicable

d) **IMPORTS:** There are no regulations in place to allow imports of any genetically engineered or cloned animals.

PART F: POLICY

a) **REGULATION:** There has been no discussion about genetically engineered animals in Chile. Any and all ongoing discussions relate to genetically engineered vegetables

i. - Responsible Ministries: FAS Chile believes that if the time comes when genetic engineered animals will be considered, the government entities that are most likely to have a role will be: 1) The Ministry of Health for all issues concerning human health and food safety; 2) The Ministry of Agriculture, through its SAG office, would address issues concerning animal health; and, 3) the Ministry of the Environment, which was created in 2010, would address issues related to the environment.

ii.- Assessment of Political Factors: none at this time

iii.- Pending legislation: none at this time

iv:- Known Discussions: FAS Chile knows of no ongoing discussion about genetically engineered animals – not among the general public or the GOC. FAS Chile believes that discussion of this topic and formulating a regulatory framework will not commence unless and until the regulatory framework for genetically engineered plants is completed.

b) LABELING AND TRACEABILITY: None for genetically engineered or cloned animals

c) TRADE BARRIERS: None known.

d) INTELLECTUAL PROPERTY RIGHTS (IPR): None that specifically apply to animals.

e) INTERNATIONAL TREATIES/FORA: genetically engineered animals have not been considered by Chile in any International fora discussion.

PART G: MARKETING

a) MARKET ACCEPTANCE: N/A

b) PUBLIC/PRIVATE OPINIONS: N/A

c) MARKET STUDIES: N/A

PART H: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES: None

b) STRATEGIES AND NEEDS: There is an opportunity for interested parties to collaborate on research projects with academia. There also is an opportunity to gather information on public opinion.

