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Chile

Agricultural Biotechnology Annual

Chile's Agricultural Biotechnology 2015

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Report Highlights:
Agricultural biotechnology is not a priority for Chile's current Administration. The situation in Chile remains the same as last year and is expected to remain that way through this Administration. Regardless of its lack of having a biotech framework and restricting planting and commercialization of genetically engineered crops, Chile accepts all imports and does not require genetically engineered products to be labeled. Commercially, Chile could be a viable producer of transgenic sugar beets, corn, and alfalfa.

Section I. Executive Summary:
On March 11, 2014, former President Michelle Bachelet began her second four-year term as president, replacing Sebastian Piñera. Bachelet served as president from 2006-2010, but was prohibited from running for consecutive terms by Chilean law.. 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 under strict regulations from the Livestock and Agricultural Service (SAG) of the Ministry of Agriculture. In addition, Ministry of Environment requires a risk assessment study. 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, the bills would regulate biotechnology. One bill would requires mandatory labeling of products and the other bill would create a biotechnology regulatory framework. Congress has yet to move forward on either of these bills.

Commercially, Chile has the potential of becoming a producer of transgenic sugar beets, corn, and alfalfa. If Chile's salmon industry were to ever lift its self-imposed ban on the use of biotech feeds, soybeans could also 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 a variety of consortiums for biotech research, which in some cases even transition to becoming companies producing different biotech products.

As with many upper-middle income 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. The Ministry of Agriculture's National Institute for Agricultural Research (INIA) also welcomes and has numerous MOU's with U.S. and other universities around the world on biotechnology 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 2014/2015 the total area of genetically engineered seed in the country was 8,817.93 hectares, 75 percent lower than previous years. Producers report that this is due to the over stock of seeds in the north hemisphere, -of which 66.6 percent were corn seeds (5,878 ha), 17.7 percent were canola seed (1,568 ha) and 15 percent soybean seed (1,370 ha). Other transgenic seeds reproduced in the country were cotton seed, tomato, and grape seeds, which in total accounted for less than 0.012 percent of the total area of transgenic seed (SAG, 2015).

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. In the season of 2013/2014, total genetically engineered seeds Chilean seed exports to the world accounted for US$190 million. (ANPROS 2014)

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 Is not a food aid recipient country.

PART B: POLICY

a. REGULATORY FRAMEWORK:

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.

For its part, the Ministry of Environment, through its Law 20.417 and its Regulations of 2013 state that the use transgenic with agricultural purposes different than seed production to export and research or development activities, they must be subject to environmental risk evaluation.

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: 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.

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 Section II, Part a, i. Responsible Government Ministries 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 under 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 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 a LLP policy but has not approved it. 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.

The last Capacity Building activity organized by post was 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 facilitated 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 CI1309

a. 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 and 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 is prepared to assist Chile in adopting a science-based regulatory framework when it is prepared to make this a priority.

FAS Chile has organized and will continue to organize biotechnology seminars with universities and researchers with the participation of U.S. scientists and speakers. By sharing information and partnering with the Chilean government to educate stakeholders on priority issues, both the public and private sector will be better informed, and the science behind genetically engineered products will be understood.

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.EndFragment