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Agricultural Biotechnology Annual

Agricultural Biotechnology Situation in Chile 2016

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Report Highlights:
Agricultural biotechnology policy has not been a priority of Chile's current administration. FAS/Santiago expects Chile's agricultural biotechnology policies to remain unchanged. While Chile lacks a biotechnology framework, restricts the planting and commercialization of genetically engineered (GE) crops, it continues to allow U.S. imports all GE crops and products (i.e. corn, feed grains, processed products for the retail sector). Chile is the fifth largest producer of seeds (GE and non-GE seeds) in the world and the United States is the largest destination for its GE produced seeds. It does not require GE products to be labeled. FAS/Santiago estimates that nearly $285 million of U.S. agricultural exports to Chile may have some kind of GE content. If Chile could produce GE products commercially, it 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 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 initially sent the project to Congress. 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 (MOE) requires a risk assessment study.

When GE ingredients are used in a food product, the Ministry of Health (MOH) requires that all events be registered. In addition, the product must be labeled only if the GE component is substantially different from its conventional counterpart.

Over nine years ago, anti-biotech groups submitted two anti-biotech bills to the Chilean Congress, which if ever implemented, the bills would regulate biotechnology. One bill would require mandatory labeling of all products that have GE content 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.

Chile's salmon industry has a self-imposed ban on the use of biotech feed, such as soybeans. This is because Japan represents 21% of Chile's export market share (the 2nd largest market after the United States) for its farmed Atlantic salmon export and the fact that Japan prohibits the use of GE feed in salmon

Although not widely publicized, Chile began landmark GE related 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.

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 has numerous MOU's with U.S. and other universities around the world on biotechnology research and development, such as Universities of Michigan, North Dakota, and California.

SECTION II. PLANT AND ANIMAL BIOTECHNOLOGY:

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

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

b) COMMERCIAL PRODUCTION: Chile has propagated GE 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 GE seeds in the southern hemisphere. (ANPROS 2016).

For Chile's 2015/2016 seed production season (September 2015 through April 2016) the total area of GE seeds planted in the country was 9,310.08 hectares (ha), which was 5.3 percent lower than previous season. The reasons for this reduction can be explained by the following factors:

- Lower value of a barrel of oil dragged the production of ethanol down and therefore the demand for corn. Thus, less corn was planted and less seeds used.
- China's economic slowdown reduced its need for grain.
- A record harvest for corn seeds in the United States in 2014, 2015 and 2016, left U.S. corn seed manufacturers with extra stocks.

Chilean production of GE seeds during the 2015/2016 season can be broken down as follows: 50 percent were corn seeds (4,681 ha), 31.8 percent were canola seed (2,963 ha) and 17.8 percent soybean seed (1,662 ha). Other transgenic seeds reproduced in the country were cotton seed, tomato, and grape seeds, which in total accounted for less than 0.03 percent of the total area of transgenic seed (SAG, 2016).

c) EXPORTS: GE seeds, previously imported from the United States are reproduced in Chile and are exported primarily to the United States and Canada. The documentation required by Chilean authorities to export GE products to Chile must contain detailed information on the types of seeds and GE events. In Chile's 2014/2015 seed production season, it exported a total of $72 million in GE seeds to the world. (ANPROS 2014)

d) IMPORTS: Chile imports processed products that contain GE ingredients and GE seeds for reproduction and re-export. Chile imports GE corn and soy-based 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. Instead of giving food aid, Chile provides technical assistance.

f) TRADE BARRIERS: Although Chile has not ratified UPOV 91trade in GE products between Chile and the United States flow, and no trade barriers are present.

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 Ministry of Agriculture's Agricultural and Livestock Service (SAG) of the Ministry of Agriculture. SAG's 2001 Resolution 1523 regulates this process, which includes field multiplication, harvest, export production, safeguard measures, byproducts, and waste. The necessary forms to introduce GE seeds to Chile can be found in Appendix 1.

SAG will review on a case-by-case-basis all requests to release any GE organism into the environment.

Materials entering Chile are classified as follows:

- Materials with "prior history" of release in the country.
- Materials with "no previous history" of release in the country.

From these two classifications listed above (with and without previous history) SAG has established the following subcategories:

1. Materials without delegated responsibility (SRD)
2. Materials with delegated responsibility (CRD)

As part of the new process for evaluating GE events under category SRD, in 2016 SAG established three subcategories that will clearly identify their differences in stages and the restrictions associated to them:

- Step 1: Research plasmid.
- Step 2: Research and development of events.
- Step 3: Trade Approval in other countries.

Research or events in "Stage 1" (Research plasmid): The events that are in Stage 1 may only be used for experimental testing on experimental stations or laboratories that belong to the company or have a history of being used as grounds for test. No trials on events or stacked events will be allowed in facilities of third parties, unless authorized by SAG.

Stacked events or events in "Stage 2" (Research and development of events): The events that are in Stage 2 will be released on properties owned by the applicant and third-party company. On the other hand, the activity of the event or stacked event that enters the country must be associated exclusively to

testing activities or experimentation, which may not generate seed from this material and therefore may not get a varietal certification, unless authorized by the Service.

Stacked events or events in "Stage 3" (With commercial approval in other countries): The events that are in Stage 3 (commercial approval in other countries) may be released in properties owned by the applicant and third-party company. The event in Stage 3 may benefit from the program of varietal seed certification.

Considering the above, the following table summarizes the new subcategories that shall take effect on the SRD events where shown: Stage 1 (Research plasmid), Step 2 (Research and development event) and Stage 3 (With commercial approval in other countries) correspond to events without vicarious liability (SRD). Subcategories are not considered for the case of CRD events.

With previous history	SRD			CDR
	Stage 1	Stage 2	Stage 3	
Without previous history	SRD			
	Stage 1	Stage 2	Stage 3	

In the case that Chile is the center of origin for the modified species, biosecurity measures will not be rendered ineffective as in the case of crops with delegated responsibility CRD (Article No. 9 Resolution No. 1,523 / 2001)

Release of GE materials with Biosecurity Measures

To release GE materials for propagation in confined areas, the applicant must submit an application to the SAG that specifies:

1. Aim of the test
2. Associated species and genetic modification
3. Storage place or deposit of the material (which will require its own approval by SAG)

The registration, approvals of events for human consumption and the labeling of GE 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 GE 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 (MOE), through its Law 20.417 and its regulations of 2013 state that the use of transgenics for agricultural purposes different than seed production to export and research or development activities, must be subject to an 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 GE ingredients can be imported without any problems, as is feed. Imports of seeds for environmental release 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.

vii. Discussions regarding regulations and research: Please refer to section v. for pending legislations. There is research/collaboration being carried out in Chile, especially on a government level through the National Institute of Agricultural Research (INIA) and with the collaboration of USDA/ARS or some U.S universities.

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.

c) STACKED or PYRAMIDED EVENTS APPROVALS: The Ministry of Agriculture (MOA) treats stacked events in field trials and reproduction of seeds as if it was a single new event. On the other hand, the Ministry of Health (MOH), regulates the imports of food products and requires all stacked and pyramided events to be registered in Chile. If the stacked and pyramided events have been registered with the U.S. Food and Drug Administration (FDA), the process is faster because they accept FDA registration. When a product uses ingredients that were produced with stacked or pyramided events, the MOA requires the registrations of all events separately. Please refer to Section II, Part a, i. Responsible Government Ministries for more details.

d) FIELD TESTING: Chile allows field trials for new events to be treated the same as the production of seeds. Biosecurity measures are defined by SAG's Resolution 1523 from 2001; please refer to section (i).

e) INNOVATIVE BIOTECHNOLOGIES: At this time, there are no initiatives to regulate innovative biotechnologies, such as genome editing, in Chile. The Minister of Agriculture has requested the Office of Studies and Agricultural Policies (ODEPA) review the innovative biotechnologies available and being used outside Chile to decide on the position the Ministry will take.

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, please refer to section (i).

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

h) MONITORING AND TESTING: There is no official monitoring or testing program for GE products.

i) 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.

j) ADDITIONAL REQUIRMENTS: No additional registration is required beyond approval and prior to use.

k) INTELLECTUAL PROPERTY RIGHTS (IPR): Congress approved the ratification of UPOV 91, and it is waiting for the President's signature. Despite ratification of UPOV being a requirement of the 2004 U.S.-Chile Free Trade Agreement, due to the sensitivity of the issue, the Bachelet Administration withdrew the regulation to review it. There is no known time frame for its introduction or modification. An eventual ratification of the TPP agreement by the Chilean Congress will force Chile to ratify UPOV 91 to be able to enjoy the benefits of this Free Trade Agreement.

l) CARTAGENA PROTOCOL RATIFICATION: Chile has signed but not ratified the Cartagena Protocol on Biosafety. The GOC has given no indication that it will ratify the Protocol in the near future.

m) INTERNATIONAL TREATIES/FORA: Since Chile is an agricultural export-based economy, with agricultural exports accounting for about 12 percent of GDP, it has taken a cautious approach to biotech issues and has played 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).

n) RELATED ISSUES: Research is being conducted in Chile by Chilean universities on climate change and food security. Also, U.S. companies with operations in Chile are working on drought resistant products, especially corn. Since it is impossible to release any of the research products for commercial use in Chile;, these products are exported to the United States and sold commercially.

PART C: MARKETING

a) 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 GE products. The groups in favor of this technology have had considerable difficulty in offsetting these fears and misperceptions. Educated Chileans, however, believe this technology can benefit Chile. FAS/Santiago believes that end-users could have a greater influential role in convincing their representatives to move the regulations through Congress, as they are the ones that see the benefits and are suffering from not being able to use it.

b) 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.

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 D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: No GE 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 GE or cloned animals.

e) TRADE BARRIERS:

PART E: POLICY

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

i. Responsible Ministries: When the time comes for the Government of Chile to GE animals the following authorities will likely have a role: 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 animal health issues and concers; 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: There are no ongoing discussion about GE animals – not among the general public or the GOC. Discussion on this topic and formulating a regulatory framework will not commence until the regulatory framework for GE plants is complete.

b)INNOVATIVE BIOTECHNOLOGIES: None at this time

c) LABELING AND TRACEABILITY: None for GE or cloned animals

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

e) INTERNATIONAL TREATIES/FORA: GE animals have not been considered by Chile in any international fora discussion.

f) RELATED ISSUES: None at this time

PART f: MARKETING

a) PUBLIC/PRIVATE OPINIONS: N/A

b) MARKET ACCEPTANCES/STUDIES: N/A