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Agricultural Biotechnology Annual

Chile's Agricultural Biotechnology Report 2018

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Report Highlights:
While Chile remains the tenth largest producer of seeds in the world and the United States is the largest market for Genetically Engineered (GE) seeds, seed developers and researchers can only use GE technology for research and propagation purposes. There is no commercial GE crop production in Chile. Chile applies a specific normative to regulate the use of GE plant material. Chile does not require GE food products derived from GE technology to carry any labels. If Chile could produce GE products commercially, it could be a viable producer of transgenic sugar beets, corn, and alfalfa

SECTION I. EXECUTIVE SUMMARY:

Political Situation:
In March 2018, Sebastian Piñera assumed his second term as president of Chile. During his first mandate (2010-2014), President Piñera signed into law the ratification of the International Union for the Protection of New Varieties of Plants 1991 (UPOV 91) and began the discussion of the implementing regulation that would make the ratification effective. President Michelle Bachelet's administration (2014-2018) withdrew the draft project of law from Congress.

During the first six months of the current Piñera's administration, Chile's Minister of Agriculture, Antonio Walker, and key members of his cabinet expressed their willingness to move forward with the implementing regulation that would finally ratify UPOV 91.

Chile does not have a biotechnology framework, however, it allows for the propagation of transgenic seeds for the export markets. Chilean farmers can only propagate transgenic seeds for export under strict regulations from the Livestock and Agricultural Service (SAG) of the Ministry of Agriculture (MOA). In addition, the Ministry of Environment (MOE) requires a risk assessment study.

While the Ministry of Health (MOH) requires the producer or importer that produce products that contain GE ingredients to register the products, products need to carry a label only if the GE product is substantially different from its conventional counterpart.

Over ten years ago, anti-biotech civil society groups, with the help of sympathetic parliamentarians, submitted two anti-biotech bills to the Chilean Congress. If they were ever implemented, they would be overly restrictive. 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.

Although not widely publicized, Chile began landmark GE related research on "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. SAG regulation does not include the possibility of commercializing such products in Chile, therefore, most of the research is moving towards not GE products as per SAG regulation they are less commercially attractive. Since 2006, The Ministries of Education, Agriculture and Economy have funded a variety of consortia on biotech research. Some of them include research on fruits plants (Biofrutales), and in the forestry sector (Genomica Forestal).

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 Memorandums of Understanding (MOUs) with U.S. universities to collaborate on biotechnology research and development, such as Universities of Michigan, North Dakota, and California.

Despite the lack of a strong regulatory framework and the fact that agricultural genetic engineering is not the first priority for this administration, trade in GE products, reproduction of seeds, or processed products with ingredients derived by genetic engineering continues, and there is no sign that it will stop in the near future.

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, SAG's regulation does not allow the commercialization of the GE derived products.

b) COMMERCIAL PRODUCTION: Chile has propagated GE seeds; mainly corn and soybean, canola and sunflower under strict field controls for re-export for more than a decade. Chile currently ranks tenth among countries exporting seeds worldwide, and ranks first in exports of GE seeds in the southern hemisphere. (Source: Chilean Association of Seed Producers ANPROS, March 2018).

For Chile's 2017/2018 seed production season, the total area of GE seeds planted in the country was 13,915.3 hectares (ha), which was 36.7 percent higher than previous season. The reasons for this increase was a higher demand for seeds in the northern hemisphere (United States and Canada) due to lower storage of seeds from previous seasons. Chile supplies the norther hemisphere with seeds in the counter-season, therefore, the amount of seeds demanded depends on the results of the harvest in the norther hemisphere in the previous season, if the production was good, the amount of seeds needed will be less.

Chilean production of GE seeds during the 2017/2018 season can be broken down as follows: 56 percent were corn seeds (7,808 ha), 26.5 percent were raps seeds (3,697 ha) and 17.3 percent soybean seeds (2,408 ha). Other GE seeds reproduced in the country were tomato, and grape seeds, which in total accounted for less than 1 percent of the total area of GE seeds (SAG, 2018).

c) EXPORTS: GE seeds, previously imported from the United States are propagated in Chile and are exported primarily to the Northern Hemisphere (the United States and Canada). Chilean authorities require that the documents to export GE products to Chile must contain detailed information on the types of seeds and GE events. In Chile's 2015/2016 seed production season, it exported a total of $71.02 million in GE seeds to the world. (Source: ANPROS report of March 2018).

d) IMPORTS: Chile imports processed products that contain GE ingredients and GE seeds for reproduction and re-export to the north mainly Canada and the U.S. Chile imported about $571 million of GE corn and GE soy-based animal feed from Brazil, Paraguay, Bolivia, Argentina, and the United States during 2017.

e) FOOD AID RECIPIENT COUNTRIES: N/A.

f) TRADE BARRIERS: N/A. See policy section.

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 Ministry of Agriculture's Agricultural and Livestock Services (SAG). SAG's 2001 Resolution 1523 regulates this process, which includes field multiplication, harvest, export production, safeguard measures, byproducts, and waste.

ii.

iii. 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 Ministry of Health (MOH) overseas the registration, approvals of GE events for human consumption, and the labeling of GE products only if they are substantially different to the conventional product. MOH's Decree 115 through the Administrative Technical Norm number 83 entitles the Public Health Institute (PHI) of the MOH to determine the evaluation on the differences and similarities of the GE products from its conventional counterpart and to determine if they can be approved in the country. PHI also needs to determine toxicity, allergenicity, and long-term effects of the GE events. If the GE events have been previously authorized by the U.S. Food and Drug Administration (FDA) the process is

shorter.

The Ministry of Environment (MOE), through its Law 20.417 and its regulations Decree 40 of 2013 states that the use of genetically modified organisms 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 current government 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. MOH regulates food products and SAG regulates feeds. 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. All feeds independently if they contain or not GE ingredients need to be registered with SAG.

v. Pertinent and Pending Legislation: There are three pieces of biotech legislation languishing in Chile's Congress that could potentially restrict U.S. exports to Chile, but they have not moved in years. These 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: Approvals for the introduction of GE seeds for reproduction or for field trials take 45 working days. In the case of GE seeds for reproduction, when they are given to a third party, the original company has 30 days to notify SAG of the name of the farmer, locations, and safeguard measures taken. MOH does not specify a timeline for the approval of GE events.

vii. Discussions regarding regulations and research: Please refer to section v. for pending legislation. 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. One example is the work on the evaluation of the resistance of GE Plum C5 and the pilot scaling of massive propagation system of cherry clones among other.

b) APPROVALS: Chile only allows for the reproduction of GE seeds for re-export. Field trials are allowed but are treated the same way as the reproduction of seeds, under SAG's strict controls. Please refer to i. Responsible Government Ministries, of section a. There is no commercial production of GE crops.

c) STACKED or PYRAMIDED EVENTS APPROVALS: According to the regulations in place, MOA treats GE stacked events in field trials and reproduction of seeds as if it was a single new GE event. However, 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 MOH accepts the FDA registration. When a

product uses ingredients that contain stacked or pyramided events, the MOA requires the registrations of all events separately. Up to this date, MOH has not implemented the registration of events or stacked/pyramided events, there are no indication that this scenario will chance in the near future.
In the case of feeds, they need to be registered with SAG independently if they contain or not GE ingredients, there are no regulatory restrictions to their use of GE feeds more than a personal ban on what to use or no to use depending of the market of exports.

Please refer to Section II, Part B, 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: The Chilean Ministry of Agriculture has standardized the approach for innovative biotechnologies and the information can be found in SAG's website.

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: MOH only requires labeling of the product when the GE derived ingredient/product is materially different from the conventional one.

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

i) LOW-LEVEL PRESENCE POLICY (LLP): N/A. The Chilean Congress has been considering a LLP policy for many years but has not approved it as it is a part of Chile's broader biotech legislation package pending approval.

j) ADDITIONAL REQUIRMENTS: N/A. No additional registration is required beyond what was mentioned above.

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- 91 being a requirement of the 2004 U.S.-Chile Free Trade Agreement, due to the public misperception and controversy over the issue, the Bachelet Administration withdrew the regulation to review it. There is no known time frame for its introduction or modification.

l) CARTAGENA PROTOCOL RATIFICATION: Chile has signed, but not ratified the Cartagena Protocol on Biosafety. The Government of Chile 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

the agricultural sector accounting for about 9.5 percent of GDP (2016), it has taken a cautious approach to biotech issues and has played a muted role in international fora, such as APEC, MERCOSUR, and Organization of American States (OAS), as well as United Nations and WTO organizations such as, CODEX, and the International Plant Protection Convention (IPPC).

During the last meeting of the Agricultural Council of the South (CAS), September 20-21, 2018, Chilean Minister of Agriculture, Antonio Walker, joined his counterparts from Brazil, Uruguay, Paraguay and Argentina and signed a declaration that referred to: Strengthen the work to prevent or solve trade issues resulting from the differences in the regulatory frameworks of GE products, which leads to the exchange of information on the regulatory frameworks, possible modifications to these, maintain a list of approved events in each CAS country, exchange information about the events in approval process, among other topics.

n) RELATED ISSUES: Chilean Universities are carrying out research on climate change and food security. In addition, U.S. seed 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 Canada.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS: There are many organizations in Chile both for and against agricultural biotechnology and both groups have 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. Chileans with more years of formal education, however, believe this technology can benefit Chile. FAS Santiago believes that farmers 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 GE products might harm Chile's "natural" image and argues that currently there are few benefits from 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: N/A.

c) EXPORTS: N/A.

d) IMPORTS: There are no regulations in place to allow imports of any GE or cloned animals. The regulations established for plants do not apply to animals. In the case of GE Hydrobiological organisms, a law will need to be developed on a case-by-case basis after a risk assessment is performed and all biosecurity measures for importing, handling, and study/introducing to the environment are considered.

e) TRADE BARRIERS: N/A.

PART E: POLICY

a) REGULATION: Chile does not have regulations in place to address animal derived from GE or cloning. There has been no discussion about GE or cloned animals in Chile. All ongoing discussions are related to GE seeds. In the case of GE Hydrobiological organisms, a law will need to be developed on a case-by-case basis after a risk assessment is performed and all biosecurity measures for importing, handling, and study/introducing to the environment are considered.

i. Responsible Ministries: 1) MOH for all issues concerning human health and food safety; 2) The MOA, through its SAG office, would address animal health issues and concerns; and, 3) the MOE, would address issues related to the environment

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ii. Assessment of Political Factors: None at this time.

iii. Pending legislation: None at this time.

iv: Known Discussions: There are no ongoing discussions about GE or cloned animals – not among the general public or the Government of Chile. Discussion on this topic and formulating a regulatory framework will not start until the regulatory framework for GE plants is complete.

b) INNOVATIVE BIOTECHNOLOGIES: None at this time. The innovative biotechnologies that have been established only relate to plants. In the case of GE Hydrobiological organisms, a law will need to be developed on a case-by-case basis after a risk assessment is performed and all biosecurity measures for importing, handling, and study/introducing to the environment are considered.

c) LABELING AND TRACEABILITY: None for GE or cloned animals. Animal derived from GE or cloning are not allowed in Chile, therefore the requirements established for plants do not apply. In the case of GE Hydrobiological organisms, a law will need to be developed on a case-by-case basis after a risk assessment is performed and all biosecurity measures for importing, handling, and study/introducing to the environment are considered.

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

e) INTERNATIONAL TREATIES/FORA: \N/A.

f) RELATED ISSUES: N/A.

PART f: MARKETING

a) PUBLIC/PRIVATE OPINIONS: N/A.

b) MARKET ACCEPTANCES/STUDIES: N/A.