Required Report: Required - Public Distribution **Date:** December 30,2020

Report Number: CI2020-0019

Report Name: Agricultural Biotechnology Annual

Country: Chile

Post: Santiago

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

There is no commercial production of Genetically Engineered (GE) crops in Chile, with the exception of seeds for re-export. Chile is home to world-wide companies that develop and propagate GE seeds and export the resulting GE seeds. If the Chilean government were to allow the commercial production of additional GE crops, Chile could be a viable producer of GE sugar beets, corn, and alfalfa. The Government of Chile (GOC) did not update its plant or animal biotechnology regulations this past year. However, this report contains updates to the Production and Trade Section (Chapter 1), as well as a new section on Microbial Biotechnology (Chapter 3).

SECTION I. EXECUTIVE SUMMARY:

In March 2011, the Chilean Congress approved the ratification of the International Union for the Protection of New Varieties of Plants 1991 (UPOV-91) and the government began drafting an implementing regulation that would make the ratification effective. President Michelle Bachelet's second administration (2014-2018) withdrew the draft implementing regulation from Congress.

The current Piñera administration (2018-2022) has shown renewed efforts in presenting draft legislation to implement UPOV-1991. In late October 2018, during a private AmCham Chile (U.S.-Chilean Chamber of Commerce) event entitled Agroindustry 2.0, Chilean Minister of Agriculture Antonio Walker noted, "Chile is in debt with the U.S. and the international community on UPOV-1991." Furthermore, in January 2020 the Ministry of Agriculture (MOA) hosted a Civil Society Council meeting, which included representatives from agricultural associations, to discuss a way forward on UPOV-1991.

MOA is planning to send "modified" draft legislation to Congress. This draft will address the concerns that triggered the legislation's withdrawal in 2018. The draft legislation will address the protection of native seed varieties, the number of years for the protection of the intellectual property rights, and the possibility for small farmers to keep seeds after harvest for personal use.

While Chilean agencies have set some regulations for biotechnology, Congress has not passed any laws to create a biotechnology framework. Despite this, Chile allows for the propagation of (GE) seeds for export markets. Chilean farmers can only propagate GE seeds for export under strict regulations from the Livestock and Agricultural Service (SAG) within MOA. In addition, the Ministry of Environment (MOE) requires a risk assessment study.

While the Ministry of Health (MOH) requires the importer or producer of products that contain GE ingredients to register the product, they need to carry a label only if the GE product is substantially different from its conventional counterpart. MOH's Decree 115 through the Administrative Technical Norm number 83 charges the Public Health Institute (PHI) of the MOH with the duty to evaluate differences and similarities of GE products from their conventional counterparts and to determine if they can be approved.

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 to be 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 non-science-based biotechnology regulatory framework. Congress has yet to move forward on either of these bills.

Although not widely publicized, Chile began landmark GE-related research on "orphan" agricultural products (non-bulk commodities), such as salmon, pine trees, stone fruit, apples, and grapes. These projects are part of the government's efforts to increase research and development using funds received from copper mining royalties. Since 2006, the Ministries of Education, Agriculture, and Economy have funded a variety of consortia that participate in biotech research. Work from these groups includes research on fruit plants (Biofrutales) and in the forestry sector (Genomica Forestal).

As with many upper-middle income countries, in Chile most research funds come from the public sector. In 2009, Chile announced several programs and affiliations with different universities in the United States, Australia, and Canada to promote 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, including Michigan State University, North Dakota State University, and University of California-Davis.

Even though Chile imports food derived from GE crops for human consumption, the country lacks a strong regulatory framework to produce GE crops in unconfined areas. Chile has the potential of becoming a producer of GE sugar beets, corn, and alfalfa.

SECTION II. PLANT AND ANIMAL BIOTECHNOLOGY:

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT: While biotech research is being done, there are no GE plants or crops that could be commercialized in Chile in the next five years.

b. COMMERCIAL PRODUCTION: Chile currently ranks fifth among countries exporting seeds worldwide and ranks first in exports of GE seeds in the Southern Hemisphere. GE seeds previously imported from the United States are reproduced in Chile and are exported primarily to the United States and Canada for the counter-season. During 2019–2020, Chile exported a total of $72 million in GE seeds. While the main destination for GE seeds is the United States (corn, soybeans, and canola), the Chilean seed industry supplies most of the Northern Hemisphere with conventional counter-seasonal seeds. Chile exported a total of $340 million worth of GE and conventional seeds. (Source: Chilean Association of Seed Producers, ANPROS).

For Chile's 2019/2020 seed production season, the total area of GE seeds planted was 14,335 hectares (ha), 25 percent higher than the previous season, which was unusually low at 12,291

ha. While a 25 percent increase seems high, it is not a trend, a result of any climatic event, or a shortage in storage in the Northern Hemisphere. According to ANPROS, the area planted is still low considering Chile reached peak GE production acreage during the 2012/2013 seed production season, in which producers planted around 35,000 ha of GE seeds.

Chilean production of GE seed during the 2019/2020 season can be broken down as follows: 57.7 percent was corn seed (8,285 ha), 22 percent was soybean seed (3,169 ha), and 20 percent was canola seed (2,879 ha). Additional GE seed production for grape vines, tomatoes, wheat, and mustard accounted for less than one percent of the total area of GE seeds (SAG, 2020). Much of this production is likely intended for research purposes only.

c. EXPORTS: GE seeds, after being imported from the United States, are propagated in Chile. These propagated seeds are then exported primarily to the United States and Canada.

d. IMPORTS: Chile imports processed products that contain GE ingredients as well as GE seeds for reproduction and re-export to the Northern Hemisphere, mainly Canada and the United States. Chile imports GE corn and GE soy-based animal feed from Brazil, Argentina, and the United States. Chilean authorities require that the documents to import GE products to Chile contain detailed information on the types of seeds and GE events.

d. FOOD AID RECIPIENT COUNTRIES: N/A.

e. TRADE BARRIERS: N/A. See Policy section

PART B: POLICY

1. REGULATORY FRAMEWORK:

i. Responsible Government Ministries: Aside from propagated GE seeds, Chile does not have a regulatory framework in place for GE product approvals. Only the reproduction of seeds for re-export is allowed under strict control from the Ministry of Agriculture's SAG. 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 reviews all requests to release any GE seed into the environment on a case-by-case-basis.

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, 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 to establish different stages in the approval process. Each stage is associated with different restrictions:

- 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): Events in Stage 1 may only be used for research in experimental stations or laboratories that belong to the developer or have a history of being used as grounds for testing. No trials on events or stacked events are 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 may be released on properties owned by the applicant and or third-party companies. However, the event or stacked event must be associated exclusively with testing activities or experimentation. Developers may not produce seed for commercial use from this material and therefore may not get a varietal certification unless authorized by SAG.

Stacked events or events in "Stage 3" (With commercial approval in other countries): Events in Stage 3 (commercial approval in other countries) may be released in properties owned either by the applicant or by a third-party company. The event in Stage 3 is eligible for varietal seed certification.

Considering the above, the following table summarizes the subcategories that fall under the SRD events: Stage 1 (Research plasmid), Stage 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	

If new GE products are originally developed in Chile, 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 SAG that specifies:

1. The objective of the test
2. Associated plant species and the GE event
3. Where material will be stored or deposited (which will require its own approval by SAG)

The Ministry of Health (MOH) oversees GE event registration, approvals of GE events intended for human consumption, and the labeling of GE products. MOH's Decree 115 through the Administrative Technical Norm number 83 charges the Public Health Institute (PHI) of the MOH with the duty to evaluate differences and similarities of GE products from their conventional counterparts and to determine if they can be approved. PHI is required to determine risks of toxicity, allergenicity, and long-term effects posed by the GE events. If the GE events have been previously authorized by the United States Food and Drug Administration (FDA), the process is shorter.

The Ministry of Environment (MOE), through Law 20.417 and the Decree 40 of 2013 regulation states that the use of GE products for agricultural purposes other than seed production for export or research must be subject to an environmental risk evaluation.

iii. Role of the Biosafety Committee/Authority:
Chile signed but has not ratified the Cartagena Protocol on Biosafety. Chile has not established a low level presence level for imports.

iv. 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. Food products that contain GE ingredients may be imported after being approved by MOH. GE corn resistant to herbicides and to some lepidoptera (BT) are authorized for animal

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 biotech legislation languishing in Chile's Congress that could potentially restrict U.S. exports to Chile, but none have moved since 2012. These are: 1) a mandatory labeling requirement (Boletin 3818-11/2005); 2) the Biotech Framework (Boletin 4690-01/2006); and, 3) a ten-year ban of GE products in Chile (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 to plum pox and the pilot project to scale up the propagation of cherry clones.

viii. GE seeds imported to Chile need to be registered with SAG every time they are imported, regardless if they were registered before.

ix. About re-registration, GER seeds need to register with SAG every time they are imported, regardless if they were registered before.

b. APPROVALS: Chile only allows for the reproduction of GE seeds to be re-exported but does not allow for commercial production of any other GE crops. Field trials are allowed but must follow SAG's strict controls. Please refer to section a. for more information.

c. STACKED or PYRAMIDED EVENTS APPROVALS: MOA treats GE stacked events in field trials and reproduction of seeds as one single new GE event, but requires the events to be registered separately. MOH regulates the imports of food products and requires all stacked and pyramided events to be registered in Chile. If the stacked and pyramid events have been registered with the U.S. Food and Drug Administration (FDA), the process is faster because MOH accepts the FDA registration. 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 for more information.

e. INNOVATIVE BIOTECHNOLOGIES: Chile's regulatory approach to New Breeding Techniques (NBTs) can be found on SAG's website. In 2017, Chile became the second country after Argentina to implement a regulatory approach (link is in Spanish) for plant products obtained through new breeding techniques including CRISPR. According to this regulatory approach, all introductions to the environment of reproductive material derived from declared NBTs will be evaluated against SAG' Resolution 1523/2001, which regulates GE products. If SAG decides that the NBTs products evaluated are not considered GE products, then the products are allowed to be produced and used in Chile without the biosafety requirements applied to GE products.

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, biosafety measures are established for every field trial approval, , such as physical isolation from sexually compatible species and post-harvest management. Please refer to section i for more information.

g. LABELING: MOH only requires labeling of the product when the GE derived ingredient/product is materially different from the conventional one. MOH's Decree 115 through the Administrative Technical Norm number 83 charges the Public Health Institute (PHI) of the MOH with the duty to evaluate differences and similarities of GE products from their conventional counterparts.

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

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

j. ADDITIONAL REQUIREMENTS: 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, the Bachelet Administration withdrew the regulation to review it as a result of public misperception and controversy over the issue. There is no known timeframe 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 soon.

m. INTERNATIONAL TREATIES/FORA: Since Chile is an agricultural export-based economy, with the agricultural sector accounting for about 11 percent of GDP (2019), it has taken a cautious approach to biotechnology issues and has played a muted role in international fora, such as the Asia Pacific Economic Cooperation Forum (APEC), the Southern Common Market (MERCOSUR), and Organization of American States (OAS), as well as United Nations Codex Alimentarius, and the International Plant Protection Convention (IPPC).

During the 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 committed to:

- Strengthening the work to prevent or solve trade issues resulting from the differences in the regulatory frameworks of GE products
- Maintaining a list of approved events in each CAS country and agreement to exchange information about the events in approval process

n. RELATED ISSUES: Chilean Universities are carrying out research on climate change and food security, while INIA is developing varieties of grapes and tree nuts resistant to fungi and virus, as well as making genetic improvements to potatoes and rice. 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 civil society organizations both for and against agricultural biotechnology. The groups against biotechnology have succeeded in instilling fear in the public's mind about the safety of GE products while groups in favor of this technology have had considerable difficulty in offsetting these misperceptions., Chileans with more years of formal education, however, believe biotechnology can benefit Chile. Post believes that farmers could have an influential role in convincing their representatives to move biotechnology regulations through Congress, as they see the benefits and are affected by lack of access to the technological.

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 adopting GE varieties of products for which Chile has a competitive advantage, including horticultural crops, salmon, and forestry products. There are no indications on this sector's attitude towards new varieties developed using innovative biotechnologies.

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 is included in this report.

PART D: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT: There is no product development on GE animals in Chile. There are no regulations in place to allow for cloning.

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.

e. TRADE BARRIERS: N/A.

PART E: POLICY

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

i. Responsible Ministries: 1) MOH is responsible for all issues concerning human health and food safety; 2) MOA, through its SAG office, is responsible for animal health issues and concerns; and, 3) MOE, is responsible for 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 discussions regarding GE 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: Discussions on innovative biotechnologies have occurred that only relate to plants. See Part B, section a. for more details.

c. LABELING AND TRACEABILITY: There are no labeling or traceability regulations for GE or cloned animals. Animals derived from GE or cloning are not allowed in Chile, therefore the requirements established for plants do not apply. See Part B, section a. for more details.

d. INTELLECTUAL PROPERTY RIGHTS (IPR): None that specifically applies 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

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

f. COMMERCIAL PRODUCTION: Post cannot confirm that biotech-derived microbes or microbial biotech derived food ingredients are commercially produced because these products are not regulated in Chile and are treated as conventional products or ingredients. If the specific

ingredients are authorized by MOH's Sanitary Regulation of Foods, then there is no requirement to indicate what technique was used to produce it.

g. EXPORTS: Since ingredients are not differentiated by the technique used to produce them, there are no restrictions on exports. Post cannot confirm that any biotech-derived microbes or microbial biotech derived food ingredients are exported from Chile to the world.

h. IMPORTS: There are no restrictions to import any biotech-derived microbes or microbial biotech derived food ingredients, as the current regulations make no distinction between GE derived products and conventional ingredients.

i. TRADE BARRIERS: See parts f), g), and h) above.

PART H: POLICY

a. REGULATORY FRAMEWORK: Chile does not have a regulatory framework for biotech-derived microbes or microbial biotech-derived food ingredients.

x. Responsible Ministries: The Ministry of Health is the competent authority concerning human health and food safety.

xi. Assessment of Political Factors: Biotech-derived microbes or microbial biotech-derived food ingredients are not regulated in Chile; they are treated as the conventional ingredients.

xii. Pending legislation: There is no pending legislation currently or in the near future.

xiv. Known Discussions: There are no discussions about microbial biotechnology – not among the general public or the Government of Chile.

b. APPROVALS: No approvals
c. LABELING AND TRACEABILITY: There is no need to label microorganism at this time as they are not regulated in Chile.

d. MONITOR AND TESTING: No monitoring or testing is required.

e. ADDITIONAL REGULATORY REQUIREMENTS: N/A.

f. INTELLECTUAL PROPERTY RIGHTS (IPR): N/A.

g. RELATED ISSUES:

PART I: MARKETING

c. PUBLIC/PRIVATE OPINIONS: N/A.

d. MARKET ACCEPTANCES/STUDIES: N/A

Attachments:

No Attachments