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Report Highlights:

This year's report does not contain significant changes from last year's report. Chile continues allowing the reproduction of seeds under strict control of the Agricultural and Livestock Service of the Ministry of Agriculture.

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. Despite the efforts of the civil society and industry representatives to move forward with the ratification of UPOV-91, the current Piñera administration (2018-2022) has no intentions of introducing a new draft for discussion in Congress.

Congress has not passed any laws to create a comprehensive biotechnology framework. However, the Chilean Livestock and Agricultural Service (SAG) within the Ministry of Agriculture has established regulations allowing for limited cultivation of GE plants. Chile allows for the propagation of genetically engineered (GE) seeds for export markets and allows some research on GE plants, but has not approved the cultivation of any other GE products.

In 2017, Chile became the second country after Argentina to implement a regulatory approach for plant products obtained through new breeding techniques, including genome editing. However, no products have yet been evaluated using this approach.

Note: All links found within this document are available only in Spanish.

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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 have been released or that could be commercialized in Chile in the next five years.

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 a pilot project to scale up the propagation of cherry clones.

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 under development are mostly intended for use in the United States and Canada.

In 2006, Chile began landmark GE-related research on “orphan” agricultural products (non-bulk commodities), such as, 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 crops ([Biofrutales](#)) and in the forestry sector ([Genomica Forestal](#)). These projects are still ongoing.

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. These include Michigan State University, North Dakota State University, and University of California-Davis.

- 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. In 2020, Chile exported a total of \$68 million in GE seeds. The main destination for GE seeds is the United States, which imports corn, soybean, and canola seeds. The Chilean seed industry supplies most of the Northern Hemisphere with conventional counter-seasonal seeds. Chile exported a total of \$260 million worth of GE and conventional seeds in 2020. (Source: Chilean Association of Seed Producers, [ANPROS](#)).

For Chile's 2020/2021 seed production season, the total area of GE seeds planted was 10,040 hectares (ha), 20 percent lower than the previous season. According to ANPROS, there is no specific reason for the reduction in the planting area other than variations in the demand from buyers.

Chilean production of GE seed during the 2020/2021 season can be broken down as follows: 50.6 percent was corn seed (5,085 ha), 25.5 percent was soybean seed (2,559 ha), and 23 percent was canola seed (2,395 ha). Additional GE seed production for brown mustard and wheat 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 reproduced in Chile. These 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 to 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 documents to import GE products that are intended to be used in seed production. These documents contain detailed information on the types of seeds and GE events.
- e. FOOD AID RECIPIENT COUNTRIES: N/A.
- f. TRADE BARRIERS: There are no substantial barriers for GE imports to Chile.

PART B: POLICY

a. REGULATORY FRAMEWORK:

In Chile, GE plants can be cultivated only under limited circumstances. Only the reproduction of GE seeds for re-export is allowed under strict control from the Ministry of Agriculture's SAG, and no GE products have been approved to be planted for any other purpose. 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.

GE materials entering Chile that are intended for seed production or research 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 delegated responsibility (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

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)

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

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. No products have yet been approved through this process, and therefore no GE products are cultivated in Chile for purposes other than seed production or research.

Biosafety Committee/Authority: Chile has a Biosafety Committee that is regulated by Law No. 19,300 of the Ministry of Environment. The Committee is chaired by the Minister of the Environment, and includes the Minister of Health; the Minister of Economy, Development and Tourism; the Minister of Agriculture, and the Minister of Energy and Mining. The Committee's main function is to make final decisions in appeals of cases where environmental risk assessments are rejected by MOE.

Regulation of GE products intended for food and feed:

[Decree 115](#), through the Administrative Technical Norm number 83, states that the Ministry of Health (MOH) oversees GE event registration, approvals of GE events intended for human consumption, and the labeling of GE products. Decree 115 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. Decree 115 states that PHI is required to determine risks of toxicity, allergenicity, and long-term effects posed by the GE events. According to the Administrative Technical Norm number 83, if the GE events have been previously authorized by the United States Food and Drug Administration (FDA), the approval process is shorter.

Regulation 3970/1998 of SAG authorizes the use of Bt and glyphosate resistant corn for animal feed.

- b. APPROVALS/AUTHORIZATIONS: Chile only allows the reproduction of GE seeds to be re-exported and does not allow for commercial production of any other GE crops. Field trials are allowed but must follow SAG's strict controls. GE seeds imported to Chile need to be registered with SAG every time they are imported, regardless of if they were registered before. Please refer to Chapter 1, Part B, Section a (Regulatory Framework) for more information.
- c. STACKED or PYRAMIDED EVENT APPROVALS: SAG 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.
- d. FIELD TESTING: Chile regulates field trials for new events under their regulations for production of seeds. Biosecurity measures are defined by SAG's Resolution 1523 from

2001. Please refer to Chapter 1, Part B, Section a (Regulatory Framework). 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](#) for cultivation of plant products obtained through NBTs, including genome editing. According to this regulatory approach, all environmental introductions of reproductive material derived from declared NBTs will be evaluated against SAG Resolution 1523/2001, which regulates GE products. If SAG decides that the genome edited products evaluated are not considered "Living Modified Organisms", then the products are allowed to be produced and used in Chile without the biosafety requirements applied to GE products. As of October 2021, SAG has not determined that any products of genome editing fall outside of Resolution 1523's definition of "Living Modified Organism". Chile has not implemented a regulatory approach for products of genome editing that are intended for food, feed, or processing.
- 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.
- g. **LABELING AND TRACEABILITY:** MOH only requires labeling of GE products when the GE derived ingredient or product is has nutritional characteristics different from those of its conventional counterpart. [Paragraph II, Article 107, section n\) of Decree 977](#) 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:** Chile monitors imports of all seeds, both GE and conventional, and importers must declare if the seeds are GE.
- j. **LOW-LEVEL PRESENCE POLICY (LLP):** Chile does not have an LLP policy.
- k. **ADDITIONAL REQUIREMENTS:** No additional registration is required beyond what is described above.
- k. **INTELLECTUAL PROPERTY RIGHTS (IPR):** Congress approved the ratification of UPOV-91, and it is waiting for the President's signature. A regulation that would implement UPOV-91 was proposed by the Bachelet Administration in 2009 but was withdrawn for review following public controversy in 2014. There is no known timeframe for its reintroduction. Ratification of UPOV- 91 is a requirement of the 2004 U.S.-Chile Free Trade Agreement

- l. **CARTAGENA PROTOCOL RATIFICATION:** Chile signed the Cartagena Protocol on Biosafety on May 24, 2000. However, Chile has not yet ratified the Protocol. The Government of Chile has given no indication that it will ratify the Protocol soon.
- m. **INTERNATIONAL TREATIES and FORUMS:** Since Chile is an agricultural export-based economy, with the agricultural sector accounting for about 11 percent of GDP (2020), it has taken a cautious approach to biotechnology issues. Chile 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:** None.

PART C: MARKETING

- a. **PUBLIC/PRIVATE OPINIONS:** There are many civil society organizations both in favor of 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. 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 technology.
- b. **MARKET ACCEPTANCE/STUDIES:** Chile's agricultural export sector remains concerned that the use of GE products might harm Chile's "natural" image and argues that 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 of the sector's attitude towards new varieties developed using innovative biotechnologies.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART A: 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 animal products.
- e. **TRADE BARRIERS:** N/A.

PART B: POLICY

- a. **REGULATORY FRAMEWORK:** 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.
- b. **APPROVALS/AUTHORIZATIONS:** N/A.
- c. **INNOVATIVE BIOTECHNOLOGIES:** Discussions on innovative biotechnologies have occurred only as they relate to plants. See Chapter 1, Part B, section e. (Innovative Biotechnologies) for more details.
- d. **LABELING AND TRACEABILITY:** There are no labeling or traceability regulations for GE or cloned animals. Animals derived from genetic engineering or cloning are not allowed in Chile, and therefore the requirements established for labeling of GE plant products do not apply.
- e. **ADDITIONAL REGULATORY REQUIREMENTS:** N/A
- f. **INTELLECTUAL PROPERTY RIGHTS (IPR):** None that specifically applies to animals.
- g. **INTERNATIONAL TREATIES and FORUMs:** N/A.
- h. **RELATED ISSUES:** N/A.

PART C: MARKETING

- a. PUBLIC/PRIVATE OPINIONS: N/A.
- b. MARKET ACCEPTANCES/STUDIES: N/A.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

- a. **COMMERCIAL PRODUCTION:** FAS Santiago 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.
- b. **EXPORTS:** Since ingredients are not differentiated by the technique used to produce them, there are no restrictions on exports derived from GE microbes. FAS Santiago cannot confirm that any biotech-derived microbes or microbial biotech derived food ingredients are exported from Chile to the world.
- c. **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.
- d. **TRADE BARRIERS:** N/A.

PART B: POLICY

- a. **REGULATORY FRAMEWORK:** Chile does not have a regulatory framework for biotech-derived microbes or microbial biotech-derived food ingredients. The Ministry of Health is the competent authority concerning human health and food safety.
- b. **APPROVALS/AUTHORIZATIONS:** N/A.
- c. **LABELING AND TRACEABILITY:** GE microbial products are not required to be labeled, as they are not regulated in Chile
- e. **MONITOR AND TESTING:** No monitoring or testing is required.
- f. **ADDITIONAL REGULATORY REQUIREMENTS:** N/A.
- g. **INTELLECTUAL PROPERTY RIGHTS (IPR):** N/A.
- h. **RELATED ISSUES:** N/A.

PART C: MARKETING

- a. PUBLIC/PRIVATE OPINIONS: There are no discussions about microbial biotechnology – not among the general public or the Government of Chile.
- b. MARKET ACCEPTANCE/STUDIES: N/A

Attachments: [Authorization for seeds.pdf](#)

[Risk assestment.pdf](#)