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Status of market, regulation and research of genetically modified crops in Chile

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ABSTRACT

Agricultural biotechnology and genetically modified (GM) crops are effective tools to substantially increase productivity, quality, and environmental sustainability in agricultural farming. Furthermore, they may contribute to improving the nutritional content of crops, addressing needs related to public health. Chile has become one of the most important global players for GM seed production for counter-season markets and research purposes. It has a comprehensive regulatory framework to carry out this activity, while at the same time there are numerous regulations from different agencies addressing several aspects related to GM crops. Despite imports of GM food/feed or ingredients for the food industry being allowed without restrictions, Chilean farmers are not using GM seeds for farming purposes because of a lack of clear guidelines. Chile is in a rather contradictory situation about GM crops. The country has invested considerable resources to fund research and development on GM crops, but the lack of clarity in the current regulatory situation precludes the use of such research to develop new products for Chilean farmers. Meanwhile, a larger scientific capacity regarding GM crop research continues to build up in the country. The present study maps and analyses the current regulatory environment for research and production of GM crops in Chile, providing an updated overview of the current status of GM seeds production, research and regulatory issues.

Contents

Introduction

Genetically Modified (GM) crops are those organisms that have been modified by the application of recombinant DNA technology or genetic engineering. These crops have been the most rapidly adopted agricultural technology in mankind's history, as evidenced by a 100-fold increase from 1.7 to 179.7 million hectares globally

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cultivated between 1996 and 2015 [1]. At the worldwide level, a small number of GM crops have been developed and released for commercial agricultural production. They include insect resistant cotton, maize, soybean and eggplant, herbicide tolerant soybean, cotton canola, maize, alfalfa and sugar beet, and viral disease resistant papaya and squash [1,2]. New crops and traits have achieved regulatory approval in specific countries, including the virus resistant bean in Brazil [3] and non-browning apple in the USA [4]. In addition, there is an increasing number of GM crops under development and not yet commercially released with traits encoding either abiotic stress tolerance or biofortification [5,6]. The environmental and economic impacts of this technology for farmers, farm workers, countries and society have been extensively reported elsewhere [7,8].

Chile is recognised for its fresh fruit, wine and seed exports and has turned food production into a global business, emerging as a key food exporter for markets in North America, Europe and Asia [9]. Globally, Chile is the 5th largest exporter of seeds in terms of value, reaching US$388 million in 2012 [10]. Subsequently, the country has become the main exporter of GM seeds from the Southern Hemisphere in order to supply counter-season markets in the Northern Hemisphere [11]. Several private companies have invested heavily in winter nurseries and research programmes for GM seeds over the last ten-years in Chile due to its singular geographic and weather conditions along with regulatory and political stability. Thus, breeders in the Northern Hemisphere, while they are in winter, can speed up their research programmes sending GM seeds for field evaluations. This leads to the development of the next generation of crops in a shorter period of time [1].

Both GM seed production and R&D activities must comply with a strict regulatory framework in Chile. However, in terms of GM crops, the country has a rather confusing scenario. The regulatory framework allows GM seed production exclusively for export and R&D activities, yet those seeds are not allowed to remain in the country. At the same time, although some rules related to GM food/feed have been issued, they are not in place and there are no restrictions for imports of GM food or feed. In spite of this confusing scenario, aware of the key role that biotechnology could play as a factor of competitiveness, in 2001 the Chilean government launched the “Programme for Biotechnology Development in the Forestry, Agricultural, and Aquacultural Sectors”. In 2003, a National Policy for the Development of Biotechnology was designed [12]. In the area of crop biotechnology these policies have encouraged initiatives from Universities and the public sector regarding plant tissue culture and the use of molecular markers for the identification and characterisation of agricultural and forestry species. In regard to GM crops, public research efforts have achieved the genetic transformation of potatoes in order to develop traits encoding either virus or disease resistance. Similar efforts have been extended to several other species relevant to Chile’s economy, such as table grapes, cherries, peaches, apples and melons. Field testing of herbicide-tolerant sugar beet, which allows for reduced production costs and thus increases their competitiveness in the marketplace, has also been carried out.

In this study we offer an updated overview of the current GM crop situation in Chile in terms of research investments, economic impacts and regulatory policies.

Production and trade

Located in the Southern Hemisphere and extending from latitude 17° to 56°S, a variety of climates can be found in Chile, from desert in the North, to Mediterranean in the center and cool and damp in South. Thus, Chile is ideally suited for counter-season activities for Northern Hemisphere locations.

Chile has become one of the most important players in the world for production of seed on a regular basis and for the offseason production (GM and non-GM) for other regions. Its advantages include clear, science-based rules and regulations for GM seed production and R&D activities, expedited import and export procedures, excellent scientific and technological capacity, good correlation with environments in North America and Europe, facilitating effective selection for important traits, well developed infrastructure for ease of transportation and communications, political and economic stability, and free trade agreements with all major markets. It currently ranks fifth among countries exporting seeds worldwide, and ranks first in exports of GM seeds in the Southern Hemisphere [10]. GM seeds produced in Chile are exported primarily to the USA [13].

In this context, Chile has multiplied GM seeds under stringent field controls for re-export for more than two decades. However, field trials with GM crops have been carried out since 1987, when the first environmental release was authorised [14]. Through the years, the main GM seeds produced in Chile have been maize, canola and soybean (Fig. 1). Other GM plant species have been sown at a considerably lower level [15]. Field trials have involved maize, canola, soybean, safflower, tomato, sugar beet, mustard,

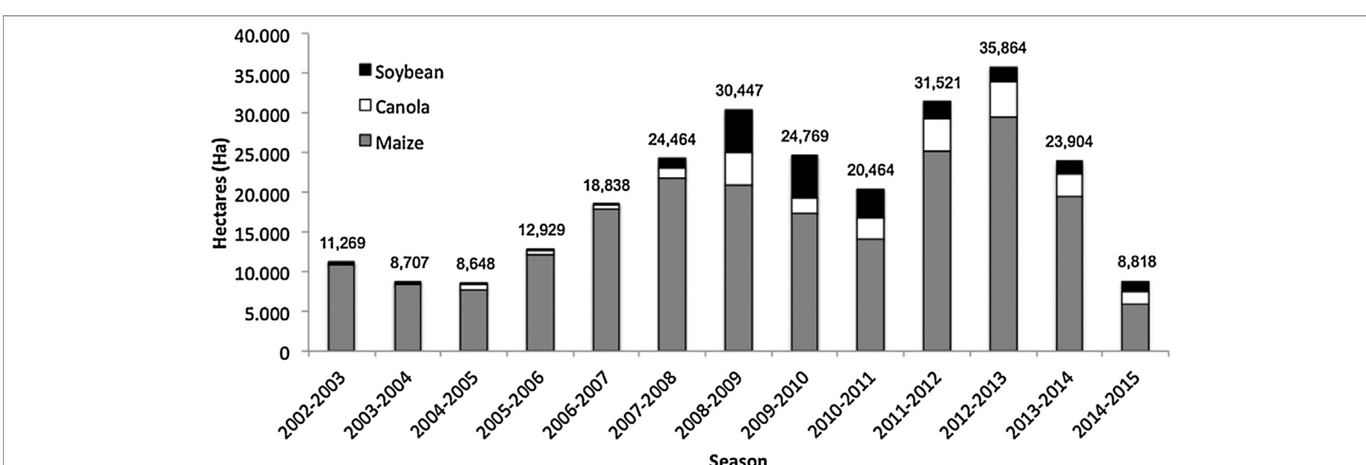

Fig. 1. GM seeds produced in Chile.
The three main GM seeds sown in the country are shown. Other GM seeds are safflower, tomato, sugar beet, mustard, rice, table grape, cotton and squash. The number of total hectares per season with GM seeds is shown. Chart was elaborated from data obtained from SAG 2015.

rice, table grape, cotton and squash. There is no GM crop production for food, feed or seed for the domestic market in Chile. Overall seed exports in Chile increased from US$163.5 million in 2004 to US$651 million in 2013. On average, every season almost 40% of seed exports are GM and R&D services to carry out field trials in order to develop new events (Fig. 2). It is worth noting that the geographic isolation of Chile provides unique conditions for preventing diseases and harmful insects, making the counter-seasonal production for the Northern Hemisphere a key marketing tool for the Chilean seed industry.

The seed crops produced in Chile for export mostly include GM seed varieties, totaling 99.6% for soybean, 83.8% for canola, and 60.8% for maize during the previous season (Chilean National Seed Producers Association, ANPROS, personal communication). In the 2014/2015 season the total area of GM seed in the country was 8,818 ha (Fig. 1) of which 67% were maize seeds, 18% canola seeds and 15% soybean seeds. Other GM seeds reproduced in the country were cotton, table grape and tomato, which in total accounted for less than 0.012% of the total area of GM seeds [15]. In contrast, during the 2013/2014 season the total area of GM seed in the country was 23,904 ha (Fig. 1) of which 82% were maize seeds, 12% canola seeds and 6% soybean seeds. GM seed exports accounted for US$190.7 million in 2014, reaching a peak of US$281.2 million in 2013 (Fig. 2). In the 2013/2014 season, there were 2426 GM seed fields producing seeds both certified and non-certified according to international standards. In addition, there were 535 GM seed field trials for R&D programmes [15].

The flourishing of the seed industry in Chile has been enabled due to coexistence between GM and non-GM seed activities. Seed companies have implemented different methods and certifications, as well as stewardship audits by owners of traits, in order to identify critical stages of the production process. Those stages are reviewed under continuous improvement criteria enabling coexistence. Furthermore, the Agricultural and Livestock Service (SAG) has clear requirements, inspections and follow-up of records. Self-regulation in the seed industry, clear regulatory requirements, along with a GPS based isolation system for effectively tracing all production sites, have been the underpinning of both, coexistence and the GM seed industry.

Regulatory framework

Environmental risk assessment

The Ministry of Agriculture's SAG is the institution that regulates and monitors the environmental release and biosafety measures of GM crops for seed production and R&D activities. In 1993, based on the Agricultural Protection Law 3557/80, SAG enacted the first specific regulation related to GM crops in Chile. Resolution 1927 regulated the import and environmental release of GM seeds only for multiplication and export purposes. It underwent some modifications with Resolution 4144 dictated by SAG in 1998. Resolution 1523, issued in 2001, updated the regulatory standards for GM crops covering those developed in Chile and abroad. The regulation included import procedures, environmental risk assessments and biosafety measures related to production, harvest and waste disposal. Current activities with GM seeds in Chile are regulated under this resolution (Table 1). Thus, where GM seed is imported to Chile, an application for import has to be submitted by the importer to the Biotechnology Unit of SAG's Plant Protection Division. The introduction of every new event in Chile must follow a thorough risk assessment, carried out by the scientific experts working for the Secretariat of the Technical Committee of GMOs. The procedures and the structure of the Committee and its Secretariat were established in Resolution 6966, issued in 2005, but the committee structure and its scope have been updated recently with Resolution 3928 (Table 1). This framework has allowed an increasing number of new event approvals for R&D purposes and a significant number of import permits for both, GM seed production and R&D activities (Fig. 3).

On the other hand, Resolution 3495 was enacted by SAG in 1997, which created the Advisory Committee for the Release of GM crops (CALT) and a Technical Secretariat was established. This Committee had essentially preventative and organisational functions. Its mission was to establish science-based biosafety measures for environmental releases and evaluate possible deregulations based on the safety record of each event. CALT underwent further modifications over the years in order to have more specific responsibilities (Resolutions 269 of 1999, 1495 of 2000, 1655 of 2000, 2004 of 2000). Over the last ten years, SAG's Resolution 6966

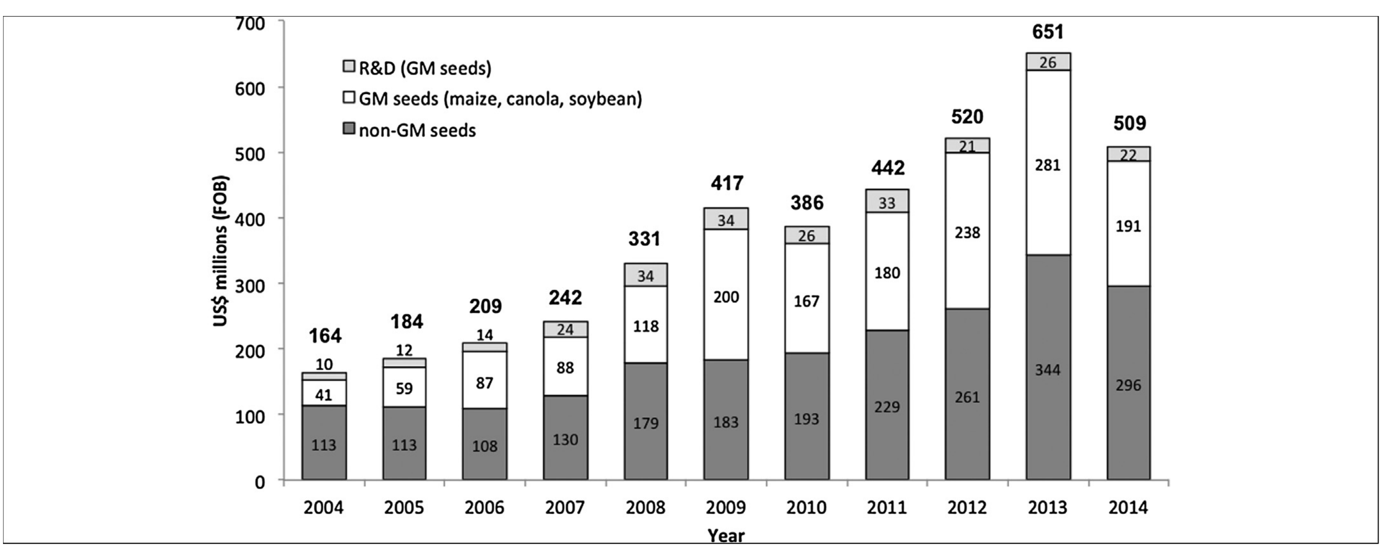

Fig. 2. Chilean seed industry's total exports.
Exports are shown by calendar year. Non-GM seeds include mainly seed of vegetables. R&D activities are related to field trials. Chart was elaborated from data provided by the Chilean National Seed Producers Association (ANPROS).

Table 1
Regulations in force related to GM crops in Chile.

Area	Agency	Regulation	Year	Scope
Agriculture	Agricultural and Livestock Service (SAG)	Resolution 3928	2015	Technical committee and secretariat for GMOs. It modifies Res 6966
		Resolution 1248	2013	Animal consumption of GM soybean MON89788
		Resolution 6229	2010	Protection of confidential information. It modifies Res 1523 art 14
		Resolution 1523	2001	GM seeds for import, environmental release and re-export
		Resolution 3136	1999	Biosafety rules for pharmaceutical products for vet care obtained in GM crops
		Resolution 3970	1998	Animal consumption of GM corn including either traits of insect resistance, male sterility, gluphosinate or glyphosate tolerance
Environment	Ministry of Environment	Law 20417	2010	GM crops for unconfined environmental release
Health	Public Health Institute (ISP)	Resolution 469	2009	Panel of experts to evaluate and approve events to be used in the food industry
	Ministry of Health	Resolution 83	2007	Procedure to evaluate events to be used in food industry
		Decree 115	2003	GM Food labeling. It modifies Decree 977 from 1996 about Food Safety Rule
Aquaculture	Sub secretary of Fisheries, Ministry of Economy	Law 20116	2001	Regulation, evaluation and authorization of the use of aquatic GMOs (plants or animal)

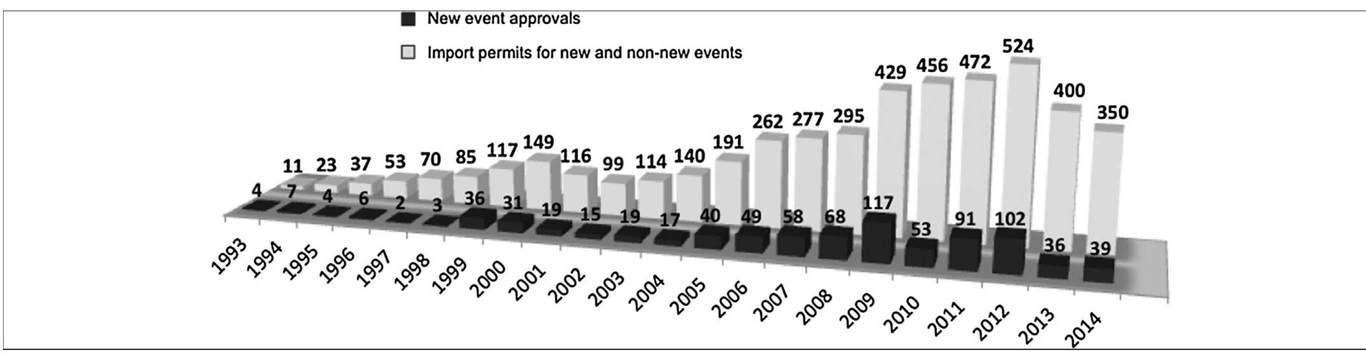

Fig. 3. Number of approvals per year for GM seed production and R&D activities in Chile.
New event approvals consider authorisation for environmental confined release for R&D purposes mainly. Once an event secures approval as new event from the environmental risk assessment perspective, this can be sown in the future for GM seed production and/or R&D purposes, getting import permits every year. One event might present several import permits every year.

governed this structure. In 2015 the regulatory framework has been updated with the Resolution 3928 in order to optimise the procedures (Table 1). This regulation consolidated and regularised the Advisory Committee and Technical Committee functions, all of which are fully complementary with the guidelines (annex III) of the Cartagena Protocol on Biosafety [16]. For instance, risk assessments should be carried out in a scientifically sound and transparent manner; risks should be considered in the context of risks posed by the non-modified recipients or parental organisms; and that risks should be assessed on a case-by-base basis.

As resolution 1523 governs GM seed production in Chile, Law 20417 of 2010 regulates the environmental release of GM crops for other purposes. This law establishes the requirement to submit GM organisms to the Environmental Impact Assessment System in order to get approvals for environmental release. The text indicates what kind of GM organisms must comply with the requirement:

> "*Development, culture or exploitation projects in mining, agriculture, forestry and hydrobiological areas using genetically modified organisms for production in unconfined areas. A procedure may define a list of species of genetically modified organisms, which because of their proven low environmental risk, are excluded from this requirement. The same regulations will establish the procedure for declaring areas as free of genetically modified organisms*".

Decree 40 of 2013 approved the procedures of the Environmental Impact Assessment System. It establishes that "production" does not include those activities pursuing research purposes. Further, it defines confined areas as those facilities and fields having physical or reproductive isolation or biosafety measures in order to avoid the environmental release of GM organisms, or to prevent effectively crossing them with sexually compatible species. The Decree also indicates that while the procedure to define a list of species of GM organisms excluded from this requirement is not issued, those species that SAG has approved under Resolution 1523 are excluded.

The undersecretary of Fisheries in the Ministry of Economy is the regulatory agency in charge of the regulation, evaluation and authorisation of the use of aquatic GM plants or animals. According to Law 20116 (Table 1) it must monitor and control the importation of aquatic GM organisms, only if Health and Environmental Risk Assessments are conducted. Furthermore, to avoid environmental conflicts, biosafety measures must be enacted. Up to now no such measures exist.

Chile signed – but has not yet ratified – the Cartagena Protocol on Biosafety, which entered into force in 2003. The number of countries signing this protocol has increased to 170 to date [17]. According to its own claims, this protocol aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. It features procedures for LMOs that are to be intentionally introduced into the environment, and for LMOs that are intended to be used directly as food, feed or for processing. Parties to the Protocol must ensure that LMOs are handled, packaged and transported under conditions of safety. Furthermore, the shipment of LMOs subject to transboundary movement must be accompanied by appropriate documentation specifying, among other things, the identity of LMOs and a contact point for further information. However, some authors have raised concerns about this protocol, pointing out that the preoccupation with GMOs has distracted attention and diverted essential resources from real problems related to biological diversity, such as the introduction of exotic species, bacterial contamination of crop plants and the sufficiency of water supplies [18].

Feed approvals

SAG's Resolution 3970, issued in 1998, established a simple but workable and predictable framework addressing animal consumption of GM crops. It approved the feed use of GM maize bearing traits for glyphosate or (and/or) gluphosinate ammonium tolerance, Lepidoptera insect resistance (Bt protein) or male sterility. This rule is still in force as the rules listed in Table 1. SAG's Resolution 1248, issued in 2013, approved for feed the soybean event MON89788, which bears a glyphosate tolerance trait. It is worth noting that the scope of these Resolutions is unclear as there are no restrictions to the import of GM food/feed. It is estimated that nearly 100% of all maize and soybeans imported to Chile are GM. Furthermore, no monitoring from SAG has been conducted on this issue except for residues coming from GM seed production.

Food approvals

Approvals of events to be used by the food industry for human consumption and labelling of food containing ingredients derived from GM crops are under regulation of the Ministry of Health. Decree 115 (2003), of the Food Safety Rule, through the Administrative Technical Norm number 83 (2007) entitles the Public Health Institute (ISP) of the Ministry of Health to evaluate on the differences and similarities of the GM product with the conventional one. ISP must determine toxicity, allergenicity and long-term effects of the events. After that, ISP communicates its determination to the Ministry of Health. The Ministry then issues an official resolution indicating when an event receives approval to be used in the food industry. Since 2008 ISP has received many events for food safety assessment (Table 2); however, the Ministry of Health has not published any final Resolution with approvals to date. It is worth noting that those events submitted in this procedure already have food approvals in several countries (Table 2). Meanwhile, food derived from GM crops is imported to Chile without restrictions.

Labelling

The Ministry of Health is also in charge of GM food labelling. By Decree 115, the Food Safety Rule (article 107, letter n) requires labelling for processed foods only if GM food/raw material is substantially different to the conventional product (Table 1). It means if there were nutritional changes in the transformed plant or vegetable it must be labeled in the final product. However, most GM crops commercially available have been shown to be substantially equivalent [19], so labelling has not been required in Chile to date.

Currently, labelling of GM food has been one of the main issues related to GM crops discussed at the political level. Seven bills related to GM crops within Chile's Congress have dealt with labelling (Table 3). However, no decisions have been made up to now.

Pending legislation

There are several pieces of legislation pending in Chile's Congress but they have not made any legislative progress in years (Table 3). Biosafety regulations are well established in Chile with regard to production of GM seeds for export under confined conditions or avoiding pollen flow. However, there are no clear regulations dealing with biosafety measures for unconfined releases. A biosafety bill has been under discussion in the Chilean Senate since 2006 (Table 3), but no agreements have been reached.

In relation to Intellectual Property Rights (IPR) of new varieties of plants, The House of Representatives, Senate, and Constitutional Court approved the ratification of the last revised act of 1991 from the International Union for the Protection of New Varieties of

Table 2
Events submitted to ISP for food safety evaluation.

			Year of submission to ISP	Selected countries with GM food approvals				
Crop	Event	Trait*	Chile	USA	Canada	EU	Brasil	Argentina
Canola	GT73	Gly	2010	✓	✓	✓		
Maize	DAS1507	LR and GA	2009	✓	✓	✓	✓	✓
Maize	DAS59122	CR and GA	2013	✓	✓	✓		
Maize	MON810	LR	2008	✓	✓	✓	✓	✓
Maize	NK603	Gly	2008	✓	✓	✓	✓	✓
Maize	MON863	CR	2009	✓	✓	✓		
Maize	MON88017	CR and Gly	2009	✓	✓	✓	✓	✓
Maize	MON89034	LR	2009	✓	✓	✓	✓	✓
Maize	Bt11	LR and GA	2009	✓	✓	✓	✓	✓
Maize	GA21	Gly	2009	✓	✓	✓	✓	✓
Maize	MIR604	CR	2009	✓	✓	✓		✓
Maize	MIR162	LR	2010	✓	✓	✓	✓	✓
Soybean	MON40-3-2	Gly	2008	✓	✓	✓	✓	✓
Soybean	MON87701	LR	2011	✓	✓	✓		
Soybean	MON89788	Gly	2010	✓	✓	✓		
Sugar beet	H7-1	Gly	2010	✓	✓	✓		

* Gly: Glyphosate tolerance; GA: Glufosinate ammonium tolerance LR: Lepidoptera resistance; CR: Coleopteran resistance.

Table 3
Bills currently in Chile's Congress related to GM crops.

Scope*	Bill	Submission year	Current situation
L	Special labeling for GM food (10039-11)	2015	Deputies Health committee. First constitutional stage***.
C	Regulation of beekeeping. It prohibits GM crops close to hives (10144-01)	2015	Senate's Agriculture committee. First constitutional stage.
L	Modifies the Consumer Protection Law including labeling of GM food and other ingredients (9703-03)	2014	Deputies Economy committee. First constitutional stage.
C L	Moratorium on the entry and cultivation of GMOs and mandatory GM foods labeling (8507-11).	2012	Archived**
C L	About GMOs: Food and medicine labeling, GMO free zones, mandatory risk assessment (7344-12)	2010	Archived
C	Forbidding of the entry and cultivation of sterile or chemical dependent GM seeds (4787-01)	2006	Senate's Agriculture committee. First constitutional stage***
C	About GM vegetables: Biosafety (4690-01)	2006	Second report of Senate's united committees of Agriculture, Environment and Health. First constitutional stage
L	GM food labeling (3818-11)	2005	Second report of Senate's Health committee. Second constitutional stage.
C	Mandatory environmental risk assessment for GMOs to protect organic farming (2992-12)	2002	Archived
L	GM food labeling (2967-11)	2002	Second report of Senate's Agriculture committee. First constitutional stage
L	GM food labeling (2985-11)	2002	Archived
C	Mandatory environmental risk assessment and GMO free zones (2703-12)	2001	Senate's Agriculture and Environment committee. First constitutional stage

* Scope of regulation. C: Cultivation; L: Labeling.
** Archived: When a bill remains over two years in a committee without being discussed and it has not been put on a discussion list.
*** Constitutional stages: At least two stages are required to approve a bill (Senate and Deputies). More stages may be applied if more discussions are needed.

Plants (UPOV 91), and is waiting for the President's signature. At the same time, an IPR bill has been discussed in Chile's Senate in order to update the current regulations ruling since 1994 under UPOV 78 guidelines. Several stakeholders and NGOs have conflated the ratification of UPOV 91 and the IPR bill under discussion with the unconfined release of GMOs into Chilean agriculture [20]. Although increased biotechnological research activity – incentivised by IPR – may lead to the creation of GM crops, IPR in new plant varieties and GM crops research are in fact separate issues [21]. Because of NGO pressure, the Government withdrew the IPR

Table 4
GM crops research supported and funded by the public sector in Chile.

	Crop	Trait	Main Institution	Public support (US$)*	Public financial source	Starting year
1	Table grape and stone fruits	Fungus and virus resistance	INIA	696,436	CORFO	2013
2	Apple	Biofortified (Vit A)	U. de Chile	455,263	FONDEF	2012
3	Citrus	Salinity	PUC	200,361	CORFO	2011
4	Table grape	Quality	INIA	1,852,036	FONDEF	2010
5	Cherry	Reapening and diseases resistance	INIA	1,177,856	FONDEF	2010
6	Maize	Drought tolerance	U. de Talca	701,698	FONDEF	2009
7	Canola	Biofortified (Carotenoids)	INIA	147,908	FONDECYT	2009
8	Apple	Fungus resistance and quality	INIA	842,750	CORFO	2008
9	Table grape	Seedless	INIA	512,000	CORFO	2008
10	Table grape	Fungus resistance	UTSFM	1,391,474	FONDEF	2007
11	Peach and nectarines	Virus resistance	INIA	129,769	CONICYT	2007
12	Apple	Sweetness	PUC	402,002	CORFO	2007
13	Potato	Drought and freeze tolerance	INIA	104,391	FONDECYT	2007
14	Eucalyptus	Drought tolerance	INIA	1,039,272	CORFO	2006
15	Table grape	Fungus and virus resistance	INIA	475,225	CONICYT	2006
16	Table grape	Drought tolerance	CEAZA	928,339	CORFO	2005
17	Plum and peach	Virus resistance	Fundación Chile	718,951	CORFO	2002
18	Wheat	Phosphurus intake	INIA	194,394	FIA	2002
19	Tomato	Freeze, drought and salt tolerance	U. de Talca	181,510	FIA	2002
20	Pinus	Botritys resistance	Fundación Chile	246,757	CORFO	2002
21	Pinus	Herbicide tolerance	Fundación Chile	149,506	CORFO	2002
22	Eucalyptus	Fungus resistance	UFRO	222,541	CORFO	2001
23	Table grape	Fungus resistance	INIA	327,591	FONDEF	2001
24	Eucalyptus	Freeze tolerance	UFRO	299,242	CORFO	2001
25	Tomato	Insect resistance	UTFSM	106,022	FONDECYT	2000
26	Table grape	Fungus resistance	INIA	402,982	FONDEF	1999
27	Plum	Virus resistance	INIA	76,234	FONDECYT	1999
28	Pinus	Insect resistance	Fundación Chile	726,959	CORFO	1998
29	Potato	Abiotic stress tolerance	USACH	196,160	FONDECYT	1997
30	Potato	Bacteria resistance	INIA	242,561	FONDEF	1996
31	Melon	Virus resistance	INIA	129,217	FONDECYT	1995
32	Potato	Bacteria resistance	PUC	976,473	FONDEF	1991
			Total	**16,253,823**		

* US Dollar (US$) to Chilean Peso Rate adjusted per year (http://www.sii.cl/pagina/valores/dolar/dolar2015.htm).

bill from the Senate for review. There is currently no timeframe for its introduction or modification.

Public research

There has been limited public research to develop GM crops in Chile. Most studies have been focused on a few forest species (pine, eucalyptus, poplars) and in some agricultural species (potatoes, melons, grapes, cherries and peach trees).

Thirty-two research projects involving genetic modification of economically relevant crops and forest species have been funded by public agencies in Chile since 1991, with a total pecuniary investment of US$16.2 million (Table 4). This amount does not consider private counterparts (pecuniary or no-pecuniary). The INIA (National Institute for Agricultural Research) leads this ranking, with 16 approved research projects and a total investment of US$8.3 million, corresponding to 51.4% of the total investment. Another eight research institutions have secured funding: six Universities and two Research Centers (CEAZA and Fundación Chile). These 32 research projects involve at least twelve different plants species, including table grape (7 projects), potato (4 projects), stone fruits (peach, plum, cherry; 4 projects) and others. Interestingly, six projects involving genetic modification of trees have been approved (three in Eucalyptus and another three in Pines). Seventeen of these projects are related to enhance biotic stress resistance; these projects include resistance to viral, bacterial and fungal diseases. Another nine projects aim to develop tolerance to abiotic stress (drought, salinity and freeze tolerance). Two projects were conceived to improve marketability through the modification of sweetness in apples and the generation of seedless grapes. Another two projects relate to biofortification (increased content of Vitamin A in apples and carotenoids in canola) and one project aims to generate herbicide tolerant Pines (Table 4).

In the period between 1991 and 2000, only 8 research projects were launched while 21 started between 2001 and 2010, showing a significant increase in the number of projects and investment. However, as of June 2015, to the best of our knowledge none of these projects have produced a commercially available product or prototype nor submitted regulatory packages seeking regulatory approvals to any regulatory agency worldwide. It is worth noting that 16 research projects have been funded by programmes from Chile's Ministry of Education (FONDEF, FONDECYT and CONICYT), with the other 14 depending on the Ministry of Economy (CORFO) and only 2 on the Ministry of Agriculture (FIA).

Finally, two technological research entrepreneurial consortia have been implemented in order to improve fruit production, a key sector for Chilean agricultural exports. Both are focused on genomics and genetic improvement in pitted fruits and grape vines [12]. Neither are included in Table 4 as they are not individual research projects.

Discussion

The main application of agricultural biotechnology in Chile is GM seed production and R&D activities in order to develop new traits and events. A comprehensive regulatory framework regarding import, GM seed production and field trials is in place (Table 1). The implementation of Resolution 1523 of 2001 has made Chile a key country for R&D activities related to GM crops. Up to 2014, 818 different GM events had been imported for field trials (Fig. 3). Events not authorised for commercial use in another country can have a previous release in Chile for R&D purposes after a detailed environmental risk assessment is carried out. In a similar way, the number of import permits for GM events has increased 4 fold since 2001, having a peak of 524 authorisations during the 2012 season (Fig. 3). It is worth noting that Chile's GM seed industry mostly relies on counter season demand, therefore when there are shortages of seeds due to biotic or abiotic stresses in North America, especially in United States, there will be more activity in Chile. However, in absence of such shortages in North America, field activities in Chile with GM seeds will be accordingly reduced. This phenomenon explains the large changes in hectares sown with GM seeds in Chile over different seasons (Fig. 1). The most dramatic differences in the hectares of GM seeds were when North America was under a critical drought and corn production was affected negatively. Thus, requirements for GM seed production boosted in Chile. In recent seasons, farmers in North America have reached a positive record of corn yields because of the weather conditions, control of biotic factors and use of technology. Thus, the demand for GM seeds from counter-season countries such as Chile decreased considerably (Fig. 1).

SAG's science-based registration and approval scheme for import, storage, production and seed processors involving GM have been critical to the success of the sector (Fig. 2). The vast majority of maize, canola and soybean seeds processed in Chile are GM. However, non-GM seeds are also processed at the same facilities. Private co-existence rules have been put in place and private testing is carried out. In this context, the implementation of a Stewardship and Quality Management System under the Excellence Through Stewardship (ETS) programme (http://excellencethroughstewardship.org) has led to the adoption of principles and management practices for the responsible management of technology-derived plant products. These initiatives have ensured the coexistence between GM and non-GM crops. It is worth noting that after more than twenty years with activities related to GM seeds in Chile, there is no evidence of a negative environmental impact on their surroundings at crop-level, farm-level and landscape-level.

While GM seed production is carried out in the central valleys of Chile, it is worth noting that the region of Arica-Parinacota, Chile's northernmost region, has become a key zone to develop research for seeds mainly due to its weather conditions. Arica has geographic isolation, given its location in a desert, which minimizes plant health problems. Further, the annual average temperature is 18.7 °C (http://www.arica.climatemps.com) and it allows several crop cycles in a calendar year. Thus, research programmes to develop new GM events can be hastened to a notably large extent. At the same time, Chile also has political and legal stability that provides clear rules for research programmes contracted in the medium and long term. State agencies related to the seed industry, such as SAG and the National Customs Service, have international credibility, which is a significant advantage over other counter season and field research providers in South America. Those factors have been considered by several seed companies, which have invested considerably in facilities and human resources in the region [22].

Agriculture is Chile's second largest source of exports after mining and represents 2.6% of GDP. Behind fruit and wine, seed exports are the third most important of Chile's agricultural exports and GM seeds contribute to almost 40% of those (Fig. 2). Because of the importance of this sector to the economy, agricultural biotechnology matters should be regulated in a comprehensive and sensible manner. Chile is in an unusual position regarding GM crops: it can produce GM seeds, but only for export purposes – no domestic use is allowed, while GM foods are being freely imported into the country without restrictions. For instance, Chile has ca. 110,000 ha of non-GM maize per year and can only address about 50% of requirements from the livestock sector and food industry. The other 50% is imported mainly from countries like Argentina and Brazil, whose adoption of GM maize is higher than 95% [23] and 82% [24] respectively. In the case of soybean, Chile does not produce this crop to a considerable degree because of the local weather conditions. The requirements for feed and food industries are supplied by imports coming primarily from Argentina, where the adoption of GM soybean rose to 100% [23].

Agricultural biotechnology and genetic engineering are powerful tools to substantially increase productivity, quality and environmental sustainability in agricultural farming [1,7,8]. It has been shown than the implementation of GM crops in Chile – for domestic purposes – would lead to several benefits. In 2011, the Chilean Government contracted a study to evaluate the economic impact of different GM crops in Chile. The main results were that GM maize, canola and sugar beet bearing herbicide-tolerance, would increase farmer profits by 4.5%, 12.5% and 27% respectively [25]. Another report looked into the environmental and economic impacts for Chilean agriculture of GM maize carrying insect resistance and/or herbicide tolerance. The authors concluded that farmers would increase their profits by US$20-76 per hectare. Further, insect resistance and stacked events would reduce the use of pesticides by 37.6% and 40.2% respectively. GM maize also would provide substantial environmental benefits, as it would reduce consumption of diesel. Thus, it is possible to reduce 42.5 kg of CO_2 for each hectare [26].

In this context, in order to support key industries in agriculture, Chile has implemented several initiatives since 2001. The "Programme for Biotechnology Development in the Forestry, Agricultural, and Aquacultural Sectors" coordinated by the Ministry of Economy was one of the five components of the "Technological Innovation Programme" as part of an agreement signed with the Interamerican Development Bank. Chile has provided a number of different governmental grant programmes to encourage investment in R&D. Thus, public agencies such as CORFO (the Chilean Economic Development Agency), CONICYT (National Commission for Scientific and Technologic Research) and FIA (Foundation for Agrarian Innovation) have been key in promoting the development of plant biotechnology. In addition, those programmes have funded all public research projects carried out in Chile since 1991 (Table 4).

The public budget of the Chilean National Innovation System was raised from US$ 322 million in 2005 to US$ 874 million in 2011, which corresponds to an increase of 170%. However, this investment in Science, Technology and Innovation represents only a 0.4% of the Gross Domestic Product (GDP) of the country estimated for 2011 (US$ 222 billion according to the IMF) [27]. In recent years, 7 out of the 34 OECD member countries invested less than 1% of their GDP in R&D, and only 2 countries invested less than 0.5%; among them Chile. Hence, Chile's investment in natural and agricultural sciences is modest compared with other countries [28]. This situation is a constraint in terms of which research initiatives should be funded. However, in part because of the very special geographical situation and isolation, Chile faces local challenges in terms of crop production and agriculture. Therefore, local investment in R&D in these areas seem critical, since it could address both global problems and local situations that are not present in other countries.

The vast majority of R&D in Chile has been funded by public funds. Thus, public support and Chilean investment are critical to address the problems that local agriculture will face in the future. For example, global warming will probably affect agriculture in several ways, including water deficit, desertification and salinity. In this scenario, the development of new crop varieties tolerant to different types of abiotic stress is mandatory. Several initiatives related to this have started in Chile over the last few years (Table 4).

Chile needs to develop and enforce regulations that respond adequately with the challenges encountered by agricultural biotechnology. Today there is no available regulatory framework that satisfies the full requirements for the development of agricultural biotechnology in Chile. Although SAG's Resolution 1523 establishes a robust framework for GM seed production, the Environmental Law is ambiguous on the issue of permitting for GM crops in Chile for domestic purposes. The procedures that describe how to apply have not been developed up to now. Legislation about biosafety being discussed into the Senate since 2006 (Table 3), would allow a legal framework for the development of GM crops. However, related legislation in matters such as industrial property rights, genetic patrimony, and access to genetic resources is as important as the biosafety regulation in order to have a robust regulatory framework for GM crops. Proper regulation for GM crops would improve access for the seed industry and farmers to better conventional genetics in a timely manner and at a reasonable cost. Further, a regulation based on a "case by case" assessment would improve competitiveness of the seed industry and growers from a global and economically liberal country. Chile's Congress is discussing several initiatives related to GM crops, however 7 out of 12 focus just on labelling, as some others misinterpret the technology and seek to ban it (Table 3). The biosafety bill is the only one seeking a workable and predictable framework based on science to deal with GM crops in Chile.

Regarding intellectual property, Chile has implemented a plant variety protection system and is member of the UPOV Convention Act of 1978 since 1996. Chile is currently modifying its IPR regulations in order to adopt UPOV Convention Act of 1991 guidelines. The aim is to support Chile's agriculture and remain as a competitive player in the world fruit, seed, wines and vegetable markets.

Developing an efficient agro-food industry must be a top priority for Chile, and research programmes must support such efforts. GM technology offers real opportunities for the development of agriculture in the country. As Chile's economy becomes more integrated into the global economy, and there are key countries and markets either promoting or reluctant on GM crops, it is time for Chile to decide on its own national policy about the technology, considering all environmental, farming and market aspects. Chile has to be able to develop a robust regulatory framework on development and commercial use of genetic modification according to the chosen strategy.

In conclusion, GM seed production and R&D activities in Chile have achieved considerable maturity in the last ten years due to the private sector's support and strict regulations governed by SAG. Better regulations are needed in order to move forward and allow Chilean farmers to use GM crops for domestic purposes if they are provided that option. Furthermore, those regulations could help to solve the particular situation in Chile where GM crops for local supplies are not grown but GM foods are imported without restrictions. Other regulations from Ministries of Environment and Health need to be addressed in order to have a robust regulatory framework related to GM crops. Research and investment in this technology, as the public sector has promoted in the last 20 years, can contribute to make Chilean agriculture more efficient and competitive. However, all these efforts must be based on a national strategy about GM crops.

Conflict of interest

MAS is employed by ChileBio, which is funded by CropLife International and companies that develop GM crops.

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