



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Directorate F - Food and Veterinary Office

DG(SANCO) 2012-6300 - MR FINAL

FINAL REPORT OF AN AUDIT
CARRIED OUT IN
CHILE

FROM 14 TO 22 MARCH 2012

IN ORDER TO EVALUATE THE CONTROL SYSTEM FOR GENETICALLY MODIFIED
ORGANISMS WITH REGARDS TO SEED INTENDED FOR EXPORT TO THE EU

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Chile from 14 to 22 March 2012 in order to evaluate the control system in place for genetically modified organisms with regard to seed intended for export to the EU and the control system to prevent the presence of genetically modified organisms (GMOs) in non-GM seeds exported from Chile to the European Union (EU).

A comprehensive control system regarding import and multiplication of GM seed and GMO trial is in place. The system aims to ensure that GMO contamination of non-GMO crops is prevented.

The system of official controls is based on a registration and approval scheme for import of GM seed, and controls of imported GM seed storage, GMO field production and seed processors involving GM seed. However, there are no official controls specific to GMO in the case of non-GM seed production. Private co-existence rules have been put in place and private testing is carried out.

The implementation of official controls of GM seed at import and field production phase should ensure, in most cases, that non-GM seed exported to the EU is not contaminated with GMO.

The vast majority of seed processed is GMO. However, non-GM seeds are also processed at the same premises, and the official controls do not verify the proper implementation of the measures put in place by the seed processor to avoid contamination of non-GM seed with GMO. No inspections are carried out at sowing at farmers multiplying GM and non-GM seed, where GMO contamination can potentially occur. No official tests are carried out to target GMO contamination of non-GM seed to be exported to the EU.

In the case of GM seed exported to the EU, it is not ensured that the information indicating that the product contains GMO is given to the importer.

Recommendations are made in the report to address the shortcomings identified during the mission.

Table of Contents

1	<u>INTRODUCTION</u>	1
2	<u>OBJECTIVES</u>	1
3	<u>LEGAL BASIS</u>	1
4	<u>BACKGROUND</u>	1
4.1	<u>PRODUCTION AND TRADE</u>	2
5	<u>FINDINGS AND CONCLUSIONS</u>	2
5.1	<u>ORGANISATIONAL ASPECTS</u>	2
5.1.1	<i><u>NATIONAL LEGISLATION OF RELEVANCE TO GMO</u></i>	2
5.1.2	<i><u>COMPETENT AUTHORITIES</u></i>	2
5.2	<u>GMO AUTHORISATION PROCEDURES</u>	3
5.3	<u>CONTROLS TO PREVENT THE PRESENCE OF GENETICALLY MODIFIED ORGANISMS (GMOs) IN NON-GM SEED</u>	4
5.4	<u>CONTROLS OF GMOs</u>	5
5.4.1	<i><u>GM SEED</u></i>	6
5.4.2	<i><u>GMO FIELD TRIALS</u></i>	8
5.4.3	<i><u>SAMPLING</u></i>	8
5.4.4	<i><u>SCHEMES IMPLEMENTED BY THE PRIVATE SECTOR</u></i>	9
5.5	<u>LABORATORIES</u>	10
6	<u>OVERALL CONCLUSIONS</u>	11
7	<u>CLOSING MEETING</u>	12
8	<u>RECOMMENDATIONS</u>	12
	<u>ANNEX 1 - LEGAL REFERENCES</u>	13

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ANPROS	National Association of Seed Producers
CA	Competent Authority
EC	European Community
Event	Genetic transformation event
EU	European Union
FVO	Food and Veterinary Office
GM	Genetically Modified
GMO(s)	Genetically Modified Organism(s)
INIA	Institute of Agricultural Research (<i>Instituto Nacional de Investigaciones Agropecuarias</i>)
ISO	International Organization for Standardization
PCR	Polymerase Chain Reaction
p35S	Promoter derived from Cauliflower mosaic virus
SAG	Agriculture and Livestock Service
tNOS	Terminator derived from <i>Agrobacterium tumefaciens</i>

1 INTRODUCTION

This audit took place in Chile from 14 to 22 March 2012, as part of the Food and Veterinary Office's (FVO) planned audit programme.

The FVO team consisted of two auditors from the FVO, and one National Expert from an EU Member State. Representatives from the competent authorities accompanied the team for the duration of the audit.

An opening meeting was held on 14 March 2012 at the headquarters of the Agriculture and Livestock Service (SAG), in Santiago, during which, the objectives and itinerary for the audit were confirmed, and additional information, necessary for the conduct of the audit, was requested.

2 OBJECTIVES

The objective of this audit was to evaluate the control systems in place for genetically modified organism with regard to seed intended for export to the EU, including authorisation, seed production, processing and commercialisation. The audit also included the evaluation of the control system in place to prevent the presence of genetically modified organisms (GMOs) in non-GM seed in particular maize.

The following table lists the sites visited and meetings held in order to achieve the objective:

Competent Authority			Comments
Competent Authority	Headquarters	2	SAG
Regional offices		3	Maule, O'Higgins and Metropolitana regions
Control sites			
Seed company		3	Maule, O'Higgins and Metropolitana regions
Seed processor		2	O'Higgins and Metropolitana regions
GMO trial		1	O'Higgins region
Laboratory			
Official laboratory		1	Department of Laboratories and Quarantine Stations of SAG

3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation, in particular Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Full legal references to EU legal acts quoted in this report are provided in Annex 1 and refer, where applicable, to the last amended version.

4 BACKGROUND

This was the first audit carried out by the FVO to Chile to evaluate the official controls for GMOs in seed intended for export to the European Union (EU). The audit took place because competent authorities (CAs) in the EU have detected traces of GMOs in non-GM maize seed originating in Chile in recent years and Chile is the largest maize seed exporter to the EU.

4.1 PRODUCTION AND TRADE

Chile has favourable conditions to produce seed. The seed is produced in summer in the southern hemisphere and can be sowed in the northern spring in the EU.

In the 2010-11 growing season, there were 2,181 GM seed fields producing seeds both certified and non-certified according to international standards. The number of GM trial fields was 695. The total GM area was 20,464.4 ha. In the 2011-12 growing season, the number of GM seed fields amounted to 2,840. In addition, there were 580 GM trial fields. The total GM area for export was 31,513.8 ha. For further data regarding GM production carried out by the regions in Chile see 5.5.

The total maize seed exported to the EU amounted to 12,416 t and 9,743 t of in 2010 and 2011, respectively representing a value of some € 70 million. The volume of GM maize seed for EU export amounted to 509.2 t in 2010 and 177 t in 2011.

With the exception of one trial of GM grapes, GM seed production and GM trials are carried out for export commissioned by foreign seed companies. The GM trials involve maize, soya bean, safflower, tomato, sugar beet, rapeseed and squash. GM tomato seed is produced in glasshouses. The trial of GM grapes is carried out by the Institute of Agricultural Research (*Instituto Nacional de Investigaciones Agropecuarias*, INIA). There is no GM production for food, feed or seed for the domestic market in Chile.

5 FINDINGS AND CONCLUSIONS

5.1 ORGANISATIONAL ASPECTS

Legal requirements:

Art. 46 (1) of Regulation (EC) No 882/2004 stipulates that Community controls shall have particular regard to the legislation of the Third Country, to the organisation of the Third Country's competent authorities, their powers and independence, and the authority they have to enforce the applicable legislation effectively and to the training of staff in the performance of official controls.

Findings:

5.1.1 National legislation of relevance to GMO

SAG Resolution No 1523 of 2001 establishes norms for import and introduction into the environment of 'Living Modified Plant Organisms' for propagation. SAG Resolution No 6966 of 2005 establishes the Technical Committee of GMOs and the Technical Secretariat.

Sanctions regarding GM trial and GM seed production can be imposed under Law 3557 of 1980 concerning agricultural protection.

5.1.2 Competent Authorities

The Agriculture and Livestock Service (SAG) under the supervision of the Ministry of Agriculture is the Competent Authority (CA) for GMOs in seed.

Within SAG, the Division of Agricultural Protection and Forestry is responsible for imports of GM material for release into the environment and controls of GM trials and GM seed production.

The Department for Laboratories and Quarantine Stations is responsible for GMO laboratory analysis.

The Seed Division of SAG is responsible for GM and non-GM seeds and carries out controls for varietal seed certification in accordance with international standards. Their responsibility does not include controls to prevent GMO presence in non-GM seed.

In addition its central office in Santiago, SAG has 15 regional and 63 local offices. In each region, one regional official coordinates the GMO controls, and in each of the local offices, at least one agronomist and one technician carry out controls. The inspectors met by the audit team were generally well trained and aware of the procedures to follow. Evidence was provided that staff involved in GMO controls receive regular training.

Conclusions:

National legislation is in place regarding controls of import and release of GMOs into the environment. The competent authority within the scope of this audit is clearly designated and tasks are clearly allocated.

5.2 GMO AUTHORISATION PROCEDURES

Legal requirements:

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms provided a basis for the evaluation of the control system including authorisation procedures.

Findings:

Authorisation of GM seeds for import and deliberate release into the environment

There is an authorisation system for import of GM seeds and their deliberate release into the environment. The release can be for seed multiplication and for trial purposes.

As required by Resolution No 1523 of 2001, where GM seed is imported to Chile, an application for import has to be submitted by the importer to the Plant Protection Division. It is done via a web based System for GM Seed import (*Sistema de Importación de Semillas Organismos Vegetales Vivos Modificados*) of SAG, which allocates a unique identification number to each application. In the case of a new GM event intended to be introduced to Chile, a detailed risk assessment is carried out by the Secretariat of the Technical Committee of GMOs¹. In the case of GM seed, where the event has already been introduced to Chile, a simplified risk assessment is carried out. The Secretariat consists of experts from the technical units of SAG and external experts working under confidentiality agreement. It evaluates the potential risks associated with the GMO release and whether the measures proposed by the applicant to mitigate the risk are adequate. A recommendation is prepared by the Secretariat of the Technical Committee of GMOs, on a case-by-case basis, to issue an import permit or not. The import permit for GMO is issued by the Division of Agricultural Protection and Forestry of SAG within 45 working days of application. In the case of GMO events, which are not new to Chile, the permit is issued within 20 working days. The deadline can be extended when additional information is requested.

The import permit for GMO includes information regarding the import point, the country of origin,

1. In their comments in response to the draft audit report, the competent authority noted that, the Technical Committee of GMOs is composed of the National Director and the heads of SAG Divisions.

the intended use of the imported seed, type of GM product, the application number, the authorisation number of the storage facility approved by SAG to store the seed after the import and the imported quantity of GM seed. Furthermore, the conditions of the release such as isolation distance, obligations of the producer and deadline of the import are also included. In one particular case, the import permit for GM maize for seed multiplication required an isolation distance of 200 m from any other maize field and 100 m isolation distance is accepted if the parental female line is the GMO and the male line is not GMO. In another case, where the GMO event to be imported was new to Chile, the required isolation distance was 300 m and the male line of the seed production was GMO.

Authorisation for GM seed multiplication and GMO trial

In the case of production of GM seed and GMO trial, the producer has to be registered in the web based 'System for GMO, seed and fruit propagating material certification' (*Sistema de Organismos Vivos Modificados certification de Semillas y Plantas Frutales*) of SAG and has to submit a request at the local office of SAG where the production will take place in order to ensure that each GM field is registered with them. Details such as the exact location of the GM seed and GMO trial field have to be submitted within 30 days after sowing.

SAG inspections verify the key information included in the import permit for the GMO and verify whether the conditions of the release specified in the import permit are met.

Conclusions:

An authorisation system of import and release of GMO into the environment is in place.

5.3 CONTROLS TO PREVENT THE PRESENCE OF GENETICALLY MODIFIED ORGANISMS (GMOs) IN NON-GM SEED

Legal requirements:

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms provided a basis for the evaluation of the control system.

Findings

There are no official controls specific to prevent the presence of GMOs in non-GM seed. In the case of non-GM seed, isolation distances according to international seed certification standards are applied. In addition, most seed companies are members of the National Association of Seed Producers (ANPROS) applying 800 m isolation distance between non-GM and GM maize seed fields (see 5.4.4 for details). The control system for import of GM seeds and their deliberate release into the environment for seed multiplication and trial purposes aims to ensure that non-GM crop production is not contaminated with GMO. The control system regarding GMOs and its implementation is explained in 5.4.

The audit team visited one non-GM maize seed production field for EU export in the Maule region. The seed company stated that they used to apply 800 m isolation distance from GM maize fields required by the ANPROS. Three years ago they moved their non-GM maize seed production to an isolated area, where no other maize production is taking place. In this particular case the farmer multiplying seeds produces non-GM seed only. The seed company stated that they provide the farmer multiplying seeds with the machinery for sowing and harvest and take care of cleaning the

equipment. Official controls of the seed production carried out by SAG inspectors did not include checks that contamination of non-GM seed by GMO is prevented.

Some private samples are taken to verify whether GMO presence in non-GM seed is prevented (see 5.4 and 5.5). Private schemes have been implemented by seed producing companies involved in EU seed export to avoid contamination of non-GM seed with GMO (see 5.4.4).

Conclusions:

There are no official GMO controls of non-GM seed. The main element to prevent GMO contamination of non-GM seed is the measures applied for GM seed production and there are some private sector initiatives to prevent cross-contamination (see 5.4).

5.4 CONTROLS OF GMOs

Legal requirements:

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms provided a basis for the evaluation of the control system.

Regulation (EC) 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of GMOs provided a basis for the evaluation of the control system.

Findings

Official controls of GMO trials and GM seed multiplication are carried out by the Division of Agricultural Protection and Forestry SAG. The control procedures are the same regardless of the possible destination country of the GM seed. Additional measures are put in place only upon specific request of the destination country. A Manual of procedures has been put in place regarding the import and release of 'Living Modified Plant Organisms'. The main objective of the inspections is to verify compliance of the measures established under the risk assessment process focusing on minimising the impact of the GMO release on the conventional and organic production. The official controls do not take into account the outcome of the private controls.

Verification of traceability of GM seed is carried out, and sampling and testing. Lateral Flow Strip Tests are carried out to verify whether the genetic element (expressed by the protein detectable by the test) and laboratory analysis are performed to verify whether the GMO event of the seed corresponds to what is indicated in the import permit for the GMO.

In the case of GMO events new for Chile or not authorised for commercial use in another country and in the case of the oilseed rape MON-00073-7 at least four inspections are performed: at pre-flowering, flowering, harvest and post-harvest. When the event is not new for the country, at least two inspections are carried out generally during the growing season and at harvest or post-harvest. Storage facilities authorised by SAG to store imported GM seed, GM fields, seed processors and destruction facilities of GM materials are inspected. A standardised report is drawn up by the SAG inspector of Plant Protection after each inspection and related data is entered to the database called 'System for GMO, seed and fruit propagating material certification'. Controls for varietal seed certification is carried out by the Seed Division of SAG.

GM materials can only be destroyed in facilities such as incinerator, compost and deep burial approved by SAG. Prior to approval, SAG carries out an inspection to check the infrastructure, the

surface and the surrounding area of such premises. SAG stated that approved establishments are visited twice a year to verify the safeguard of the material, the destruction process and the documentation. It is also checked whether the volume of the material for destruction is registered.

The audit team visited GM and non-GM seed multiplication and GMO trial sites in Maule, O'Higgins and the Metropolitana regions, which have the largest number of GMO fields in Chile and are involved in seed export to the EU.

The Maule region has the largest area of seed production in Chile. In the growing season 2011-12, seed was produced on 18,758 ha (48% of the seed production in Chile) in this region. The GM seed multiplication accounted for 70% involving GM maize, GM soya bean and GM rapeseed. The conventional seed is produced mainly for EU export. No seed processing took place in this region and no GMO trials were performed during this growing season. SAG regional office of Maule has four local offices and 10 staff are allocated to carry out GMO related controls. Some of the GMO staff is also involved in controls for varietal certification of conventional seed production.

There are some 8,000 ha of GM seed produced in the O'Higgins region for export only. This region has the second largest area of seed production in Chile. GM and conventional maize GM and conventional rape seed, GM soya bean and GM pumpkin, conventional sunflower and conventional sugar beet are produced. Maize has the largest area of production accounting for more than 85% of the seed production. There are 10 seed processors involved in GM maize seed processing. In the case of GMO events new for Chile or not authorised for commercial use in another country, at least five inspections are performed and when the event is not new for the country, at least three inspections are carried out, which is one inspection more in each case than the minimum requirement. SAG regional office of O'Higgins has four local offices and 6 staff allocated to carry out GMO related controls.

The Metropolitana region had 943 GM seed fields on 3,011 ha in the growing season 2011-12 having the third largest number of GMO fields in Chile. Some 96% of the surface of GMO area was GM maize (2,904 ha) followed by soya bean (some 170 ha). There are 8 seed processors based in this region.

5.4.1 GM seed

Regarding GM seed, official inspections are carried out at storage facilities of imported seed, GM seed multiplication sites and seed processing establishments dealing with GM seed. No controls are carried out at sowing and prior to sowing as details of the production are not available for the inspector at that stage (see 5.2).

A research program was carried out by SAG to verify the reliability of the isolation distances between GM and non-GM crops enforced by them. Maize and rape seed samples were taken in 2011 from the neighbouring fields (see also 5.5).

In the case of GM seed for EU export, it is not officially required to indicate on the label/accompanying documents that the product is GMO².

Storage of GM seed

Companies can store imported GM seed in storage facilities approved by SAG only. SAG carries out inspection to check the conditions of the store room, whether there is a designated area for GM seed, it is locked and it has a restricted access. An annual permit is granted, which can be renewed.

2. In their comments in response to the draft audit report, the competent authority noted that, in the case of GM seed for EU export, although it is not officially required to indicate on the label/accompanying documents that the product is GMO, the documentation submitted for certification at the time of phytosanitary inspection prior to export to EU indicate the status of GMO in order to ensure traceability.

Approved establishments are visited when GM seed, which is new to Chile or not authorised for commercial use in another country, is received and for renewal of the storage permit. An inspection report is drawn up by the SAG inspector of Plant Protection after each visit. The SAG inspector in O'Higgins region stated that non-compliance is detected rarely. In such case, e. g. where the storage records do not indicate the correct quantities of the GM seed received, the inspector immediately informs the company to provide clarification and the seed is seized. Once the deficiency has been rectified, the seed is released. There are 43 storage facilities authorised by SAG for GMO seed. SAG stated that each facility is used only by one seed producing company. Imported GM seed is generally not tested by SAG to verify the GMO event indicated in the import permit before sowing. However, the competent authority stated that, there had been 10, 8 and 5 random samples taken at the point of entry in 2009, 2010 and 2011, respectively.

GM maize seed multiplication

The audit team visited a GM maize seed production of 0.27 ha of a female parental line in the Metropolitana region. The producer stated that when planning the production location they use the Isolation System of ANPROS (see 5.4.4). The seed company works with farmers multiplying seeds on a contract basis. The contract specifies the conditions of the seed production including requirements to be taken into account as the production involves deliberate release of a GM crop into the environment. Sowing and harvest machinery is maintained and provided by the seed company. The seed company stated that separate machines are used for GM and non-GM seed production.

A demonstration of a SAG inspection was observed by the audit team. The inspector explained that inspections are performed at pre-flowering, harvest and/or post harvest stages. During the pre-flowering period the inspector checks, using GPS, whether the location of the field is identical with what has been declared. The isolation distance from other seed production fields and GMO trials of the same crop is also checked against the distance required in the import permit. The inspector stated that the isolation distance from commercial maize fields is checked by inspectors responsible for seed varietal certification. A standardised report is drawn up by the seed inspector and a copy of the seed inspection report is handed over to the SAG inspector of Plant Protection for information. The producer is obliged to inform SAG of the harvest one day before the planned harvest date. The harvest control by SAG includes checking the waybill accompanying the harvested crop for quantity, place of destination of the transport and whether it is indicated that the product is GMO. The inspector checks whether the harvester is properly cleaned e.g. with a portable air pressure cleaning machine. It is also checked whether loading of the truck with the harvested crop is taking place inside the plot where the crop was harvested and whether the harvested crop is covered on the truck in such a way as no spillage occurs. In the harvest period, two complete harvest processes of GM crop can be checked by SAG per day and 6-8 additional harvests can be controlled partially as the plots are small and harvests take place at the same time. After harvest, irrigation of the plot and superficial incorporation is carried out to induce germination. After a 60-day-period following harvest, the SAG inspector inspects the field for volunteer plants. The inspector stated that post-harvest control is carried out on each GM seed plot and that volunteer plants are found in approximately 5% of the GM fields. In these cases the producer is informed and corrective action is required. Follow-up visits are carried out to verify whether all volunteer plants have been removed. A standardised inspection report is drawn up by the SAG inspector after each inspection visit including follow-up. The result of each inspection is entered into the SAG's web system for GMO, certification of seed and fruit propagating materials.

The audit team also observed a demonstration of inspection carried out by SAG in the O'Higgins region at a GM maize seed production. The seed company works with farmers multiplying seeds on

a contract basis. The sowing machinery is rented by the farmer multiplying seeds who is responsible for the cleaning to avoid contamination of non-GM seed with GMO, whereas the harvesting machinery is provided by the seed company. The inspection carried out by SAG followed the same principle as the inspection observed by the audit team in the Metropolitana region.

Maize seed processing

At seed processors involved in GM seed processing, SAG inspections are carried out in the seed processing season after harvest. It is checked whether the truck transporting GM seed is covered to avoid spillage when it arrives to the seed processor and traceability of GM seed is verified in various stages of the processing based on documentary verifications. There are no official requirements specific to prevent GMO cross-contamination at seed processors.

The audit team observed a demonstration of inspection carried out by SAG in the Metropolitana region at a seed processor exporting to the EU and other countries. The company processes maize, soya bean and sunflower seed. Their processing capacity is 500 t/day. Some 80-90% of the processed maize seed is GM and the rest is non-GM seed. The non-GM seed is exported only to EU. There are separate production lines used for GM and non-GM seed processing when both materials are processed at the same time. However, when only GM seed is under process, production lines dedicated to non-GM seed are also used. The processor stated that thorough cleaning takes place after processing GM seed and before non-GM seed is processed again. He further stated that side products of the GM seed processing are collected separately and destroyed. The seed is exported in big bags/bulk liners to the EU in most of the cases, where the product is stored and can be repackaged. The seed processor stated that each lot of non-GM seed for EU export is sampled and analysed for GMO presence (see 5.5.3 for details). The seed processor further stated that only batches with negative test results are shipped to the EU. SAG inspection with regard to GMO observed by the audit team included checking the documentation of the GM seed to be exported to the EU in order to verify traceability. The inspector checked the production lines dedicated for GM seed processing for traceability including unloading, drying, sheller and packaging. It was also checked whether the side products of the GM seed processing are separately collected. The SAG inspector did not verify the implementation of the cleaning protocol put in place to avoid GMO contamination of non-GM seed. SAG inspects each seed processor three times, on average, between March and May every year.

The audit team observed a demonstration of inspection carried out by SAG also in the O'Higgins region at a seed processor exporting to the EU and other countries. The company processes GM and non-GM maize seed. Only non-GM seed is exported to the EU. Their daily processing capacity is 300 t/day and some 7-8,000 t of seed is processed annually. The inspector explained that it is checked whether the truck is covered to avoid spillage, traceability is verified in the dryer, sheller and the sorting plant by checking the documentation. The company stated that they implement a cleaning protocol in the production lines in order to avoid GMO contamination of non-GM seed. The inspector did not verify the implementation of the cleaning protocol. SAG inspects each seed processor two times, on average, during the seed processing season every year.

5.4.2 GMO field trials

Control procedures of GMO trials carried out by SAG are the same as in the case of GM seed multiplication. The same registration and authorisation process is followed as explained in 5.3.

The audit team visited a GM maize trial in the O'Higgins region. The company is involved in crop production and research. Mainly trials of GM soya bean are carried and followed by GM and non-

GM maize. Non-GM trials are carried out for an EU Member State company. The trial visited by the audit team involved 10 GMO events on 0.97 ha. The SAG inspector had controlled the trial twice prior to the audit. One inspection was carried out before flowering, which included verification of the phenological phase of the crop, the surrounding crops and the isolation distance from other maize crops. The second inspection took place some 3 weeks later, when the phenological phase and the isolation distance were checked again. The inspector stated that the harvest and post-harvest controls are carried out in the same way as in the case of GM seed. A sampling was also observed at the GMO trial field visited (see 5.5.3 for details).

5.4.3 Sampling

SAG performs sampling of GM seed to verify the genetic modification. Leaf and seed samples can be analysed by Lateral Flow Strip Tests or can be sent to the Biotechnology laboratory of SAG for molecular analysis. SAG further stated that 3,300 test strips are distributed every growing season among the regions. There were 106 in 2010, 53 in 2011 and 7 samples taken and analysed by the SAG Biotechnology laboratory in 2012 by the time of the audit.

The audit team observed a sampling carried out by SAG in a GM maize trial field involving 10 GMO events. One leaf sample was drawn per GM event some meters from the edge of the field regardless the size of the plot. In order to demonstrate the procedure, the leaf samples were tested with Lateral Flow Strip Tests to verify the protein expressed by the events declared in the import authorisation for GMO. Normally, the samples are labelled and transferred under cooled conditions to the local SAG office where Lateral Flow Strip Tests are performed. SAG informed the Audit team that they use several types of Lateral Flow Strip Tests targeting proteins corresponding to glyphosate and glufosinate resistance and the relevant 'cry' varieties for insect resistance. In general, the tests for the corresponding genetic event are also carried out; in some cases tests to exclude the presence of other genetic elements are used. In the case of doubts, the material is sent to the Biotechnology laboratory of SAG to perform the GMO analysis.

The audit team observed a demonstration of sampling by SAG inspector at a seed processor. The sampling followed the rules of the International Seed Testing Association. SAG stated that the same sampling procedure is followed when GM seed is sampled and sent to the laboratory to verify the declared GMO event.

The seed processor visited by the audit team in the Metropolitana region stated that they sample each lot of non-GM seed for EU export. The sample size is 1 kg per lot. The individual samples of the lot are transferred to the company's internal laboratory to form a compound sample of 1.5 kg out of 6 to 7 lots which corresponds to a batch. The size of the batch of seed is about 70 t. The seed processor stated that the 1.5 kg of the compound sample correspond to 3,500 to 5,000 maize seed kernels. The compound sample is analysed in the company's laboratory based in another country. The seed processor further stated that the analysis is based on the screening elements p35S and tNOS which allow, at present, the detection of any GM maize line planted for seed production in Chile. The sensitivity of the procedure was stated by the company to be 0.0028%. The audit team noted, that the procedure explained by the company does not consistently ensure an analytical sensitivity below 0.02%, depending on the kernel size. No further details such as sample number and analytical results were provided as the company considers such information as confidential.

5.4.4 Schemes implemented by the private sector

The audit team met ANPROS. The organisation has 65 members, which are seed producing companies representing 98% of the seed producers. They developed a system, which allows

producers to plan seed production taking into account isolation distances from other seed production of the same crop. Depending on the type of seed produced, the isolation distance varies between 200 and 800 m in the case of maize. For example in the case of conventional maize, the isolation distance is 800 m from GM maize fields. The isolation distances included in the system have been developed based on international standards and own experiences. This system also includes identification of GMO free production areas.

When a seed company plans the seed production, before the sowing, the intended field is measured by a GPS device. The principle is to draw a circle from the middle of the field using the longest distance to the edge as radius. The circle is then used for calculation of isolation distances. The GPS coordinates and the type of the seed production are entered to the web based isolation system of the ANPROS. A map in the system helps the user to identify the exact location of the seed fields in close vicinity of the intended place of production. Zones of GMO free productions are also included in the system and are highlighted on the map. The software evaluates the data entered by the producer and indicates if there is a restriction to proceed with the sowing. Where the isolation distance is not respected, the system does not allow to register the seed production field. The producer has to agree with the party/ies whose production is located within the required isolation distance. Only when an agreement to adjust the production area is reached can the field be registered in the ANPROS system, which is obligatory for every member. ANPROS checks annually 10% of the seed fields registered with them for compliance with the isolation requirements.

A program called 'Excellence Through Stewardship' is followed by companies performing GMO trials or multiplying GM seed. This is a biotechnology industry-coordinated initiative to promote the global adoption of stewardship programs and quality management systems for the full life cycle of biotechnology-derived plant products. Most of the companies exporting GM seed to the EU are involved. SAG stated that experiences gained under the programme regarding GMO trial and GM seed production are shared with SAG following each growing season. The program was started three years ago.

Conclusions:

The official and private controls put in place with regard to GM seed and GMO trials should ensure, in most cases, that the cross-contamination with GMO is avoided.

The vast majority of seed processed is GMO. However, non-GM seeds are also processed at the same premises, and the official controls do not verify the proper implementation of the measures put in place by the seed processor to avoid contamination of non-GM seed with GMO. No inspections are carried out at sowing at farmers multiplying GM and non-GM seed, where GMO contamination can potentially occur. No official tests are carried out to target GMO contamination of non-GM seed to be exported to the EU.

In the case of GM seed exported to the EU, it is not ensured that the information indicating that the product contains GMOs appears on the label or on the accompanying document.

5.5 LABORATORIES

Legal requirements:

Art. 46 (1)(d) and (c) of Reg. (EC) No 882/2004 stipulate that Community controls shall have, particular regard to the resources including diagnostic facilities available to competent authorities, and the training of staff in the performance of official controls.

Findings:

The Biotechnological Laboratory under the Department of Laboratories and Quarantine Stations is responsible for GMO analysis. The equipment for GMO analysis was introduced in 2006 by the project “Harmonisation of the analytical capacities between the laboratories of the SAG and the agricultural laboratories of the European Union”. The project was co-financed by the EU and the Chilean government, in which the EU contributed 604,444 € (60.3%) and Chilean government contributed 397,300 € (39.7%).

The laboratory is not accredited in accordance with standards EN ISO/IEC 17025 for the detection of GMO.

The laboratory is well equipped the key instrumentation includes three modern real-time PCR instruments and several conventional thermal cyclers. The organisation of the laboratory and the measures in place to prevent cross contamination are adequate. Each methodological step is carried out in a separate room; some of the rooms are equipped with clean cabinets.

In general, two trained biochemists scientists demonstrating a proper knowledge to carry out the analysis. This is considered as appropriate taking into account the number of samples analysed annually.

The methods put in place for the detection of GMO are based on real-time PCR. The laboratory applies a screening targeting the Cauliflower mosaic virus p35S, and event specific detection methods (European reference methods) for the soya bean events, three rapeseed events and 12 maize events. The Division of Agricultural Protection and Forestry of SAG requests the implementation of methods for GMO analysis according to the GM seed imported and planted for export in Chile. The process of method implementation is under constant development. The laboratory states that the limit of detection is 0.1% using European reference materials.

The number of official tests carried out was 16 in 2009, 106 in 2010, and 53 in 2011. The main objective of the analysis was the verification of the genetic event. Some analysis was undertaken to check for cross-pollination in the neighbouring areas in 2011 within the framework of a public research project regarding maize and rape seed.

Only one non-compliant sample has been reported so far due to mislabelling which was clarified later on by trace back.

Besides official samples, samples from private entities are analysed upon request. The number of private samples varies between 10 and 50 samples annually. The objective is to detect GM material in non-GM seeds.

The laboratory takes part regularly in proficiency tests organised by the Joint Research Centre of the EU. In the last test round, the laboratory detected several GM maize events in a sample and quantified them correctly. The data checked by the audit team from the last three rounds demonstrated very good results.

Conclusions:

The Biotechnological Laboratory is well organised, well equipped and adequately staffed. Methods implemented in the laboratory correspond to the GM events imported and planted for export in Chile. The tests results are based on reliable procedures from the sample reception to the final tests results. However, the GMO laboratory is not accredited under any quality assurance standard such

as EN ISO/IEC 17025.

6 OVERALL CONCLUSIONS

A comprehensive control system regarding import and multiplication of GM seed and GMO trial is in place. The system aims to ensure that GMO contamination of non-GMO crops is prevented.

The system of official controls is based on a registration and approval scheme for import of GM seed, and controls of imported GM seed storage, GMO field production and seed processors involving GM seed. However, there are no official controls specific to GMO in the case of non-GM seed production. Private co-existence rules have been put in place and private testing is carried out.

The implementation of official controls of GM seed at import and field production phase should ensure, in most cases, that non-GM seed exported to the EU is not contaminated with GMO.

The vast majority of seed processed is GMO. However, non-GM seeds are also processed at the same premises, and the official controls do not verify the proper implementation of the measures put in place by the seed processor to avoid contamination of non-GM seed with GMO. No inspections are carried out at sowing at farmers multiplying GM and non-GM seed, where GMO contamination can potentially occur. No official tests are carried out to target GMO contamination of non-GM seed to be exported to the EU.

In the case of GM seed exported to the EU, it is not ensured that the information indicating that the product contains GMO is given to the importer.

7 CLOSING MEETING

A closing meeting was held on 22 March 2012 at the headquarters of SAG in Santiago, during which the main findings and conclusions of the audit team were presented. The CA provided clarifications and provisionally accepted these preliminary findings and conclusions.

8 RECOMMENDATIONS

The competent authority in Chile is recommended to ensure :

N°.	Recommendation
1.	That the risk of contamination at sowing and at seed processing is addressed in order to ensure that the system provides guarantees that non-GM seed exported to the EU is not contaminated by GMO and that therefore it is not subject at import to requirements of Directive 2001/18/EC, in particular Articles 19 and 21.
2.	That official tests are carried out to verify that non-GM seed exported to the EU is not contaminated by GMO and therefore not subject, at import, to requirements of Directive 2001/18/EC, in particular Articles 19 and 21.
3.	That the GM seed exporter provides the EU importer with the information necessary to ensure that the labelling provisions of Directive 2001/18/EC and Regulation (EC) No 1830/2003 can be met.
4.	That the laboratory involved in official controls applies the principles of internationally

N°.	Recommendation
	recognised quality assurance techniques and are evaluated and/or accredited under officially recognised quality management and assurance programmes equivalent to international standards such as ISO/IEC 17025, to ensure the reliability of analytical results.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6300

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004 - Article 46 (TC)	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Dir. 2001/18/EC	OJ L 106, 17.4.2001, p. 1-39	Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC