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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ARGENTINA

FROM 10 TO 19 MAY 2011

IN ORDER TO ASSESS THE CONTROLS OF AFLATOXIN CONTAMINATION IN PEANUTS
INTENDED FOR EXPORT INTO THE EUROPEAN UNION

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 Argentina, from 10 to 19 May 2011.

The objective was to assess the control systems in place to control aflatoxin contamination in peanuts, intended for export into the European Union (EU), and to follow up action taken by the Competent Authorities (CAs) in response to the recommendations made by the FVO in report DG(SANCO)/2005-7627.

There have been no major changes in the control system for the prevention of aflatoxin contamination in peanuts intended for export to the EU since the previous mission DG(SANCO)/2005-7627. Official supervision in this area is well developed and managed. Since the previous mission, further efforts have been made to address recommendations regarding sampling, implementation of Good Manufacturing Practices (GMP) and HACCP, laboratory performance, export procedures and labelling of consignments. Some shortcomings were still found with regard to the storage conditions of raw peanuts. In addition, Argentina had not carried out any research on the most appropriate transport conditions. These might be some of the possible reasons behind the high number of rejections at EU borders.

As regards the recommendations made in the mission report DG(SANCO)/2005-7627, five out of the six have been addressed and one concerning the lack of research into the most appropriate transport conditions is still pending action.

The report makes a number of recommendations to the competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

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ABBREVIATIONS AND SPECIAL TERMS USED IN THIS REPORT

Abbreviation	Explanation
CA(s)	Competent Authority(ies)
CAC/RCP	Codex Alimentarius Commission/Recommended Code of Practice
CAC/GL	Codex Alimentarius Commission/Guideline
CCA(s)	Central Competent Authority(ies)
CN	Combined Nomenclature
CODEX	Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations and World Health Organization
DG (SANCO)	Health and Consumers Directorate-General
DICA	Department of Agri-Food Quality
EU	European Union
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice
GMP	Good Manufacturing Practice
GSP	Good Storage Practice
HACCP	Hazard Analysis Critical Control Points
HPLC	High Performance Liquid Chromatography
INTA	National Institute of Agricultural Technology
IPM	Integrated Pest Management
ISO	International Organisation for Standardization

MARIA	Customs electronic database
MERCOSUR	Southern Common Market (<i>Mercado Común del Sur</i>)
MS(s)	Member State(s)
OAA	Argentina National Accreditation Body
PT	Proficiency test
RASFF	Rapid Alert System for Food and Feed
SENASA	National Agri-Food Health and Quality Service
TC(s)	Third Country(ies)

1 INTRODUCTION

The audit took place in Argentina from 10 to 19 May 2011 in order to assess controls on aflatoxin contamination in peanuts, intended for export to the European Union (EU). The audit team comprised two auditors from the Food and Veterinary Office (FVO) and one Member State (MS) expert.

The audit was undertaken as part of the FVO's annual audit programme in the context of a series of audits in third countries (TCs) to evaluate control systems and operational standards in this sector.

The team was accompanied during the audit by a representative of the central competent authority (CCA), the National Agri-Food Health and Quality Service (SENASA).

An opening meeting was held on 10 May 2011 with the CCA, the SENASA. At this meeting, the objectives of and itinerary for the audit were confirmed, and additional information required for the satisfactory completion of the audit was requested.

2 OBJECTIVES AND SCOPE

The objectives of the audit were to:

- Verify whether the control systems are in place to control aflatoxin contamination in peanuts intended for export to the EU within specified EU contaminant limits, complying with or being at least equivalent to Commission Regulation (EC) No 1881/2006;
- Follow-up recommendations of report Health and Consumers Directorate-General (DG (SANCO))/2005-7627.

In terms of **scope**, the audit reviewed the controls on the production and export, including the national legislation, competent authority (CA) organisation, their controls and enforcement capability.

In pursuit of this objective, the following sites were visited :

Competent Authorities			Comments
Competent authorities	Central	1	SENASA
	Regional/Local	1	SENASA local office in General Deheza, Cordoba province
Laboratories			
Private approved laboratories		2	Visits to two private laboratories designated for official analysis of aflatoxins in peanuts intended for EU export in Cordoba province
Producers			

	4	Visits to four large-scale peanut growers in Cordoba province
Processors		
	4	Visits to four peanut processors/exporters in Cordoba province
Points of Export		
	1	Visit to customs office in General Deheza, Cordoba province
Other Sites (e.g. Research Centre)		
	4	Visit to the National Institute of Agricultural Technology (INTA), Manfredi station Visit to the University of Rio Cuarto Visits to two certification bodies responsible for sampling and certification of peanuts intended for EU export

3 LEGAL BASIS AND STANDARDS

3.1 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 which stipulates that EU controls in TCs may verify compliance or equivalence of TC legislation and systems with EU feed and food law and EU animal health legislation. These controls shall have particular regard to the assurances which the TC can give regarding compliance with, or equivalence to, EU requirements.

A full list of the legal instruments referred to in this report is provided in Annex 1. EU legal acts quoted in this report refer, where applicable, to the most recently amended version. Full references to the EU acts quoted in this report are given in Annex 1.

3.2 STANDARDS

Additionally Guidelines and Codes of Practice of the Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations and World Health Organization (CODEX) were taken into account in the frame of the audit.

A full list of applicable standards referred to in this report is provided in Annex 2. Reference to

specific provisions of these texts is provided at the beginning of each section.

4 BACKGROUND

The FVO has carried out missions to the main exporting countries to evaluate official control systems for preventing aflatoxin contamination in foodstuffs. The reports on these missions are available on the DG (SANCO) internet site at http://ec.europa.eu/food/fvo/ir_search_en.cfm.

The report of the mission DG(SANCO)/2005-7627 contained recommendations to the CAs of country, and action plans were received, which were considered satisfactory to address the recommendations of the reports.

Information on foodstuffs found to have public health implications is disseminated as alert notifications through the Rapid Alert System for Food and Feed (RASFF) to all MSs and to the exporting country. In the case of peanuts, the notifications relate to the aflatoxin content of goods exceeding the EU limits of 2 ppb for aflatoxin B1 and 4 ppb for total aflatoxins in peanuts for direct human consumption and 8 ppb for aflatoxin B1 and 15 ppb for total aflatoxins in peanuts for further sorting or any other physical treatment, before human consumption. From 2008 to the time of the audit, 209 notifications concerning aflatoxins in peanuts from Argentina had been sent through the RASFF (including 12 in 2011) The breakdown of these notifications and the volume of imports into the EU from 2008 to 2010 is shown in Table 1 .

Table 1

TC	Imports to EU (metric tonnes)			Number of RASFF notifications		
	2008	2009	2010	2008	2009	2010
Shelled peanuts (CN code 1202 20 00)	287 000 (NL,UK, FR)	282 000 (NL,UK, FR, PL)	326 000 (NL, UK, DE, FR, PL)	29	73	95

Source: Eurostat, Comext database

In view of the persistently high number of RASFF notifications since the previous mission DG(SANCO)/2005-7627, the FVO decided to undertake this audit .

5 FINDINGS AND CONCLUSIONS

5.1 RELEVANT NATIONAL LEGISLATION

Legal requirements

Article 46(1)(a) of Regulation (EC) No 882/2004 stipulates that EU controls shall have, inter alia particular regard to the legislation of the TC.

Regulation (EC) No 1881/2006 lays down the specific standards for the admissible levels of aflatoxins and sets maximum levels for certain contaminants (including mycotoxins) in foodstuffs.

Regulation (EC) No 401/2006 lays down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.

Findings

Since mission DG(SANCO)/2005-7627, the following changes have been made in the relevant national legislation:

- Secretary of Agriculture, Livestock, Fisheries and Food (SAGPyA) Resolution 62/2007 establishes a mandatory registration system for peanut processors exporting their products to the EU. In addition, mandatory implementation of Good Manufacturing Practices (GMP) and HACCP is also required under this Resolution. The audit team was informed by the CA that the requirement to implement GMP entered into force on 1 January 2008, but the requirement to implement HACCP was postponed and eventually entered into force on 1 May 2011 (SENASA Resolution 197/2010). According to SENASA, the deadline for HACCP implementation was extended mainly due to the need for additional time for discussions between all stakeholders in order to agree on a unified approach within the sector.
- Regarding Resolution 736/2006 on the creation of a national network of assay and diagnostics laboratories and on the requirements for the inclusion of private laboratories within this network, the audit team noted that several of its requirements had not been implemented in the case of laboratories authorised for aflatoxin analysis in peanuts (Article 28 on report formats, Article 30(a) on the reporting of quarterly statistics to SENASA). The audit team was informed by SENASA that Resolution 736/2006 is framework legislation applicable to all food products, however the Articles mentioned have been applied in other areas such as control of food hygiene and residues but not in the case of aflatoxins in peanuts.

In addition to legislation adopted since the previous FVO mission DG(SANCO)/2005-7627, the following Department of Agri-Food Quality (DICA) circulars issued since the mission are also relevant in the context of this audit:

- DICA Circular No 234/2005, which addresses recommendations 3 and 5 in mission report DG(SANCO)/2005-7627 by requiring the analytical certificate issued for aflatoxin analysis to include a lot number for each consignment to be exported and all official samples taken for aflatoxin analysis to be transported to the laboratory in opaque bags.
- DICA circular No 1/2007 on the mandatory registration requirements for all peanut processors exporting peanuts to the EU.

- DICA circular No 2/2007 on the minimum information to be included in the analytical report on aflatoxin determination in peanuts intended for EU export.
- DICA circular No 3/2007 on the process for registration of peanut processors exporting peanuts to the EU and for official control of the implementation of GMP.
- DICA circular No 4/2010 on the validity of the analytical certificate of aflatoxin analysis for EU export (30 days) and the requirement that all consignments with aflatoxin levels above the EU limits for peanuts intended for further processing in the EU are not subject to re-sampling.

The audit team was informed by SENASA that the current registration system under Resolution 62/2007 does not involve peanut growers (primary producers), and that the current registration system for establishments involved in peanut export does not include the registration of peanut exporters not owning process facilities (brokers owning warehouses). However, the audit team was informed by the CA that, in such cases, peanuts for EU export can only come from peanut processors registered under Resolution 62/2007.

The audit team obtained evidence of communication of the latest updated list of registered establishments (April 2011) both to the SENASA local office visited in General Deheza in the region of Cordoba, and to the two authorised certification bodies responsible for certification (including sampling) of peanut consignments intended for EU export.

The audit team was informed by SENASA that, as far as GMP requirements are concerned, reference is made to MERCOSUR Resolution No 80/1996, which establishes general GMP principles for food establishments. According to the CA this Resolution does not cover specific aspects of GMP for peanut processing.

The audit team obtained evidence that, since the previous mission DG(SANCO)/2005-7627, a wide range of Good Agricultural Practice (GAP) Guides have been developed by INTA and made available to stakeholders.

Conclusions

There is a good legal framework for the control of peanut exports to the EU, which among other things requires peanut processors to meet food hygiene requirements, implement procedures based on HACCP principles and to be registered in line with the requirements of Articles 3-6 of Regulation (EC) No 852/2004 in conjunction with Article 10 of that Regulation.

There is no general hygiene and registration requirement for peanut growers (primary producers) equivalent to the requirements of Articles 4(1) and 6 of Regulation (EC) No 852/2004 in conjunction with Article 10 of that Regulation.

Sufficient information on GAP and GMP is available to peanut growers and processors.

5.2 COMPETENT AUTHORITIES

Legal requirements

Article 46(1)(b) and (c) of Regulation (EC) No 882/2004 stipulate that EU controls shall have, inter alia, particular regard to the organisation of the TC's CAs, their powers and independence, the authority they have to enforce the applicable legislation effectively, and the training of staff in the performance of official controls.

Findings

Competent Authorities

There have been no major changes in responsibilities for the official control of peanuts for EU export since the previous mission DG(SANCO)/2005-7627.

Two SENASA units are relevant in the context of this audit:

- DICA is responsible for the certification and auditing of certification bodies and RASFF follow-up, and also for measures/sanctions in the event of certification bodies, processors and exporters failing in the certification process;
- the National Directorate for Regional Operations is responsible for the coordination of official control activities conducted by SENASA's 14 Regional Departments and its 360 local offices, including control of the implementation of GMP at peanut processors and supervision of the loading of peanut consignments intended for EU export.

The audit team observed that since the previous mission DG(SANCO)/2005-7627, the number of authorised certification bodies responsible for certification (including sampling) of peanut consignments intended for EU export has changed: instead of three certification bodies, two are currently authorised to perform such tasks.

The audit team observed that no CA is designated to supervise implementation of GAP at peanut growers (primary producers). According to SENASA, responsibility for supervision lies entirely with the private sector, mainly peanut processors.

The other responsibilities for the official control of peanut production and processing remain as described in mission report DG(SANCO)/2005-7627.

SENASA usually provides information to stakeholders via official circulars and also publishes some information on its website. Evidence of such communication was shown to the audit team (see the list of circulars above).

The audit team saw evidence that since the previous mission DG(SANCO)/2005-7627, training has been organised by INTA for stakeholders in all the major peanut-cultivating areas on good practices in peanut cultivation and processing. In addition, the audit team was informed at the peanut farms and processors visited that regular training is also provided to peanut growers by the technical staff of peanut processors.

The audit team was informed by the CA that two-day training courses had been organised for SENASA staff in July and August 2010, which also covered the assessment of HACCP in peanut processors. In addition, similar training for the industry on the implementation of HACCP was organised in September 2010. However, the audit team noted that official controls to assess the implementation of procedures based on HACCP principles in peanut processors exporting peanuts to the EU had not yet started.

Customs authorities

In the context of this audit, customs authorities are responsible for the customs clearance of consignments for EU export, as already described in mission report DG(SANCO)/2005-7627.

Other authorities/bodies

The main tasks of the two research institutions — INTA and University of Rio Cuarto — were already described in mission report DG(SANCO)/2005-7627 (point 5.2.3), and there have been no major changes since.

INTA has a wide range of research projects addressing aflatoxins, with the main focus on improving the resistance of peanuts to *Aspergillus spp.* According to INTA, specific projects in this regard are currently being implemented and the first results could be expected within the next 5-6 years. In addition, research is also being undertaken to improve the general management of GAP principles. The intention is to provide guidelines to farmers on keeping records of their farming activities. Draft guidelines had been already developed and a copy was provided to the audit team.

The audit team was informed by representatives of the University of Rio Cuarto responsible for research in the area of mycotoxins on the progress of the bio-control project to reduce mycotoxins in cropping systems by using non-aflatoxigenic strains competing with *Aspergillus flavus*. The project is at an advanced stage and the University is currently in the process of having inoculants registered by the Argentinian authorities for commercial use.

The audit team noted that no research had been undertaken to date to investigate possible peanut contamination during transport from Argentina to Europe (recommendation made in the previous mission report DG(SANCO)/2005-7627). SENASA informed the audit team that several attempts had been made to ask help from the Commission services to develop such a project together, but no feedback had been received to date.

The Argentine Peanut Chamber is a non-governmental organisation acting as an umbrella organisation for the peanut industry. 27 of the 30 peanut processors in Argentina are members of the Chamber. In addition, both certification bodies designated for sampling and laboratory analysis for aflatoxin control are members of the Chamber, as well as some peanut growers and 5 peanut exporters (brokers). Among its many tasks, the Chamber is responsible for the coordination of the Argentine Peanut Foundation. The Foundation's activities are financed by the peanut processors and mainly involve the financing of research activities in the area of peanut cultivation and processing.

Conclusions

There have been no major changes in the responsibilities of the CAs since the previous mission DG(SANCO)/2005-7627.

No CA is designated for the official control of peanut growers (primary producers), so there is no CA to provide guarantees that peanut growers producing peanuts for EU export follow requirements at least equivalent to those of Annex I to Regulation (EC) No 852/2004 in conjunction with Article 10 of that Regulation and the requirements established in the national GAP guides.

There is good communication between CAs and stakeholders to ensure adequate implementation of the legal requirements established for the export of peanuts to the EU.

A significant progress has been made in the training of stakeholders regarding HACCP, peanut cultivation and processing.

Official controls on the implementation of procedures based on HACCP principles in peanut

processors exporting peanuts to the EU have not yet started. Therefore, the exact level of implementation of procedures based on HACCP principles in these establishments is not known to the CA (see also point 5.3).

A good amount of research is being carried out into the prevention of aflatoxin contamination. However, no research has been undertaken to date to investigate possible contamination during transport from Argentina to Europe, so the recommendation made in the previous mission report DG(SANCO)/2005-7627 has not been addressed.

Additional activities to promote good practices in peanut cultivation and processing have been undertaken by non-governmental organisations.

5.3 OFFICIAL CONTROLS ON PRODUCTION AND PROCESSING

Legal Requirements

Article 46 (1) (e) and (b) of Regulation (EC) No 882/2004 stipulate that EU controls shall have, inter alia, particular regard to the existence and operation of documented control procedures and control systems based on priorities, and the CA's capability to enforce applicable legislation;

Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in peanuts (CAC/RCP 55-2004) provides recommended practices based on Good Agricultural Practices (GAP), Good Manufacturing Practice (GMP) and Hazard Analysis Critical Control Points (HACCP).

EU aflatoxin levels are specified in the Annex of Commission Regulation (EC) No 1881/2006.

Findings

Cultivation (GAP)

According to the information from the Argentine Peanut Chamber, peanuts in Argentina are cultivated in an area of approximately 220 000 ha by approximately 1600 farmers.

The audit team visited four peanut growers in Cordoba province (Cordoba province accounts for approximately 85 % of the total peanut cultivation area in Argentina). All of them were large-scale growers with areas bigger than 700 ha. One was an independent grower contracted by a large peanut processor while the other three growers visited were part of a processing company.

The audit team noted at the farms visited that all growers were aware of the GAP guidelines developed by INTA and had regularly participated in training provided either by INTA or by peanut processors.

All peanut growers kept log books on their farming activities, which also included information on the implementation of the Integrated Pest Management (IPM) system.

All farmers visited were aware of the risks of mould growth, and considered crop rotation, proper harvesting periods and quick field drying of the product as critical steps in reducing the growth of mould.

The audit team observed in the farms visited that the peanut cultivation process generally involves a 4-5-year cycle with corn and soyabean being the most common crops used in crop rotation. The usual practice is to plant peanuts after cultivation of soyabean and in some cases maize. Direct sowing is used, which means that remains from the previous crop are left on the field after harvest.

During the on site visits the audit team explained to the farmers, that based on the results of the research provided in this area maize as part of crop rotation might contribute to the development of *Aspergillus spp.* in the soil. However, according to the farmers visited by the audit team, the use of maize is important from the point of view of carbon production and due to economic and/or agronomic reasons no alternatives are available. In addition, to avoid the risk of drought due to the shortage of rainfall during the vegetation period of peanuts, it is important to keep remains of the previous crop on the field to maintain moisture in the soil. This is important to avoid drought stress of peanuts, which is a risk factor for aflatoxin contamination.

Processing (GMP, HACCP, GSP etc.) and storage

According to the CA, 28 peanut processors are authorised to process peanuts for EU export. As already mentioned in the chapter on CAs, no information is yet available on the exact level of the implementation of procedures based on HACCP principles in these establishments. SENASA estimates that some 90 % of the establishments have put in place procedures based on HACCP principles.

The audit team visited four processing plants in the Cordoba province. All establishments visited had an HACCP system in place. Three of them were also certified for HACCP by external certification bodies.

All processors visited had traceability systems to enable tracing back to groups of farmers or plots. More detailed traceability is not possible, as after reception and drying products are stored in bulk in large warehouses.

All the plants visited generally followed the Codex Alimentarius Code of Practice CAC/RCP-55-2004 for the prevention and reduction of aflatoxin contamination in peanuts. They had in-house mycotoxin control measures in place for each lot of incoming peanuts, and dry hot-air blanching in combination with electronic sorting machines for colour sorting of peanuts was used in all establishments visited. The audit team observed in some establishments visited the storage of raw peanuts in pods before processing (with a storage period of up to 10 months). In the case of those establishments, storage conditions were not fully in line with the requirements of point 3.5 of the Codex Code of Practice, in particular as there was no possibility to control the relative humidity and temperature in order to reduce the risk of mould growth and to aerate the storage area. In addition, the storage area was in one case open to birds and insects.

Mission report DG(SANCO)/2005-7627 recommended that products should be labelled in line with the requirements of EU legislation for the labelling of peanuts intended either for direct human consumption or for further sorting or other physical treatment before human consumption. In the establishments visited, the audit team was informed by representatives of the establishments that peanuts for EU export are labelled depending on the level of aflatoxins in the product as follows:

- if the level of aflatoxins in the product is above 2 ppb for aflatoxin B1 and 4 ppb for total aflatoxins, specific indication is given on the label that the product is subject to further sorting or other physical treatment before human consumption;
- if the product complies with the aflatoxin limits of 2 ppb for aflatoxin B1 and 4 ppb, no specific indication is given on the label;
- if requested by EU importers, products complying with the aflatoxin limits of 2 ppb for aflatoxin B1 and 4 ppb can be labelled as products for further sorting or other physical treatment before human consumption.

Non-conforming products

According to SENASA and Customs, no consignments rejected at the EU border due to aflatoxin contamination had so far been returned to Argentina. However, if this were to happen, this would be considered as an import and the national aflatoxin limit of 20 ppb for total aflatoxins would apply.

Representatives of the peanut industry stated that when a product is rejected at EU borders it is generally sold to another non-EU country, sold as animal feed or sent to the peanut oil industry. In the case of the establishments visited, no consignments rejected had been sent back to Argentina. If consignments intended for EU export fail an aflatoxin test, the options are as follows:

- products are sold in the domestic market,
- peanuts are sold to another country, or
- peanuts are sent for peanut oil production.

In the case of one establishment visited, a further option was also mentioned, where peanuts are reprocessed (resorted) and a new application is made for EU export.

Conclusions

At the farms visited, the implementation of GAP was documented and generally followed the national GAP guidelines and principles established in the Codex Alimentarius Code of Practice CAC/RCP-55-2004 for the prevention and reduction of aflatoxin contamination in peanuts.

Maize as part of crop rotation might contribute to the development of *Aspergillus spp.* in the soil. However, crop rotation without maize is not possible due to economic and/or agronomic reasons.

At the peanut processors visited, GMP principles established in the Codex Alimentarius Code of Practice CAC/RCP-55-2004 were followed. Only few shortcomings were observed: in particular, the storage conditions of raw peanuts in some establishments did not fully comply with the requirements set out in point 3.5 of the above-mentioned Code of Practice.

The exact level of HACCP implementation in establishments processing peanuts for export to the EU is not known to the CA.

The recommendation made in mission report DG(SANCO)/2005-7627 regarding the labelling of peanuts intended for EU export has been addressed.

There are procedures in place to ensure that peanuts rejected at EU borders because of aflatoxin contamination are not re-exported to the EU.

5.4 PROCEDURE FOR EXPORTING TO THE EU

Legal requirements

Article 46(1)(h) of Regulation (EC) No 882/2004 stipulates that EU controls shall have, inter alia, particular regard to the assurances which the TC can give regarding compliance with, or equivalent to, EU legislation.

Findings

There have been no major changes in the export procedure since the previous mission DG(SANCO)/2005-7627 (point 5.5 of report). The only change in the procedure concerns the registration of establishments for EU export as already described above (which also requires the implementation of GMP and HACCP). In addition, improvements have been made in response to

the recommendation made in mission report DG(SANCO)/2005-7627 regarding a clear link between all relevant export documents and peanut consignments. As from 1 May 2006, lot numbers are indicated in all documents issued by certification bodies, including the sampling report and analytical report sent to SENASA for launching their export control procedure.

Another recommendation made to the CAs in mission report DG(SANCO)/2005-7627 was to ensure that Customs releases only peanut consignments approved by SENASA for EU export. The audit team was informed that, in 2006, an additional document had been required and was followed for 6 months, but was later abandoned as it resulted in significant delays in the export procedure. Currently, there is a link between Customs and SENASA control via the Customs electronic database (MARIA). According to the explanation given by SENASA, MARIA indicates for which products information should be made available to customs agents on SENASA controls prior to the customs clearance procedure. Information on the completion of SENASA controls has to be entered in the database by the customs agent. MARIA allows the customs clearance procedure to continue only if such confirmation is entered in the database. The audit team was informed that if consignments fail the certification procedure, an additional notification is sent to Customs. However, according to the SENASA office in General Deheza, to date only very few such cases had been reported and none in recent years.

According to the representatives of one of the certification bodies visited, the time between completion of laboratory analysis and the issuance of a certificate for EU export is in general 10 to 20 days. According to the processors visited, it takes another 25-30 days before the consignment arrives at the EU border. In the authorised laboratories visited, the audit team was informed that they accept a maximum of 60 days between the sampling date and the exporter's request to issue the final laboratory report (report submitted to SENASA for launching their export control procedure as described under point 5.5 of report DG(SANCO)/2005-7627).

According to SENASA (based on their RASFF follow-up study), no peanuts have been exported to EU from any other companies than those authorised for EU export.

Conclusions

There is a clear export procedure in place for peanuts exported to the EU.

The recommendation made in report DG(SANCO)/2005-7627 regarding a clear link between all relevant export documentation and the peanut consignment has been addressed.

The recommendation made in report DG(SANCO)/2005-7627 to ensure that Customs releases only peanut consignments approved by SENASA for EU export has been addressed.

5.5 METHOD OF SAMPLING CONSIGNMENTS

Legal requirements

Article 1 of Regulation (EC) No 401/2006 requires that sampling for the official control of mycotoxin levels in foodstuffs be carried out in accordance with the methods set out in its Annex I. Concerning nuts (e.g. peanuts), the method of sampling is laid down in Annex I.D.

Findings

The audit team observed in both certification bodies visited that sampling guidelines had been developed and made available to the sampling staff. In addition, all guidelines referred to the most recent EU legislation on sampling of peanuts for aflatoxin controls (Regulation (EC) No 178/2010, which amends Framework Regulation (EC) No 401/2006).

The audit team observed two separate sampling procedures conducted by both authorised certification bodies.

The first sampling was conducted on a typical consignment of 25 tonnes (20 x 1250 kg bags). A spear with a maximum volume for peanuts of 2 kg, made from 10 sections, was used to take samples throughout the whole bag (from top to bottom). According to instructions given to the sampling staff, at least 1 sample from each bag has to be taken (in the case of the sampling demonstration observed, 2 samples were taken from each bag). An aggregate sample of 40 kg is packed in an opaque bag, sealed and taken to the laboratory for analysis. In the laboratory, an aggregate sample is quartered and a 2x10 kg sample is taken for analysis.

A second sampling was also conducted on a consignment of 25 tonnes (20 x 1250 kg bags). A spear with a maximum volume for peanuts of 900 g, made from 6 sections, was used to take samples throughout the whole bag (from top to bottom). At least 1 sample from each bag was taken and an additional 8-10 samples were taken randomly in order to make an aggregate sample of 25 kg. The sample was packed in an opaque bag, sealed and taken to the laboratory for analysis.

Conclusions

Both samplings observed followed requirements equivalent to those of Regulation (EC) No 401/2006.

The recommendation made in the previous mission report DG(SANCO)/2005-7627 regarding the use of opaque bags for official samples has been addressed.

5.6 LABORATORY SERVICES

Legal requirements

Article 46(1)(d) and (c) of Regulation (EC) No 882/2004 stipulate that EU controls shall have, inter alia, particular regard to the resources including diagnostic facilities available to CAs, and the training of staff in the performance of official controls.

Article 2 of Regulation (EC) No 401/2006 requires that sample preparation and methods of analysis used for the official control of mycotoxin levels in foodstuffs comply with the criteria set out in its Annex II.

Points 41 and 42 of CODEX Guidelines CAC/GL 26-1997 on the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems lays down that inspection services should utilize laboratories that are evaluated and/or accredited under officially recognized programmes to ensure that adequate quality controls are in place to provide for the reliability of test results. In accordance with Guidelines of CODEX CAC/GL 27-1997, point 3, the laboratories should comply with ISO/IEC Guide 17025.

Findings

Currently, 7 of the 26 authorised laboratories in the National Network of Laboratories of Assay and Diagnostics are involved in the official control of aflatoxins in peanuts for export to EU. These 7 laboratories belong to 2 private companies: four to one and three to the other. At the moment, there are no public laboratories performing official aflatoxin analyses in peanuts intended for export to the EU. SENASA's Directorate-General for Laboratories and Technical Control carries out audits of the authorised laboratories once every 2 years. It also organises and evaluates Proficiency Tests (PTs) once a year, in compliance with the requirements of Articles 22 and 23 of Resolution 736/2006.

Authorised private laboratories

The audit team visited two of the authorised laboratories. The audit team found that the laboratories had sufficient trained staff and that the premises and equipment were fit for purpose.

The audit team found that both laboratories had been accredited since 2005 and 2007, respectively, by the National Accreditation Body (OAA) for the analysis of aflatoxins (B1, B2, G1, G2 and total) in peanuts by HPLC according to International Standard ISO/IEC 17025. Both laboratories had a Quality Manager and a Quality Manual.

Both laboratories followed similar analytical procedures apart from some minor differences. The procedures were based on extraction of the toxins from peanuts with methanol/water. One of the laboratories used the slurry approach by adding water to the peanuts and forming a homogenous paste before adding methanol. The other laboratory used Carrez reagents to obtain clear extracts. No other clean-up methods were used in either laboratory. Determination of the toxins was by HPLC with bromide postcolumn derivatisation using a Kobra® cell, followed by fluorescence detection. One of the laboratories used a mixture of the four aflatoxin standards in solution and the other used individual aflatoxin standards in solid form. In the former case, the mixture of the four aflatoxin standards in solution was provided by and prepared in a different laboratory of the same company, after checking spectrophotometrically the real concentration of each of the four aflatoxin solutions individually. The audit team noted the recent acquisition of a new spectrophotometer for doing this task in the laboratory visited.

Both laboratories had validated their analytical procedures in-house, participated regularly in proficiency tests organised for peanuts by international and national entities, with satisfactory z-scores, and used their own reference materials as part of their daily quality control. Both laboratories used control charts, and their quality control measures can be considered sufficient taking into account the number of analyses performed annually. One laboratory used 7-point calibration curves in the validation study, although the quantification of toxins during daily work was based on the response factor of a single standard concentration. The other laboratory used 3-point calibration curves.

The analytical reports issued by both laboratories were not totally in accordance with EU requirements. One of the laboratories did not mention the value of the expanded uncertainty for total aflatoxins and neither laboratory gave any precise information about the recovery rates for aflatoxin B1 and total aflatoxins. In addition, the value for the expanded uncertainty for aflatoxin B1 needed to be updated in one of the laboratories and no clear evidence supporting the quantification limits given in the analytical report could be found upon examination of the raw validation data in the other laboratory.

Regarding the number of samples analysed and rejected by both laboratories during 2010 from lots intended to be exported to the EU, the audit team was given the following figures: in one laboratory, 6500 samples were analysed, with 87 % below the 4 ppb limit, 7 % between 4 and 15 ppb and 6 % above 15 ppb, and in the other, 3700 samples were analysed, with 19 % found to contain aflatoxins above the 4 ppb limit.

Processor laboratories visited

In three of the four processor premises visited, the audit team checked the laboratories for performing 'in situ' analysis of aflatoxins using HPLC in raw peanuts for the acceptance/rejection of incoming consignments. In two cases, the equipment and analysts were provided by a private laboratory also authorised for the official control of aflatoxins in processed peanuts for export to the EU. This laboratory was one of the above-mentioned authorised laboratories visited.

Conclusions

Both authorised laboratories visited were accredited by OAA according to the requirements of ISO/IEC 17025, which is in line with point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997.

Apart from some minor deficiencies, both laboratories performed correctly in terms of validation, participation in PTs, the use of reference materials and quality control measures.

In the case of both laboratories, the analytical reports did not fully conform to the requirements of Regulation (EC) No 401/2006.

5.7 PRIVATE CONTROLS ON PEANUTS

Findings

The audit team noted that three of the peanut growers/processors visited had their HACCP systems certified by private certification schemes and one of the establishments visited was in the process of being certified.

Conclusions

All peanut growers/processors visited were subject to private certification schemes of their HACCP systems, which provide some guarantees as to the compliance of peanuts with EU aflatoxin limits.

5.8 RESPONSE TO RASFF NOTIFICATIONS

Legal requirements

Point 6 of CODEX Guidelines CAC/GL 25-1997 requires exchange of information between countries on rejections of imported food. In particular the food control authorities in the exporting country should undertake the necessary investigation to determine the cause of any problem that has led to the rejection of the consignment. The food control authority in the exporting country, if requested, should provide the authorities in the importing country with information on the outcome of the necessary investigation, if available. Bilateral discussions should take place as necessary.

Findings

There have been no major changes in the RASFF follow-up procedure since the last FVO mission No 7627-2005. Since 2009, SENASA has had direct access to the RASFF database and it is able to download all RASFF notifications concerning aflatoxins in peanuts from Argentina. The audit team was informed by SENASA that companies concerned by RASFF notifications are not obliged to provide SENASA with information on their export activities, so in some cases follow-up was not possible until these companies had been visited.

The audit team noted that one of the establishments visited was aware of only one notification from 2010, while at least five notifications had been issued since 2008. In response to the company statement, SENASA provided evidence of communication of those notifications to the company, except for one, where SENASA stated they were not aware of it as it was not available to them via the RASFF.

The audit team was informed by the CA that the investigations undertaken had not identified any possible reason why consignments cleared in Argentina were still rejected at EU borders.

The audit team noted in the summary RASFF follow-up table for 2010 provided by SENASA that for approximately 40 % of the RASFF notifications, a certain amount of aflatoxins had already been detected during the certification process in Argentina and in some cases the aflatoxin content was

close to the EU aflatoxin limits.

Conclusions

There are clear procedures established for RASFF follow-up, with some shortcomings noted in the communication between SENASA and peanut processors concerned by RASFF notifications.

6 OVERALL CONCLUSION

There have been no major changes in the control system for the prevention of aflatoxin contamination in peanuts intended for export to the EU since the previous mission DG(SANCO)/2005-7627. Official supervision in this area is well developed and managed. Since the previous mission, further efforts have been made to address recommendations regarding sampling, implementation of Good Manufacturing Practices (GMP) and HACCP, laboratory performance, export procedures and labelling of consignments. Some shortcomings were still found with regard to the storage conditions of raw peanuts. In addition, Argentina had not carried out any research on the most appropriate transport conditions. These might be some of the possible reasons behind the high number of rejections at EU borders.

As regards the recommendations made in the mission report DG(SANCO)/2005-7627, five out of the six have been addressed and one concerning the lack of research into the most appropriate transport conditions is still pending action.

7 CLOSING MEETING

A closing meeting was held on 19 May 2011 with representatives of the CCA. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit.

The CCA made initial comments and provided some additional information.

8 RECOMMENDATIONS

The CAs are invited to provide details of the actions taken and planned, including for deadlines for their completion ("action plan"), aimed at addressing the recommendations set out below, within 25 working days of receipt of this report.

The CA should:

Nº.	Recommendation
1.	Ensure that primary producers of peanuts (peanut growers) producing for EU export are registered and they implement food hygiene requirements equivalent to the requirements of Articles 4(1) and 6 of Regulation (EC) No 852/2004 in conjunction with Article 10 of that Regulation.
2.	Ensure that food business operators exporting peanuts to the EU implement standards at least equivalent to those required by Article 5 of Regulation (EC) No 852/2004 on food safety procedures based on HACCP principles, in conjunction with Article 10 of

N°.	Recommendation
	that Regulation.
3.	Ensure that storage conditions in peanut processing and storage facilities comply with the requirements set out in Codex Alimentarius Code of Practice CAC/RCP-55-2004 for the prevention and reduction of aflatoxin contamination in peanuts.
4.	Consider undertaking research into the possible contamination of peanuts during the long-term storage of raw peanuts at peanut processors and during the transport of peanuts from Argentina to Europe.

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

http://ec.europa.eu/food/fvo/ap/ap_ar_2011-6033.pdf

ANNEX 1 – EUROPEAN UNION ACTS QUOTED IN THE REPORT

Legal Reference	Official Journal	Title
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Reg. 1152/2009	OJ L 313, 28.11.2009, p. 40-49	Commission Regulation (EC) No 1152/2009 of 27 November 2009 imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 401/2006	OJ L 70, 9.3.2006, p. 12-34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs

ANNEX 2 – STANDARDS QUOTED IN THE REPORT

Reference number	Full title	Publication details
CAC/RCP 55-2004	Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in peanuts (CAC/RCP 55-2004)	http://www.codexalimentarius.net/web/standard_list.jsp
CAC/GL 25-1997	Guidelines for the exchange of information between countries on rejections of imported food (CAC/GL 25-1997).	http://www.codexalimentarius.net/web/standard_list.jsp
CAC/GL 26-1997	Guidelines on the design, operation, assessment and accreditation of food import and export inspection and certification systems (CAC/GL 26-1997).	http://www.codexalimentarius.net/web/standard_list.jsp
CAC/GL 27-1997	Guidelines for the Assessment of the competence of testing laboratories involved in the import and export control of food (CAC/GL 27-1997).	http://www.codexalimentarius.net/web/standard_list.jsp