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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

PERU

FROM 09 TO 19 SEPTEMBER 2013

IN ORDER TO ASSESS THE CONTROLS OF MYCOTOXIN CONTAMINATION IN SPICES
INTENDED FOR EXPORT INTO THE EUROPEAN UNION AND TO FOLLOW UP AUDIT
DG(SANCO)/2011-6030

Executive Summary

This report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Peru, from 09-19 September 2013.

The objective was to assess the control systems in place to control aflatoxin contamination in paprika intended for export into the European Union (EU). In particular, the audit team followed up on action taken by the Competent Authorities (CAs) in response to recommendations made by the FVO following an earlier audit on the same topic in 2011.

Overall, there are some significant improvements made since the 2011 audit. Of the ten recommendations in the previous audit report, seven have been fully addressed. New legislation is in place since April 2011 which places the responsibility for food safety on the food business operators and requires them to register and be approved by the Plant Health National Service (SENASA). The process of registration and approval is at a preliminary stage. The SENASA laboratory visited, although not yet accredited, has validated methods for the analysis of mycotoxins. In addition a mycotoxin monitoring programme for paprika samples from primary producers and processors has been in place since 2011. All producers are familiar with good agricultural practice and SENASA is actively involved in providing training in this area.

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

Table of Contents

1	<u>INTRODUCTION</u>	1
2	<u>OBJECTIVES AND SCOPE</u>	1
3	<u>LEGAL BASIS AND STANDARDS</u>	2
	3.1 <u>LEGAL BASIS</u>	2
	3.2 <u>STANDARDS</u>	2
4	<u>BACKGROUND</u>	2
5	<u>FINDINGS AND CONCLUSIONS</u>	3
	5.1 <u>RELEVANT NATIONAL LEGISLATION</u>	3
	5.2 <u>COMPETENT AUTHORITIES</u>	4
	5.3 <u>OFFICIAL CONTROLS ON PRODUCTION AND PROCESSING</u>	5
	5.3.1 <u>CULTIVATION AND PROCESSING</u>	6
	5.3.2 <u>NATIONAL MONITORING PROGRAMME OF CONTAMINANTS</u>	8
	5.4 <u>PROCEDURE FOR EXPORTING TO THE EU AND HANDLING REJECTED CONSIGNMENTS</u>	9
	5.5 <u>METHOD OF SAMPLING CONSIGNMENTS</u>	10
	5.6 <u>LABORATORY SERVICES</u>	10
	5.7 <u>RESPONSE TO RASFF NOTIFICATIONS</u>	12
6	<u>OVERALL CONCLUSION</u>	13
7	<u>CLOSING MEETING</u>	13
8	<u>RECOMMENDATIONS</u>	13
	<u>ANNEX 1 – EUROPEAN UNION ACTS QUOTED IN THE REPORT</u>	14
	<u>ANNEX 2 – STANDARDS QUOTED IN THE REPORT</u>	15

ABBREVIATIONS AND SPECIAL TERMS USED IN THIS REPORT

Abbreviation	Explanation
ADEX	Peruvian Exporters Association
CA(s)	Competent Authority(ies)
CAC/GL	Codex Alimentarius Commission/Guideline
CAC/RCP	Codex Alimentarius Commission/Recommended Code of Practice
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
EU	European Union
FAPAS	Food Analysis Performance Assessment Scheme, UK
FBO(s)	Food Business Operator(s)
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice(s)
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Points
HPLC-FD	High Performance Liquid Chromatography-Fluorescence Detector
HPLC-/MS/MS	High Performance Liquid Chromatography – Tandem Mass Spectrometry
ILAC	International Laboratory Accreditation Cooperation

ISO	International Organisation for Standardization
LC/MS/MS	Liquid Chromatograph – Tandem Mass Spectrometry
LOD	Limit of Detection
LOQ	Limit of Quantification
MS(s)	Member State(s)
OTA	Ochratoxin A
PROMPERU	Commission for the Promotion of Peru Export and Tourism
RASFF	Rapid Alert System for Food and Feed
SENASA	Plant Health National Service
SOP(s)	Standard Operation Procedure(s)
TC(s)	Third Country(ies)
UPLC	Ultra Performance Liquid Chromatography
UPLC / MS	Ultra Performance Liquid Chromatography / Mass Spectrometry

1 INTRODUCTION

The audit took place in Peru from 9 to 19 September 2013 in order to assess controls on mycotoxin contamination in spices (paprika), intended for export to the 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 Plant Health National Service (SENASA).

An opening meeting was held on 9 September 2013 with the CCA, SENASA, Customs Service and representatives from the Commission for the Promotion of Peru Export and Tourism (PROMPERU) and Peruvian Exporters Association (ADEX). At this meeting, the objectives of and itinerary for the audit were confirmed.

2 OBJECTIVES AND SCOPE

The objectives of the audit were to:

- Verify whether the control systems are in place to control aflatoxin contamination in spices (paprika) 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))/2011-6030).

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 Authority/ies			Comments
Competent authorities	Central	1	Plant National Health Service (SENASA), Customs Service, PROMPERU and ADEX
	Regional	3	Regional Executive Directorates of SENASA
Laboratory/ies			
Public laboratory		1	SENASA laboratory in Lima
Private laboratory		1	Small private laboratory

Producers /Processors / Exporters		
	4	4 large growers / processors that exported to EU

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 EU 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.

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 audits to the main exporting countries to evaluate official control systems for preventing aflatoxin contamination in foodstuffs. The reports on these audits 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)/2011-6030 contained recommendations to the CAs of Peru, and action plans were received, which were considered satisfactory to address the recommendations of the report.

In order to protect public health, a maximum level for Ochratoxin A (OTA) in spices was established in the EU in 2010. To enable the producing countries to put prevention measures in place and not to disrupt trade to an unacceptable extent, a higher maximum level, applicable within short notice, was established for a limited period of time (applicable until 1 July 2012), before the maximum level reflecting the level assumed to be achievable by applying good practices enters into application. An assessment of the achievability of levels for OTA in Peru by applying good practices was foreseen before the stricter level would apply. Following this assessment, although the FVO had observed in a second audit a significant improvement in the application of good practices

in Peru compared to the first audit, it was obvious that the stricter levels were not yet achievable on a consistent basis by Peru. The Commission considered it appropriate to postpone once again the application of the stricter level until the end of December 2014.

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. For paprika, notifications relate to the mycotoxin content of goods exceeding the EU limits of 30 ppb OTA, 5 ppb aflatoxin B1 and 10 ppb total aflatoxins.

Since April 2011 (when the previous audit DG(SANCO)/2011-6030 took place) eight RASFF notifications relating to mycotoxins in paprika from Peru were notified.

Table 1

Peru	Imports to EU (metric tonnes)			Number of RASFF notifications		
	2011	2012	2013 to July.	2011	2012	2013
Whole Paprika (Capsicum annum) Combined Nomenclature ((CN) code ex 0904 20 10)	3267	5893	795	5	2	1
Crushed or ground Paprika (Capsicum annum) (CN code ex 0904 20 90)	1415	2744	314			

Source: Eurostat, Comext database, RASFF window

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 401/2006 lays down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.

Include additional/other relevant specific legislative requirements in place, if required

Findings

In the previous audit report, Recommendation No 7 stated, *'Consider establishing a legal basis for the official control of mycotoxin contamination in paprika intended for export to the EU'*.

Since the 2011 audit, new legislation has come into force. The Supreme Decree N° 004-2011-AG, was published in the Peruvian Official Gazette "El Peruano" and came into force on April 28th 2011. This is a significant step forward which provides a legal basis for SENASA to implement a wide range of measures in primary production and processing of agricultural food and feed for the domestic market as well as for imports and exports. The Supreme Decree N° 004-2011-AG also provides the legal basis whereby the primary producers and food business operators (FBOs) are responsible for the safety of their produce. The legislation provides a legal basis for carrying out official controls on mycotoxin contamination in paprika intended for export.

All relevant legislation is available on the web site of SENASA www.senasa.gob.pe

Conclusions

New legislation introduced since the previous audit has provided the legal basis for the official control of mycotoxin contamination in paprika. Therefore Recommendation No 7 of the previous audit report has been addressed.

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

In the previous audit report, Recommendation No 3 stated, *'Ensure that adequate training has been provided to officials responsible for the control of mycotoxins contamination in paprika exported to the EU'*.

SENASA is the CCA for this audit and is responsible for the surveillance and sanitary and phytosanitary control of plants, animals, products and by-products of plant and animal origin. SENASA is also responsible for the registration, control and enforcement of agricultural pesticides and veterinary drugs as well as being responsible for the supervision of the national organic production and agro-food safety.

SENASA at regional level has decentralized executive offices in each of the 25 regions of the country with qualified personnel in the areas of food safety, plant health, animal health, pesticides, veterinary drugs and organic production.

SENASA, has exclusive competence for technical issues, standards, and monitoring related to the safety of agricultural-livestock foods for primary production and processing targeting human consumption and animal feed, whether produced nationally or abroad.

SENASA has developed a training plan for staff in charge of the inspection and control of paprika in the primary processing stage. The Sanitary Training Programme includes aspects related to Hygiene General Principles and Good Practices for Production and Processing, as indicated in Article 48 of Supreme Decree No 004-2011-AG, Agrifood Safety Regulation.

The audit team confirmed that SENASA provided training to officials responsible for the control of mycotoxin contamination in paprika.

Conclusions

The CCA and its regional executive offices are clearly designated.

The CCA has provided training to officials responsible for the control of mycotoxin contamination and therefore Recommendation No 3 of the previous audit report has been adequately addressed.

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;

The Code of Practice for Spices and Dried Aromatic Plants Codex Alimentarius Commission / Recommended Code of Practice (CAC/RCP 42 – 1995);

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

Findings

In the previous audit report, Recommendation No 1 stated *'Ensure that all establishments where paprika for export to the EU is produced and processed are registered, equivalent to the requirements of Articles 6 of Regulation (EC) No 852/2004 in conjunction to Article 10 of the same Regulation'*.

Official controls are only performed since 2013 in the frame of granting sanitary authorisations. The audit team visited four growers and processors in three regions in Peru. In one region visited there were no longer any exports of dried paprika to the EU.

Through two Official Letters N ° 818-2011-AG-SENASA-DIAIA and No. 0179-2013-AG-SENASA-DIAIA primary producers and processing establishments of paprika have been informed of the requirement to apply to SENASA to obtain the relevant Sanitary Authorisation.

All producers visited are registered with SENASA. The audit team was informed, that paprika exporters have been notified by letter and through publication of material on SENASA's home page of the need to comply with EU regulations on food safety and permitted mycotoxin levels.

In the Arequipa region three out of the four exporters of paprika to the EU were visited. Two of the companies have received sanitary authorisation from SENASA.

5.3.1 Cultivation and Processing

In the previous audit report, Recommendation No 2 required the CA to *'Ensure that food business operators exporting spices to the EU implement standards at least equivalent to those required by Article 5 of Regulation (EC) No 853/2004 on food safety procedures based on Hazard Analysis and Critical Control Points (HACCP) principles in conjunction to Article 10 of the same Regulation'*;

Recommendation No 4 stated *'Ensure that storage conditions in paprika processing and storage facilities comply with the requirements set out in CODEX Code of Hygienic Practice CAC/RCP 42-1995 for Spices and Dried Aromatic Plants'*;

Recommendation No 8 stated *'Consider implementation of Good Agricultural Practice (GAP)/ Good Manufacturing Practice (GMP) principles by all paprika growers and processors that produce paprika for export to the EU'*;

Recommendation No 10 stated *'Consider undertaking research into alternative methods of drying paprika to ensure that methods used by paprika growers are suitable to avoid mycotoxin contamination during the drying process'*.

The Executive Directorates of SENASA in the regions have implemented training courses for producers in the regions. SENASA has established guidelines on Good Production Practices and Hygiene and requires producers of paprika to implement and comply with HACCP and sanitary Standard Operating Procedures (SOPs), according to Article 14 of Supreme Decree no 004-2011-AG, Agrifood Regulation. In 2011, there were 3,151 producers trained in GAP, GMP, HACCP, pesticide use and other relevant topics. In 2012, there were 2,649 producers trained in GAP, GMP, HACCP and food safety legislation among other topics. During 2012 and 2013 an export association ran courses for paprika producers in Barranca – Lima, Chiclayo and Ica.

Arequipa Region

In the Arequipa region, currently three out of the four producers were exporting to the EU. Two of the three companies are working with contracted out growers however, the number of out growers being used have been reduced since 2011. One company has stopped working with out growers based in the Ica region after experiencing high levels of OTA in 2012. Two of the companies have own field production of paprika and the third one is working with contracted out growers. They exported in 2013 between 400 and 1800 tons of paprika to the EU. One company stated that they increased their export volume of paprika to the EU while the second and third one reported a reduction of about 50% of the export volume.

All three companies visited by the audit team in Arequipa apply GAP systems which focus on reducing the risk of mycotoxin occurrence. SENASA has developed and distributed to the exporters and farmers a specific GAP guideline which describes measures to reduce the risk of mycotoxin occurrence. The measures include, careful irrigation, screening for moulds, selection of healthy fruits and drying on plastic covers. Since 2006 the GAP system of one of the companies is externally inspected and certified by an international operating GAP scheme.

One of the FBOs visited in Arequipa undertakes an in house laboratory test for yeast and moulds on all consignments. In addition it uses an external laboratory to analyse its own samples for mycotoxins. This occurred 3-4 times per year, usually upon sight of mould growing on the paprika in the field. All laboratory reports from the private laboratory relating to mycotoxins were reviewed by the audit team and were found to be within the specification. However, the private laboratory was neither accredited nor using validated methods.

In addition two out of the three companies run comprehensive HACCP based self control systems,

which include sampling for analysis on aflatoxin and OTA. The third establishment is in the final stages of implementing a HACCP plan. The exporters stated that their customers in Europe sample and analyse all shipments prior to export since 2011. The exporter is responsible for sending the samples to his customer in Europe where analysis are performed in EU laboratories. No consignments were rejected since 2011 and no exceedances of mycotoxin levels were reported by the importers in Europe.

During the site visits by the audit team the staff met at the growers and producers were considered to be satisfactorily trained in GAP and HACCP.

Piura Region

In the Piura region, the number of exporters of paprika to the EU has decreased from four exporters in 2011 to one remaining exporter in 2013.

The audit team visited this company in the Piura region which consisted of a large growing capacity of approximately 4500 HA of which approximately 330 HA were under paprika cultivation. It has a drying area for paprika of 12 HA within the farm. In addition it had a processing and packing facility. In 2011 this enterprise exported 1628 tonnes of paprika. In 2012, 2170 tonnes were exported and it is expecting to export 2000 tonnes in 2013.

Since 2006 this enterprise is inspected and certified by an international operating GAP scheme. Specific measures are in place to reduce the risk of the occurrence of mycotoxins during production. For example during the growing season about 15 applications of mixtures of fungicides and insecticides are applied to the crop. Another measure that was introduced in 2013 following mycotoxin problems in 2012, is earlier harvesting prior to the start of the raining season. Two separate collections of paprika are undertaken instead of three previously through the use of plant hormones during flowering.

Additional standard measures are plant distance between the rows, water management and the systematic collection of damaged fruit during growing and harvesting periods.

The company applies two different drying systems, in one case rice husks are used to cover the soil on which the paprika is dried and in the other case drying takes place on virgin desert soil. The company is running a HACCP system which includes sampling for mycotoxins of each plot.

Three out of the four companies visited in Arequipa and Piura, had fully implemented HACCP systems. All the plants visited generally followed the CODEX Standard CAC/RCP42-1995 on hygiene practice for Spices and Dried Aromatic Plants. However, the storage conditions of paprika pods in some establishments did not always comply with the requirements of the above-mentioned standard as it was not possible to control the humidity and temperature to reduce the risk of mould growth. All producers visited apply GAP and GMP systems with the aim of avoiding the occurrence of mycotoxins. SENASA informed the audit team that there are no resources available for research on paprika production.

5.3.2 National Monitoring Programme of Contaminants

In 2011 through Chief Resolution N ° 141-2011-AG-SENASA, a National Monitoring Programme of Contaminants was authorized which brought about the first contaminant monitoring plan in Primary Agricultural Food, through the approval of Directorial Resolution N ° 107 - 2011-AG-SENASA-DIAIA.

The SENASA laboratory has provided the data for the monitoring programme from the paprika harvesting campaigns of 2011 and 2012.

2011-2012 Monitoring Programme

There were forty two samples taken for official control from the producers and processors and analysed in 2011 for mycotoxins. There were fourteen samples found to have OTA levels higher than the limit of quantification (LOQ) of 2µg/kg reported by the SENASA laboratory. Samples were taken in the following seven regions: Ica, La Libertad, Lima-Callao, Arequipa, Tacna, Lambayeque and Piura.

In Ica, 11 samples were taken, eight of which were positive for OTA. The concentrations of OTA were in the range of 2.2 -72.2 µg/kg. Three of these, positive samples showed results between 27.7-30.8 µg/kg.

In La Libertad, two samples were taken, in Lima-Callao, seven samples, in Arequipa, 10 samples, in Tacna, 2 samples and from these four regions no positive samples for OTA were found.

In Lambayeque, four samples were taken and one sample was positive for OTA (OTA 64.04 µg/kg) and aflatoxin B1 (84.3 µg/kg)

In Piura, six sample were taken and three samples were positive for OTA (2.74 -605.54µg/kg). One sample was positive for OTA (177.85 µg/kg) and aflatoxin B1 (19.7 µg/kg).

2012-2013 Monitoring Programme

The audit team received the following data from SENASA. Fifty five samples were taken for official control from the producers and processors and analysed in 2012-2013 for mycotoxins. There were 12 samples found to be higher than the LOQ of 2 µg/kg. Samples were taken from the same seven regions as in 2011.

In Ica, 11 samples were taken and one sample was positive for afla B1 (55.436 µg/kg)

In La Libertad, seven samples were taken and one sample was positive for aflatoxin B1 (2.96 µg/kg).

In Lima Callao, eight samples were taken and no positive samples were detected.

In Arequipa, five samples were taken and one sample was positive for OTA (3.1 µg/kg).

In Tacna, six samples were taken and one sample was positive for aflatoxin B1(34.232 µg/kg).

In Lambayeque, nine samples were taken and two samples were positive for OTA (10.1-85.3 µg/kg) and one sample was positive for OTA (16.1 µg/kg) and Aflatoxin B1 (5.69 µg/kg). In addition one sample was positive for aflatoxin B1and B2 (8.93 and 0.70 µg/kg).

In Piura, seven samples were taken and two samples were positive for OTA (11-65.6 µg/kg) and one sample was positive for OTA (175.5 µg/kg) and aflatoxin B1(8.45 µg/kg).

Overall, seven positive samples were found to be contaminated with levels of OTA greater than 30 µg/kg for 2011. In 2012-2013, four samples were found to be contaminated with levels of OTA greater than 30 µg/kg.

Conclusions

Considerable progress has been made to ensure that GAP/GMP/HACCP principles are implemented by all paprika growers and processors that produce paprika for export to the EU. This addresses

Recommendation No 1, relating to registration of facilities, Recommendation No 2, relating to HACCP and Recommendation No 8, relating to GAP/GMP.

Recommendation No 4 relating to storage conditions for paprika has not been addressed.

Recommendation No 10 relating to research into alternative methods of drying paprika to avoid mycotoxin contamination has not been addressed.

A national monitoring programme of contaminants was implemented in 2011.

5.4 PROCEDURE FOR EXPORTING TO THE EU AND HANDLING REJECTED CONSIGNMENTS

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

Recommendation No 9 of the previous audit report stated '*Consider putting procedures in place to provide guarantees that paprika rejected at EU borders and returned to Peru due to mycotoxin contamination is not re-exported back to the EU*'.

The exit points of paprika exported from Peru to international markets are located in the region of Lima (Seaport of Callao) and Piura (Seaport of Paita). In these exit points SENASA has inspectors that inspect, verify and certify that the exported product is compliant with phytosanitary regulations.

Article 25 of Supreme Decree No 004-2011-AG deals with the imports or re-exports of Primary Agricultural-Livestock Foods (Animal and Plant Origin) and / or Animal Feed rejected by the destination country. The exporter has specific obligations towards SENASA. Within 48 hours of the product arriving back in Peru, the exporter is required to alert SENASA of the situation. SENASA undertakes relevant analyses to determine whether if the rejected product can be reintroduced on to the domestic Peruvian market or re-exported to another country or be destroyed.

Conclusions

The actions taken by SENASA address the requirements of Recommendation No 9, which deals with providing guarantees that paprika rejected at EU borders is not re exported back to the EU.

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 and spices, the method of sampling is laid down in Annex I.E.

Findings

In 2012, SENASA issued Procedure PRO-SIAG-07: Collection and sending samples of agricultural food and feed, (March 2012), which is used for the execution of the Annual Plan for contaminant monitoring and for inspection activities in quarantine control when samples are sent for laboratory analysis. However, it does not cover the sampling of mycotoxins. At the time of the audit no written procedure on the sampling of mycotoxins was in place.

Two sampling exercises were observed by the audit team, one in Arequipa and one in Piura.

The sampling exercise in Arequipa, took place in the store of one of the exporters. The inspector in charge took 15 incremental samples from the top of 15 different sacks at different locations of the lot by hand. The sample was sealed in a plastic bag and the bag was marked with a pen. However, the sample weight was not measured at the end of the sampling exercise (approximately 3kg instead of the required 10kg for the relevant lot of approximately 11 tonnes). The inspector was not clear about the size of the lot. Therefore the sample could not be guaranteed to be representative. This is not in line with Regulation (EC) 401/2006 in relation to the number of incremental samples and final weight.

The inspector stated that he had received general training in sampling in 2012.

The second observed sampling exercise took place in Piura. The lot size was approximately three tonnes. The inspector took 60 incremental samples from 20 sacks. The sample was mixed and one laboratory sample and one counter sample each of 1kg were taken. The observed sampling was in line with Regulation (EC) 401/2006.

Conclusions

The first sampling exercises observed by the audit team was not in line with the requirements of Regulation (EC) 401/2006, the second sampling exercise was satisfactory.

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 Alimentarius Commission/Guidelines CAC/GL 26-1997 on the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems lay 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

In the previous audit report Recommendation No 5 *'Ensure that all laboratories performing official controls are evaluated and/or accredited under officially recognised programmes (ISO/IEC 17025 standard) to make sure that adequate quality controls are in place to confirm the reliability of test results (point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997)'*.

The FVO team visited the SENASA laboratory in Lima for the analysis of contaminants. The laboratory is not yet accredited but will be subject to an accreditation audit by ANSI-ASQ National Accreditation Body from the United States of America. This accreditation body is recognised by the International Laboratory Accreditation Cooperation (ILAC).

The infrastructure of the laboratory was appropriately laid out. The audit team tracked one sample which was positive for OTA from reception by the laboratory to the issuing of the results. The traceability of the sample was satisfactory. Analytical results are reported with measurement uncertainty. The laboratory staff do not make any judgements on the compliance of the results, this is the responsibility of SENASA central office.

The validation of the methods for mycotoxin was satisfactory. The limit of detection (LOD) was between 0.2µg/kg -0.5 µg/kg. These limits are low enough to comply with the limits of the current legislation. The LOQ was between 0.3 µg/kg -2 µg/kg. The grinder used for the preparation of the bulk sample was adequate. However, there was no documented evidence to confirm the homogeneity of the sample which would be used for analysis.

The equipment for the analysis of aflatoxin and OTA consisted of two Liquid Chromatographs Tandem Mass Spectrometry (LC/MS/MS), one Ultra Performance Liquid Chromatography (UPLC) and one High Performance Liquid Chromatography (HPLC). In addition, the laboratory is equipped with a high performance liquid chromatography fluorescence detector (HPLC-FD).

At the time of the audit the HPLC tandem mass spectrometry (HPLC/MS/MS) equipment was not in operation due to technical problems which were detected in May 2013. The repair of the equipment would not take place until November 2013. To overcome this problem the laboratory is implementing an analytical method for aflatoxin in the UPLC / MS system and an analytical method for ochratoxin in the HPLC-FD system.

As an external quality control, the SENASA laboratory participates with good results in the proficiency tests of the UK based, Food Analysis Performance Assessment Scheme (FAPAS) in the relevant areas of aflatoxin and OTA.

The audit team visited a private laboratory which undertook mycotoxin analysis for processors and exporters of paprika. The laboratory was not accredited for mycotoxin analyses. The mycotoxin methods that are used in this laboratory are not validated. The quality of the analytical results are not as prescribed by ISO/IEC 17025. The audit team was informed that there are currently no plans to develop validated methods for mycotoxins.

Conclusions

Progress has been made at the SENASA laboratory to validate methods for mycotoxin analysis.

The SENASA laboratory is not yet accredited for mycotoxin analysis therefore Recommendation No 5 of Report DG(SANCO)2011-6030 has not yet been addressed.

The homogeneity of the ground sample, from which the laboratory sample is taken is not proven.

5.7 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

In the previous audit report Recommendation No 6 stated *'Ensure that the RASFF follow-up procedure developed provides for effective enforcement measures taken against all exporters involved in notifications (point 6 of CODEX Guidelines CAC/GL 25-1997)'*.

The audit team checked the follow up of two RASFF notifications and these had been satisfactorily undertaken. One of these companies involved in the RASFF notification in 2011 was visited by the audit team. This exporter had subsequently changed his system and had introduced an in house laboratory. All lots are now sampled and analysed before they buy from the growers. Additional samples are taken and analysed after entering the processing unit, during processing and before export. Additionally the company is buying only produce from the Arequipa region, as the exporter stated that the produce from this region has a lower risk of mycotoxin contamination than in the Ica region.

The newly introduced legislation Supreme Decree No 004-2011-AG provides a legal basis for effective enforcement measures to be taken against exporters involved in notifications, mainly through the revoking of the establishment's sanitary authorisation.

The audit team confirmed that there are good procedures in place for the follow up of RASFF notifications.

Conclusions

There are satisfactory procedures for following up RASFF notifications. The approach by SENASA coupled with the introduction of the new legislation fully addresses Recommendation No 6 of Report DG(SANCO)2011-6030.

6 OVERALL CONCLUSION

Overall, there are some significant improvements made since the 2011 audit. Of the ten recommendations in the previous audit report, seven have been fully addressed. New legislation is in place since April 2011 which places the responsibility for food safety on the FBOs and requires them to register and be approved by SENASA. The process of registration and approval is at a preliminary stage. The SENASA laboratory visited, although not yet accredited, has validated

methods for the analysis of mycotoxins. In addition a mycotoxin monitoring programme for paprika samples from primary producers and processors has been in place since 2011. All producers are familiar with GAP and SENASA is actively involved in providing training in this area.

7 CLOSING MEETING

A closing meeting was held on 19 September 2013 with representatives of the CCA, Customs Service, PROMPERU and ADEX. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit.

8 RECOMMENDATIONS

The CAs are invited to provide details of the actions taken and planned, including 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:

N°.	Recommendation
1.	Ensure that storage conditions in paprika processing and storage facilities comply with the requirements set out in CODEX Code of Hygienic Practice CAC/RCP 42-1995 for Spices and Dried Aromatic Herbs.
2.	Ensure that paprika consignments intended for export to the EU are sampled following the requirements at least equivalent to Commission Regulation (EC) No 401/2006.
3.	Ensure that all laboratories performing official controls are evaluated and / or accredited under officially recognised programmes (ISO/IEC 17025 standard) to make sure that adequate quality controls are in place to confirm the reliability of test results (point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997).

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=2013-6983

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. 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 42-1995	Code of hygiene practice for spices and dried aromatic plants (CAC/RCP 42-1995)	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