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Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

AZERBAIJAN

FROM 14 TO 22 NOVEMBER 2012

IN ORDER TO ASSESS THE OFFICIAL CONTROL SYSTEMS IN PLACE FOR AFLATOXIN CONTAMINATION IN HAZELNUTS INTENDED FOR EXPORT TO THE EUROPEAN UNION

Executive Summary

This report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Azerbaijan from 14 to 22 November 2012.

The objectives of the audit were to assess the control systems in place to control aflatoxin contamination in hazelnuts intended for export to the European Union (EU) and to follow up on audit DG(SANCO)/2009-8167.

Since the previous FVO audit, some progress has been made in improving the implementation of good agricultural practices and the laboratory performance by some of the official laboratories. The Competent Authority (CA) underwent reorganisation after the previous audit, at the end of 2009, which did not have an impact on the allocation of responsibilities. However, shortcomings (some already identified during 2009) related to the CA export procedure, staff knowledge on EU sampling requirements, management of the non-compliant lots, laboratory performance and follow-up of RASFF notifications were observed. These shortcomings affect the ability of the CAs to ensure that hazelnuts exported to the EU do not contain aflatoxins exceeding the maximum levels laid down in Regulation (EC) No 1881/2006.

In relation to the action plan provided by the CCA in response to the nine recommendations made following audit DG(SANCO)/2009-8167, the audit team found that two recommendations had not been addressed and seven had not been fully addressed.

The report contains recommendations to the Competent Authorities of Azerbaijan aimed at addressing the identified shortcomings.

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ABBREVIATIONS AND SPECIAL TERMS USED IN THIS REPORT

Abbreviation	Explanation
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)
CCEC	Consumer Commodity Expertise Centre
CCIC	Central Customs Inspection Centre
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
ELISA	Enzyme-Linked Immunosorbent Assay
EU	European Union
FVO	Food and Veterinary Office
GAP	Good Agricultural Practices
GMP	Good Manufacturing Practice
GOST	Technical State Standards of the former Soviet Union
HACCP	Hazard Analysis Critical Control Points
HPLC	High Performance Liquid Chromatography
ISO	International Organisation for Standardization
LATAK	Latvian National Accreditation Bureau

MA	Ministry of Agriculture
MED	Ministry of Economic Development
MH	Ministry of Health
MS(s)	Member State(s)
RASFF	Rapid Alert System for Food and Feed
RCHE	Republic Centre of Hygiene and Epidemiology
SCC	State Customs Committee
SOP	Standard Operation Procedure
SPCS	State Phytosanitary Control Service
SSAPPCR	State Service for Antimonopoly Policy and Protection of Consumer Rights
TC(s)	Third Country(ies)

1 Introduction

The audit took place in Azerbaijan from 14 to 22 November 2012 in order to assess controls on aflatoxin contamination in hazelnuts intended for export to the European Union (EU) and to follow up on audit DG(SANCO)/2009-8167. The audit team comprised two auditors from the Food and Veterinary Office (FVO) and one national expert from a Member State (MS).

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 the control systems and the operational standards in this sector.

The audit team was accompanied throughout the audit by representatives from the central competent authority (CCA) – the Consumer Commodity Expertise Centre (CCEC) of the State Service for Antimonopoly Policy and Protection of Consumer Rights (SSAPPCR) which is under the Ministry of Economic Development (MED).

An opening meeting was held on 14 November 2012 with the CCA and representatives from the laboratory of the State Phytosanitary Control Service (SPCS) under the Ministry of Agriculture (MA), the laboratory of the Republic Centre of Hygiene and Epidemiology (RCHE) under the Ministry of Health (MH) and the laboratory of the Central Customs Inspection Centre (CCIC). At this meeting, the objectives of the audit and the itinerary were confirmed.

2 Objectives and Scope

The objectives of the audit were to:

- Assess whether the control systems in place to control aflatoxin contamination in hazelnuts intended for export to the EU are adequate to ensure that the produce concerned is within the specified contaminant limits laid down in EU legislation;
- Follow-up on actions taken by the Competent Authorities (CAs) in response to recommendations made by the FVO in the previous report DG (SANCO)/2009-8167.

In terms of scope, the audit reviewed the controls on the production, processing and export, including the national legislation in place, as well as the organisation of CAs, their controls and enforcement capability.

Attention was paid to examining the implementation of corrective actions promised in response to recommendations made in report DG (SANCO)/2009-8167 of the previous FVO audit to Azerbaijan covering the same scope. Where relevant, references to the specific recommendations are included under heading 5 of the current report.

In pursuit of these objectives, the following sites were visited :

Competent Authority/ies			**Comments**
Competent authorities	Central	2	Opening and closing meeting
	Regional/Local	1	Meeting with staff of the SSAPPCR regional office in Sheki-Zagatala region
Laboratory/ies			

Public laboratories	4	Central Food Test Laboratory under the MED, laboratory of the SPCS under the MA, laboratory of the RCHE under the MH, laboratory of the CCIC
Producers		
Primary producers	2	Producers of hazelnuts in Sheki-Zagatala region
Processors		
Processing plants	7	Factories processing hazelnuts for export to the EU in Sheki-Zagatala region

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 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.

3.2 Standards

Additionally Standards, 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. A previous audit DG (SANCO)/2009-8167 took place in 2009 in Azerbaijan which highlighted deficiencies in relation to implementation of official controls of hazelnuts (sampling procedure, traceability and laboratory performance). The report - published on the Health and Consumers Directorate-General (SANCO) website at http://ec.europa.eu/food/fvo/ir_search_en.cfm - made nine recommendations (seven related to laboratory performance) in respect to the action required from the CA. An action plan was received from the CCA in relation to the implementation of these recommendations, which are also

published on the same website. Where relevant, references to the recommendations and the action plan are referenced under headings 5 of the current report.

In accordance with Article 15 (1) of Regulation (EC) No 882/2004 foodstuffs imported into the EU are regularly checked by the CAs of the MSs. Regulation (EC) No 669/2009 establishes the list of products from certain countries subject to a higher level of official controls on imports. Currently, hazelnuts from Azerbaijan are subject to such higher levels of controls with established inspection frequency of 10 %.

Information on foodstuffs which were found to have public health implications are disseminated as alert notifications through the Rapid Alert System for Food and Feed (RASFF) to all MSs and to the exporting countries. In the case of hazelnuts the notifications relate to the mycotoxin content of goods exceeding the EU limit of 8.0 µg/kg for aflatoxin B_1 and 15.0 µg/kg for total aflatoxin in hazelnuts which are subject to sorting or other physical treatment before consumption and 5 µg/kg for aflatoxin B_1 and 10 µg/kg for total aflatoxin in hazelnuts for direct human consumption.

From 2010 up to the time of the audit 4 notifications relating to aflatoxins in hazelnuts from Azerbaijan have been communicated through the RASFF. The breakdown of these notifications, as well as the volume of imports into the EU, is presented below in table 1.

Table 1: Hazelnuts import volumes from Azerbaijan and RASFF notifications

	2010	2011	2012 (to date)
Imports to the EU (in metric tonnes)	3 024	3 714	Not available yet
Number of RASFF notifications	0	2	2

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.

Article 10 of Regulation (EC) No 852/2004 requires that imported food shall meet the hygiene requirements laid down in Articles 3 to 6 of this Regulation.

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 the previous FVO audit in 2009, the main national legislation regarding official controls on hazelnuts intended for export to the EU remains unchanged as it has been described in report

DG(SANCO)/2009-8167.

An amendment to the Sanitary and Epidemiological Rules and Norms, issued by the MH, was adopted (30 April 2010). Annex 11 of this document, regarding foodstuffs intended for export to the EU, refers to Regulation (EC) No 1881/2006 as amended and lays down maximum levels for aflatoxins in hazelnuts intended for export to the EU equivalent to the relevant EU requirements. However, Decision No 3276 of 2007 on the official controls of foodstuffs of plant origin exported to the EU, which establishes the provisions for maximum levels of aflatoxins in hazelnuts intended for export to the EU and the sampling methods for aflatoxins analysis of hazelnuts, remained unchanged since the 2009 FVO audit.

The CCEC (the CA) indicated in their reply to the previous audit's recommendations that in order to address recommendations 1 (*Consider following the requirements of point 33 of the Code of practice of the Codex Alimentarius for the prevention and reduction of aflatoxin contamination in tree nuts (CAC/RCP 59-2005) regarding traceability*) and 2 (*Ensure that hazelnut consignments intended for export to the EU are sampled following the requirements at least equivalent to Commission Regulation (EC) No 401/2006*) of report DG(SANCO)/2009-8167 relevant chapters of Decision No 3276 of 2007 would be amended by June 2010 at the latest.

The audit team noted that the national provisions necessary to ensure the implementation of the Decision No 135 of 2005 laying down the certification requirements of foodstuffs intended for export to the EU have not been adopted. As a result, the quality certificate for hazelnuts intended for export to the EU from the MED has not been implemented yet.

The CA stated that the necessary amendments to the national legislation will be proposed by MED working groups established in order to implement the adopted “Azerbaijan Government action plan on legal approximation of the legislation of the Republic of Azerbaijan with the EU *acqui*, 2010 - 2012". The audit team was not provided with any deadlines for these actions.

Conclusions

As mentioned in report DG (SANCO)/2009-8167, there is a set of national legislation relevant to the scope of this audit including some provisions which are in line with those laid down in the relevant EU legislation. However, the provisions regarding sampling methods for aflatoxin analysis and maximum levels for aflatoxins in hazelnuts differ from the EU requirements.

The CCA, in response to the previous audit's recommendations 1 and 2, committed itself to amend Decision No 3276 of 2007. The relevant recommendations have not 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

5.2.1 The State Service for Antimonopoly Policy and Protection of Consumer Rights

The CCA within the scope of this audit is the SSAPPCR under the MED. SSAPPCR was established (Presidential Decree No 203 of 25 December 2009) after the merging of the State Office

for Control of Consumer Market and the State Service for Antimonopoly Policy. Within SSAPPCR the relevant CA responsible for the official controls on foodstuffs intended for export to the EU is the CCEC. The CCEC control responsibilities and tasks have remained unchanged as described in report DG (SANCO)/2009-8167. Currently the Food Unit is comprised of a Head of Unit, his deputy and three officials (a chief engineer-technologist, an engineer-technologist and an adviser).

Training of staff

The CA informed the audit team that training programmes, study visits and workshops were organised on topics such as food hygiene, Good Manufacturing Practices (GMP) and Hazard Analysis and Critical Control Points (HACCP) for the staff. The audit team was provided with certificates for participation of CA's officials in training courses. However, none of the officials has received specific training on the EU requirements for sampling of hazelnuts for aflatoxin analyses. The audit team noted that the knowledge of EU requirements of the CA officials met was adequate from a general point of view, but needed to be improved regarding hazelnut sampling for aflatoxin analyses and assessment of HACCP based procedures.

The audit team was informed that a training project is planned for 2013 in relation to the issue of aflatoxin contamination in hazelnuts.

5.2.2 State Customs Committee

The State Customs Committee (SCC) is responsible for customs export clearance of hazelnut consignments outside Azerbaijan in the context of this audit. Following internal instructions issued in 2006, all hazelnut consignments intended for export to the EU are checked by sampling and laboratory analysis for aflatoxin contamination (B_1 and total aflatoxins) prior to export.

The SCC is also responsible for rejected consignments at EU borders returned to Azerbaijan (see section 5.3.4). These consignments are not considered as imports.

5.2.3 Other Authorities/Bodies

Details about the other official authorities involved in the context of this audit have been described in report DG (SANCO)/2009-8167. No changes in their responsibilities have occurred since the previous audit. In summary:

- the MH issues a hygiene certificate for hazelnut consignments intended for export to the EU; this certificate is a pre-requisite document for the issue of the MED quality certificate. For this purpose hazelnuts are checked by sampling and laboratory analysis for aflatoxin B_1 (see section 5.6.2).
- the SPCS under the MA issues phytosanitary certificates for each hazelnut consignment exported to the EU. For this purpose hazelnuts are checked by sampling and laboratory analysis for aflatoxin B_1 level (see section 5.6.3) prior to export.
- the State Committee on Standardisation, Metrology and Patent issues the conformity certificate which is related to the equipment used in the processing establishments and laboratories.

Conclusions

The CAs involved in the context of this audit have remained unchanged in terms of responsibilities since the last audit.

Although some training has been provided to the CA's staff, the inspectors involved in the official controls of hazelnuts intended for export to the EU do not have adequate knowledge of EU requirements for sampling of hazelnuts for aflatoxin analysis.

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 the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005, Revisions 2006, 2010) sets out recommended practices based on Good Agricultural Practice (GAP), GMP and Good Storage Practice.

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

Findings

5.3.1 Hazelnut Cultivation

According to the CA, in 2011, hazelnuts were cultivated on 29 300 ha, mainly in the Sheki-Zagatala region. The hazelnut production for 2011 was approximately 14 - 15 000 metric tonnes.

The audit team met 2 hazelnut farmers who deliver hazelnuts to the processors visited. The applied hazelnut cultivation practices are the same as described in report DG (SANCO)/2009-8167. The audit team noted that the farmers met followed the GAP principles, such as pruning of hazelnut trees, irrigation depending on the season, use of natural manure and harvesting by shaking the trees and collecting the hazelnuts on protective sheets. Both farmers stated that they do not use pesticides. One of the farmers met stated that samples were sent to the processing companies for checking the moisture level of the hazelnuts and to make a decision whether the hazelnuts are dry enough for delivery to the processing company.

At the hazelnut orchard visited, owned by one of the hazelnut processing companies, the know-how on all farming activities, including proper harvesting period, was provided by a recruited agricultural engineer.

The farmers met declared to have received training and written materials on GAP (including issues of aflatoxins) at workshops and seminars organised by the MED, MA and aid organisations. The audit team was informed of activities carried out by the CA in co-operation with different implementing agencies on training the farmers and distribution of technical documentation on GAP. One of the farmers met stated that with the support of an implementing agency he had started a field trial for the introduction of new hazelnut varieties.

The CA stated that official controls are carried out only on hazelnut orchards owned by the hazelnut processors. These checks are performed during the annual inspections of the processing establishments and are based on Decision No 3276 of 2007 which lays down provisions, among other things, on hygiene which are equivalent to some aspects of Regulation (EC) No 852/2004. At the hazelnut orchard visited the audit team was provided only with one report for official inspection carried out in 2006.

5.3.2 Processing and Storage

A national register is kept by the CA for hazelnut processors granted with an approval code number for export to the EU. The CA provided information on 20 processing companies approved to export hazelnuts to the EU in 2012. Two are located in Baku and the remaining 18 are in the Sheki-Zagatala region.

Seven hazelnut processing companies exporting to the EU have been visited by the audit team.

The audit team was informed by six of the companies visited that they had not exported hazelnuts to the EU in 2012 because of the bad quality of the harvest (very hot summer and raining during harvest time).

The official controls on hazelnuts intended for export to the EU, including authorisation of processing establishments to export hazelnuts to the EU, inspection of establishments, sampling for aflatoxin analysis, issue of quality certificates for export of hazelnuts to the EU, follow-ups of RASFF notifications are performed by the central level staff from the Food Unit of CCEC (see section 5.3).

There is an official control programme for inspections of processing establishments authorised to export hazelnuts to the EU. This programme requires that inspections are conducted once per year. Official inspections of processing establishments based in the Sheki-Zagatala region are carried out by two inspectors, one from the central level of the CA and one from the CA regional office and include inspection of the hazelnut farms (orchards) owned by the processor. All hazelnut processing companies visited have been registered and inspected once per year by the CA in 2011 and 2010.

Inspectors are required to use standard check lists during inspections in accordance with the Decision No 3276 of 2007. In the plants visited inspections had been carried out at the required frequency and using standard check lists for hygiene and HACCP plan checks.

A HACCP plan, generally following the HACCP principles, was available in all establishments visited and aflatoxin contamination of hazelnuts has been identified as a hazard. HACCP plans were assessed by the CA inspectors and, in some cases, recommendations for improvement were given. However, in four of the companies visited where the HACCP plan was assessed as satisfactory, the audit team noted that HACCP based procedures:

- did not follow all of the HACCP principles (e.g. in some establishments the critical control points were identified but the critical limits were not monitored);
- were not always implemented as required by the HACCP plan. For example, the critical limits for storage temperature defined in the HACCP plan (0^{o}C to 10^{o}C) differed from the critical limits set out in the monitoring logbooks (18.5^{o}C). There were records indicating temperatures of 20^{o}C or 21^{o}C but this had not triggered any corrective action from the company. Only one processor visited described an adequate corrective action when the temperature critical limits had been exceeded

There was no evidence that attention is paid to assess the effectiveness of the implemented specific measures to control aflatoxin contamination in hazelnut processing.

Inspection reports were drafted after every inspection visit. The audit team was not provided with copies of inspection reports during the establishments' visits. All operators stated that these documents were sent to their headquarters in Baku. The audit team checked inspection reports provided by the CA. These reports contained information for the detected non-compliances and the deadlines for corrective actions.

The processing companies visited purchased hazelnuts from the local market, directly from farmers

or received them from their own orchards. All establishments visited had established traceability systems in the form of the registration of incoming and outgoing products. They kept on file all information related to the products received, including the name of the seller, quality control data at reception and files for export documentation. Representatives from the establishments visited stated that, once hazelnuts are processed it is virtually impossible to trace their origin to individual farmers. In some processors visited traceability to the farm was possible when hazelnuts were provided from their own orchards. Other operators met demonstrated traceability to groups of farmers.

The hazelnut processors met explained that they store the incoming hazelnuts up to five months. They stated that they process according to the orders of their clients and do not store final products for more than two weeks. In the establishments visited, the audit team noted that the facility used for storing the incoming hazelnuts did not always follow the requirements of section 2.8 of the Codex Code (CAC/RCP 59-2005, Revisions 2006, 2010). In particular, the facilities did not always provide protection against access of insects, rodents and birds and also did not have equipment to measure the ambient temperature and the relative humidity.

In all processors visited internal checks were performed on the hazelnuts with regard to the moisture level (at reception, after the drying process and in the final product) and a number of quality checks (mouldy, rotten, empty and damaged nuts) were performed at reception and in the final product. During processing, hazelnuts are dried to a moisture level of 5 - 6% and hand sorted to remove damaged and mould affected kernels. Some of the processors visited applied checks for the level of internal mould contamination of the incoming hazelnuts by cutting with a teaser bar 100 kernels randomly taken. The acceptable level was up to 2% contaminated kernels.

5.3.3 Non- Conforming Products

According to the CA, when EU maximum levels for aflatoxins in hazelnuts are exceeded, export of the consignment to the EU is not allowed. Companies have the following options for handling a non-compliant lot: (a) re-process and re-sample; (b) export to another market where the aflatoxin levels found comply with the legal limits; (c) put on the domestic market where the aflatoxin levels found comply with the national limits. In case of highly contaminated lots the CA orders their destruction.

The CAs and the processors visited stated that, in most cases, the non-compliant lots are re-processed and re-sampled under the supervision of the CAs. If after that, the EU limits for aflatoxin in hazelnuts were achieved, the consignment could be resubmitted for export to the EU. However, no evidence was provided that the CA monitored the re-processing and re-bagging, of non-compliant lots.

Customs authorities are responsible for allowing the re-introduction into the territory of Azerbaijan of consignments rejected at the EU border. However, there is no legal requirement for them to notify the return of the consignment to the CA. Therefore, no supervision can be made

Conclusions

The application of the GAP recommended in the Codex Code (CAC/RCP 59-2005, REV.1-2006) by hazelnut farmers met by the audit team was adequate. However, the current official control system does not provide guarantees that requirements at least equivalent to those laid down in Annex I to Regulation (EC) No 852/2004 are applied by all hazelnut farmers supplying hazelnut processors exporting hazelnuts to the EU.

All hazelnut processors visited had established HACCP based procedures. However, the official control on the implementation and the maintenance of these procedures was not always adequate

and some shortcomings were identified.

Some of the storage facilities of the processing establishments visited were not in line with the requirements for storage conditions at least equivalent to those laid down in section 2.8 of CAC/RCP 59-2005, Revisions 2006, 2010 and Chapter 1.2(c) and (d) of Annex II to Regulation (EC) No 852/2004.

There is a practice for re-sorting hazelnut consignments found non-compliant for export to the EU. However, as aflatoxin contamination was found in the analysed consignment and given the heterogeneous aflatoxin distribution in the consignment, this procedure does not provide equivalent assurances, as to the aflatoxin status of consignments certified for export to the EU, to those laid down in EU legislation.

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

Four CAs are involved in sampling and testing for aflatoxins in hazelnuts intended for export to the EU and issuing certificates or permission for export. All these CAs work independently on the basis of their own legislation.

The procedure for issuing by the MED of a quality certificate for export of hazelnuts to the EU was described in report DG (SANCO)/2009-8167. This procedure had been implemented by the CA very rarely. According to the export data provided by the CA, in 2010 and 2011 about 255 hazelnut consignments were exported to the EU. For that period the MED had issued only nine quality certificates for hazelnut exports to the EU (four in 2010 and five in 2011). The aflatoxin analysis, necessary for the issue of the quality certificate, were carried out in the laboratory of the RCHE of the MH. This laboratory performs only analysis for aflatoxin B_1 with a non-validated analytical method (see section 5.6.2). The audit team was provided with a quality certificate issued in 2011. The certificate stated that the hazelnuts were tested by the laboratory of the RCHE for determination of both aflatoxin B_1 and total aflatoxins and comply with the EU requirements.

According to the national provisions in place (Decision No 135 of 2005) hygiene certificate issued by the MH is required for each hazelnut consignment intended for export to the EU. The audit team noted at one of the processing companies visited, which had exported 49 hazelnut consignments to the EU in 2011, that only one hygiene certificate has been issued by the MH. Furthermore, the certificate was issued due to a request from the EU customer.

There are national provisions in place which require a phytosanitary certificate for export of foodstuffs. This certificate is issued by the SPCS of MA on the basis of analytical results only for aflatoxin B_1. The laboratory of the SPCS carries out the analysis using a non-validated analytical method (see also point 5.6.3). The phytosanitary certificate does not state whether the exported hazelnuts comply with the EU requirements.

There are Customs internal instructions in place (issued in 2006) which require consignments of hazelnuts intended for export to the EU to be sampled and analysed by the laboratory of the CCIC (see section 5.6.4). If the results of the analysis comply with the EU levels for aflatoxin B_1 and total aflatoxins, the consignments are released.

Conclusions

Hygiene and phytosanitary certificates for export of hazelnuts to the EU are issued on the basis of analytical results only for aflatoxin B_1 which is not in line with the requirements laid down in Regulation (EC) No 1881/2006.

The guarantees on whether the level of aflatoxins in hazelnuts exported to the EU are in line with maximum levels at least equivalent to those set out in Regulation (EC) No 1881/2006 is affected by the fact that export certificates currently issued are based on laboratory analysis performed with non-validated methods.

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 hazelnuts, the method of sampling is laid down in Annex I.D.

Codex Standard 193-1995 provides for a sampling plan for total aflatoxins in hazelnuts intended for further processing .

Findings

Most hazelnut consignments are exported by trucks and the typical consignment size is 18 – 22 metric tonnes. Official sampling of hazelnuts intended for export to the EU is carried out according to the procedure laid down in Decision No 3276 of 2007. The audit team noted that staff met from the CA and CCIC laboratory had inadequate knowledge on the provisions for subdividing big lots into sublots. They always take a 30 kg aggregate sample of hazelnuts from lots weighing more than 15 metric tonnes.

The CA stated that in the framework of the official controls samples for aflatoxin analysis are taken only in case of a request for issue of a quality certificate for export of hazelnuts to the EU or an investigation of RASFF notification. However, the audit team evaluated a sampling demonstration for a consignment of hazelnuts. The net weight of the consignment was 9,600 kg (120 bags of 80 kg). Company staff opened 10% of the bags (i.e. 12 bags) and from each one an incremental sample of 300 g was taken to produce an aggregate sample of 30 kg. Currently, the samples are sent for analysis to the laboratory of the RCHE of the MH. The audit team checked the laboratory's sample receipt log book and noted that the weight of the samples delivered to the laboratory was 3 kg.

In the SPCS laboratory visited, the size of the incoming samples was checked. The audit team noted that the size of the accepted samples widely varied.

At the CCIC laboratory the sample size submitted by the customs officials was 20 kg independently of the size of the sampled consignment (see section 5.6.4).

The findings above indicate that recommendation 2 *'Ensure that hazelnut consignments intended for export to the EU are sampled following the requirements at least equivalent to Commission Regulation (EC) No 401/2006*' of the report DG(SANCO)/2009-8167 has not been addressed (see section 5.1).

Conclusions

The sampling observed by the audit team was not in line with the requirements of Regulation (EC) No 401/2006 and recommendation 2 of the report DG(SANCO)/2009-8167 regarding sampling of hazelnuts intended for export to the EU has not 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.

Codex requirements for sample preparation and criteria for analytical methods to be used for testing of aflatoxins in hazelnuts intended for further processing are laid down in Codex Standard 193-1995.

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 Guide 17025.

Findings

The audit team visited four official laboratories under the MED, MH, MA and Customs authority.

5.6.1 Central Food Test Laboratory

This laboratory is the official control laboratory of CCEC (the CA) for aflatoxin analysis of hazelnuts intended for export to the EU. In 2012, it has obtained ISO 17025 accreditation by the Latvian National Accreditation Bureau (LATAK) for microbiological and chemical analysis. It was stated that this laboratory is the first food testing laboratory in Azerbaijan to receive ISO 17025 accreditation. The audit team noted that the aflatoxin analyses in hazelnuts are not included in the scope of the accreditation. This indicate that recommendation 3 *'Ensure that laboratories performing official controls are accredited under official recognised programs (ISO 17025) to ensure that adequate quality controls are in place to provide for the reliability of test results (point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997)*' has been partially addressed.

Currently, hazelnut samples are not analysed for aflatoxins in the laboratory. For the purpose of the quality certification procedure, the necessary aflatoxin analyses are carried out by the laboratory of the Republic Centre of Hygiene and Epidemiology under the MH.

The laboratory has 15 staff of which three staff is involved in the analysis of hazelnuts for aflatoxins. This staff has received training for the analysis at the Joint Research Centre, Institute for Reference Materials and Measurement, Geel, Belgium (certificates provided).

The method of analysis for aflatoxins in hazelnuts which is as outlined in ISO 14123:2007. A certificate of analysis for the commercially available mixed aflatoxin standard was provided as was a certificate of analysis for the immunoaffinity columns used in the method. The staff demonstrated the capability to prepare a set of five calibration standards, and generate satisfactory calibration curves with good chromatographic separation for aflatoxin B_1, B_2, G_1, and G_2 using HPLC, post-column derivatisation and fluorescence detection. However, no samples of hazelnuts have been analysed for aflatoxins to date.

The laboratory has not participated in any proficiency tests, the analytical method is not validated and no method performance parameters (e.g. recovery, precision etc.) or details about quality control checks were available. The laboratory stated that it proposed to carry out the validation of the analytical method in the context of the analysis of a proficiency test sample from a proficiency test provider during 2013 and apply for accreditation of the validated method from LATAK thereafter with the intention of completing the project by end 2013.

The audit team noted that while the laboratory has made good progress since the 2009 FVO audit, it has not yet validated an analytical method for the determination of aflatoxin in hazelnuts.

5.6.2 Laboratory of the Republic Centre of Hygiene and Epidemiology

This laboratory is within the MH and has 70 staff of which eight are responsible for the analysis of aflatoxins in hazelnuts. The laboratory is not accredited to ISO 17025 but is working to achieve this accreditation. This laboratory has been analysing hazelnuts for some years, e.g. 54 samples were analysed in 2011, and 11 samples have been analysed (to date) in 2012.

Official samples of hazelnuts (30 kg) are taken at the processors sites and a 3 kg sub-sample from this 30 kg is delivered to the laboratory for analysis. A sample receipt log book to record incoming samples was available for inspection. The laboratory staff described a procedure whereby a 250 g sample of nuts is taken from the 3 kg sub-sample, ground to a fine powder and then a 25 g sub-sample of this finely ground powder is subjected to analysis. The analytical method used is as described in GOST 30711:2001: 'Foodstuffs: Methods for detection and determination of aflatoxins B_1 and M_1 content'. Evidence was provided for the calibration of the balance used.

The analysis is performed using HPLC and post-column derivatisation and fluorescence detection. The staff demonstrated the capability to prepare a set of four calibration standards and generate calibration curves. The laboratory staff was not in a position to show a chromatogram for a sample that illustrated contamination with aflatoxins in any quantity. There is no validation report for the method and method performance parameters are not available.

The audit team noted that the analytical method used quantifies only aflatoxin B_1 which is not in line with the requirements laid down in Regulation (EC) No 1881/2006. The sample size used in the method of analysis is inappropriate for the reliable determination of aflatoxins contamination in hazelnuts. Furthermore, there is no validation report for the method used.

5.6.3 Laboratory of the State Phytosanitary Control Service

This laboratory has 16 employees, three of which are responsible for analysis of aflatoxins in hazelnuts. The laboratory is not accredited to ISO 17025. It began analysis of hazelnuts for aflatoxins in 2011. The laboratory analysed 476 samples in 2011 and 380 samples (to date) in 2012.

The analytical method employed is enzyme-linked immunosorbent assay (ELISA) using commercially available ELISA kits. This is a screening method for aflatoxin B_1. Samples complying with the limits for aflatoxin B_1 are logged retrospectively after the analysis has been completed and toxicology reports issued. Samples that do not comply with the legislative limit for aflatoxin B_1 are usually communicated by phone to the phytosanitary inspectors, who took the samples (this practice is not in line with clause 5.8.2 of ISO 17025), together with the instruction that the lot requires 'further sorting'. Standard operating procedure (SOP) and validation report for the method were not available, as well as details about quality control parameters (e.g. recovery etc.).

One major shortcoming of the whole analytical method is the sample size taken for the analysis. Usually three kg are delivered to the laboratory by the inspectors and a sub-sample of approximately 250 g is taken from this by the laboratory staff. For each individual analysis a sample of 5 g is taken from the 250 g sub-sample. This equated to approximately 7 - 10 individual hazelnuts for each analysis, depending on the size of the nuts. This approach can lead to a very high probability of false negative results for aflatoxin contamination.

The audit team noted that the analytical method used quantifies only aflatoxin B_1 which is not in line with the requirements laid down in Regulation (EC) No 1881/2006 and the traceability of all samples submitted to the laboratory is not available. The calibration of basic laboratory equipment used is not in place. The sample size analysed is inappropriate for the reliable determination of aflatoxins in hazelnuts.

5.6.4 Laboratory of the Central Customs Inspection Centre

This laboratory has 30 employees three of which are responsible for analysis of aflatoxins in hazelnuts. The laboratory is not accredited to ISO 17025 but is working to achieve this accreditation. The laboratory analysed 65 samples in 2011 and 26 samples in 2012 (to date). Samples are logged electronically in an Excel spreadsheet since the beginning of 2012.

The method used for the aflatoxin analysis in hazelnuts followed closely that described in ISO 14123:2007. Commercially available mixed stock standards (certificate of analysis was provided) and commercially available immunoaffinity columns are used. The laboratory has also purchased several certified reference materials for checking the performance of the analytical method. Five calibration standards are prepared and calibration curves with acceptable correlation coefficients were available for all four aflatoxins. Good chromatographic separation for aflatoxin B_1, B_2, G_1, and G_2 using HPLC, post-column derivatisation and fluorescence detection was achieved. A validation report for the method was available showing the usual parameters, recovery, precision, limit of detection, measurement uncertainty etc. These parameters are in line with those given in ISO 14123:2007. Control charts for recovery were available as was a procedure for dealing with non-conforming work. This indicates that Recommendation 6 *'Ensure that laboratory performance criteria for aflatoxin analysis follow the requirements at least equivalent to point 4.3.1 of Annex II to Regulation (EC) No 401/2006*' has been partially addressed as only this laboratory is currently capable of fulfilling this recommendation.

The laboratory has successfully participated in one proficiency round organised by a proficiency test provider (aflatoxins in almond paste) achieving Z-scores $\leq \pm 2$. A SOP for the method was available. This finding indicates that recommendation 4 *'Ensure that laboratories performing official controls are participating in proficiency testing schemes for food analysis to ensure that adequate quality controls are in place to provide for the reliability of test results (point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997)*' has been partially addressed as only this laboratory has participated in one proficiency test for aflatoxins in nuts.

Results for aflatoxin B_1 and total aflatoxins are reported with recovery rate and measurement of uncertainty. This indicates that recommendations 7 *'Ensure that there is a standard approach to the reporting of analytical results in relation to the rate of recovery and the expanded measurement of uncertainty, to ensure clear interpretation of results and to provide equivalence with the provision of Annex II to Regulation (EC) No 401/2006'* and 9 *'Ensure that hazelnuts consignments intended for export to the EU are analysed for both aflatoxin B1 and total aflatoxin (Regulation (EC) No 1881/2006) and comply with the maximum levels laid down in the above Regulation*' have been partially addressed as only this laboratory is currently capable of fulfilling these requirements

The typical sample size submitted by the inspectors to the laboratory is 20 kg. This is split into 2×10 kg sub-samples at the laboratory, one of which is stored and one analysed which is not in line with the requirements of Regulation (EC) No 401/2006. The 10 kg sample is ground to a fine powder and then homogenised in a laboratory knife mill. A 50 g sample from this homogenised 10 kg sub-sample is analysed. During the discussion with the laboratory staff, the audit team learned that 20 kg samples submitted by the customs inspectors have been taken from lots of hazelnuts greatly exceeding 20 tonnes without dividing the lot in sub-lots (e.g. the 20 kg sample traced in the laboratory was taken from a lot of 44 tonnes), which is not in line with the requirements of Regulation (EC) No 401/2006.

The audit team noted that the laboratory has made significant progress in implementing a validated method for aflatoxins analysis in hazelnuts since the last audit and is preparing for accreditation of this method in 2013. This indicates that recommendation 5 *'Ensure that laboratories performing official controls use methods of analysis which have been validated according to the principles laid down by the Codex Alimentarius Commission to ensure that adequate quality controls are in place to provide for the reliability of test results (point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997)*' has been partially addressed as only this laboratory has a validated method.

In all laboratories performing aflatoxin analysis of hazelnuts intended for export to the EU, suitable equipment is not available for the homogenisation of a 10 kg sub-sample of hazelnuts. This indicates that recommendation 8 *'Consider that laboratories designated for the analysis of aflatoxins in hazelnuts to be exported to the EU have the necessary equipment for grinding samples taken from large consignments to achieve complete homogenisation (Annex I to Regulation (EC) No 401/2006)*' has not been addressed.

Conclusions

At present there are three laboratories performing aflatoxin analyses in hazelnuts intended for export to the EU. All of them are not accredited for these analyses. This is not in line with the relevant Codex Alimentarius requirements (point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997).

The two laboratories of the SPCS and of the RCHE visited have not validated the analytical procedure which is not in line with the requirements laid down in point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997. The performance criteria for aflatoxins are not in line with the requirements at least equivalent to point 4.3.1 of Annex II to Regulation (EC) No 401/2006.

In both laboratories of the SPCS and of the RCHE visited estimation of measurement uncertainty is not undertaken and the recovery factor is not reported which is not in line with the requirements at least equivalent to Annex II to Regulation (EC) No 401/2006.

The sample preparation, in particular the homogenisation is only carried out in a part of the laboratory sample. This is not in line with the requirements at least equivalent to Regulation (EC) No 401/2006.

The grinding equipment used was not suitable for the proper homogenisation of the samples taken from large consignments. This is not in line with the requirements at least equivalent to Regulation (EC) No 401/2006.

These deficiencies in the performance of the laboratories visited affect the ability of the CAs to ensure that the hazelnuts exported to the EU do not contain aflatoxins exceeding the EU maximum levels listed in Regulation (EC) No 1881/2006.

All but one of the recommendations from report DG (SANCO)/2009-8167 addressing the laboratories performance have been partially addressed and the recommendation concerning availability of equipment for grinding samples taken from large consignments has not been

addressed.

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

The audit team was informed that the Delegation of Azerbaijan in Brussels receives RASFF notifications. The Food Unit within the CCEC is the responsible authority for follow-up of RASFF notifications concerning aflatoxins contamination in hazelnuts exported to the EU.

The CA informed the audit team that since 2009 they had not officially received any RASFF notifications within the context of this audit and no follow-up investigations were carried out. The CA does not have access to the RASFF window.

Conclusions

Since 2009 there is no adequate system in place for transmission of RASFF notifications to the CA and adequate RASFF follow-up were not carried out in the last 3 years in the context of the audit.

6 Overall Conclusion

Since the previous FVO audit, some progress has been made in improving the implementation of good agricultural practices and the laboratory performance by some of the official laboratories. The Competent Authority (CA) underwent reorganisation after the previous audit, at the end of 2009, which did not have an impact on the allocation of responsibilities. However, shortcomings (some already identified during 2009) related to the CA export procedure, staff knowledge on EU sampling requirements, management of the non-compliant lots, laboratory performance and follow-up of RASFF notifications were observed. These shortcomings affect the ability of the CAs to ensure that hazelnuts exported to the EU do not contain aflatoxins exceeding the maximum levels laid down in Regulation (EC) No 1881/2006.

In relation to the action plan provided by the CCA in response to the nine recommendations made following audit DG(SANCO)/2009-8167, the audit team found that two recommendations had not been addressed and seven had not been fully addressed.

7 Closing Meeting

A closing meeting was held on 22 November 2012 with the CCA and representatives of the SPCS laboratory under the MA, the RCHE laboratory under the MH, the CCIC laboratory and the EU

Delegation to Azerbaijan. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The CAs 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:

N°.	Recommendation
1.	Ensure that official staff involved in controls on aflatoxin levels in hazelnuts for export to the EU have adequate knowledge of the EU requirements on sampling for aflatoxin analysis to provide guarantees that the exported hazelnuts do not contain aflatoxins at levels exceeding those set out in Article 1 of Regulation (EC) No 1881/2006.
2.	Ensure that storage conditions in hazelnut storage facilities are in line with the requirements set out in Codex Alimentarius Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in tree nuts (CAC/RCP 59-2005, Revisions 2006, 2010) and Chapter 1.2(c) and (d) of Annex II to Regulation (EC) No 852/2004.
3.	Ensure that sampling procedures for aflatoxins analysis in hazelnuts intended for export to the EU meet requirements at least equivalent to those laid down by Commission Regulation (EC) No 401/2006.
4.	Ensure that hazelnut growers meet food hygiene requirements at least equivalent to those set out in Article 4(1) of Regulation (EC) No 852/2004.
5.	Ensure that hazelnut processors implement procedures based on HACCP principles in line with the requirements in Article 5 of Regulation (EC) No 852/2004.
6.	Ensure that laboratories performing official controls are accredited under officially recognised programs such as ISO 17025, participate in proficiency testing schemes for food analysis and use methods of analysis which have been validated according to the principles laid down by the Codex Alimentarius Commission, to ensure the reliability of the test results (point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997).
7.	Ensure that the aflatoxin analytical method used in laboratories involved in the official control of hazelnuts intended for export to the EU is in accordance with the performance criteria established in Regulation (EC) No 401/2006 to guarantee that hazelnuts meet aflatoxin limits foreseen in Article 1 of Regulation (EC) No 1881/2006.
8.	Ensure that there is a standard approach to the reporting of analytical results in relation to the rate of recovery and the expanded measurement of uncertainty, to ensure clear interpretation of results and to be in line with the provision of Annex II to Regulation

N°.	Recommendation
	(EC) No 401/2006.
9.	Ensure that samples for aflatoxin analysis in hazelnuts intended for export to the EU are finely ground and mixed thoroughly to achieve complete homogenisation in line with requirements equivalent to those laid down in Annex I to Regulation (EC) No 401/2006.
10.	Ensure that hazelnuts consignments intended for export to the EU are analysed for both aflatoxin B1 and total aflatoxin (Regulation (EC) No 1881/2006) and are in line with the maximum levels laid down in the above Regulation.
11.	Ensure that the necessary investigation is undertaken in response to all RASFF notifications on hazelnuts exported from Azerbaijan to the EU in order to determine the cause of any problem in line with point 6 of CODEX Guidelines CAC/GL 25-1997.

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=2012-6296

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
Reg. 882/2004	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
Reg. 669/2009	OJ L 194, 25.7.2009, p. 11-21	Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC

Annex 2 – Standards Quoted in the report

Reference number	Full title	Publication details
CAC/RCP 59-2005	Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005, Revisions 2006, 2010).	http://www.codexalimentarius.net/web/standard_list.jsp
CODEX STAN 193-1995	Codex General Standard for Contaminants and Toxins in Food and Feed	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