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FINAL REPORT OF A MISSION

CARRIED OUT IN

AZERBAIJAN

FROM 17 TO 25 NOVEMBER 2009

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

Executive Summary

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in Azerbaijan from 17 to 25 November 2009.

The objective was to assess the control systems in place to control aflatoxin contamination in hazelnuts intended for export to the European Union (EU).

There are a number of competent authorities (CAs) designated in the context of this mission. However, the lack of coordination and cooperation leads to an inconsistent export procedure.

The processing companies have established a traceability system but around 10% of the cases traceability to the individual farmers is not possible. This is not in line with 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).

The sampling carried out by the different CAs are not carried out following the requirements of Regulation (EC) No 401/2006.

Hazelnut consignments are only analysed on the basis of aflatoxin B1. Total aflatoxin levels are not tested. This is not in line with the requirements at least equivalent to Regulation (EC) No 1881/2006.

Important shortcomings have been identified in the laboratories visited. The two laboratories testing aflatoxins for hazelnuts intended for export to the EU are neither accredited to ISO 17025 nor participate in proficiency testing scheme (point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997). The analytical procedure has not been validated (point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997). The performance criteria for aflatoxins is not in line with the requirements at least equivalent to point 4.3.1 of Annex II to Regulation (EC) No 401/2006. Estimation of measurement uncertainty is not undertaken and the recovery factor is not reported (Annex II to Regulation (EC) No 401/2006). The limit of detection for aflatoxin B1 in one of the laboratories visited is higher than the EU maximum limit for aflatoxin B1 (Regulation (EC) No 1881/2006).

Since the RASFF notifications in 2005 and 2006, the CA has raised awareness of all stakeholders. Hazelnut farmers and processing companies have generally implemented good agricultural practices (GAP) and good manufacturing practices (GMP). However, the official control system set up for hazelnuts intended for export to the EU is not adequate due to the lack of cooperation and coordination between the CAs, the important deficiencies identified in relation to laboratory performance and sampling, and the limited knowledge by the CAs on the EU requirements.

The report makes a number of recommendations to the competent authorities of Azerbaijan to address the deficiencies noted.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
CA	Competent Authority
CCA	Central Competent Authority
CCEB	Consumer Commodity Expertise Bureau
EU	European Union
FBO	Food Business Operator
FSMQCU	Foodstuffs Safety Management and Quality Control Unit
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice
GOST	State Standards
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Point
HPLC	High Performance Liquid Chromatography
ISO	International Organisation for Standardization
LOQ	Limit of Quantification
MA	Ministry of Agriculture
MED	Ministry of Economic Development
MH	Ministry of Health
MS	Member States
RASFF	Rapid Alert System for Food and Feed

SCC	State Customs Committee
SCSMP	State Committee on Standardization, Metrology and Patent
SOCCM	State Office for Control of Consumer Market
SOP	Standard Operation Procedure

1 INTRODUCTION

The mission took place in Azerbaijan from 17 to 25 November 2009. The mission team comprised two inspectors from the Food and Veterinary Office (FVO) and one Member State (MS) expert.

The mission was undertaken as part of the FVO's planned mission programme.

The inspection team was accompanied during the mission by representatives from the central competent authority (CC) the State Office for Control of Consumer Market (SOCCM) of the Ministry of Economic Development (MED).

An opening meeting was held on 17 November on the premises of SOCCM, attended by representatives of SOCCM. At this meeting, the objectives of and itinerary for the mission were confirmed by the inspection team, and additional information required for the satisfactory completion of the mission was requested.

2 OBJECTIVES OF THE MISSION

The objective of the mission was:

- To verify whether the control systems are in place to control aflatoxin contamination in hazelnuts intended for export to the European Union (EU) within specified EU contaminant limits, complying with or being at least equivalent to Commission Regulation (EC) No 1881/2006.

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

Competent authority visits			Comments
Competent authority	Central	3	State Office for Control of Consumer Market (SOCCM) State Customs Committee (SCC) Ministry of Health (MH)
	Regional	1	Sheki-Zagatala region of the SOCCM
Laboratory visits		3	
Public laboratories		3	Customs laboratory, the laboratory of the Republic Centre of Hygiene and Epidemiology, and the Ministry of Economic Development laboratory
Farmers			

Hazelnut farmers	4	Sheki-Zagatala region: Qabala and Zagatala
Processing establishments		
Hazelnut processing and export companies	3	Baku and Sheki-Zagatala region

3 LEGAL BASIS FOR THE MISSION

The mission was carried out in agreement with the SOCCM of the MED and under the general provisions of Community legislation, in particular:

- Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

Full references to the acts quoted in this report are given in the Annex. Legal acts quoted in this report refer, where applicable, to the last amended version.

4 BACKGROUND

4.1 OVERVIEW OF PREVIOUS MISSIONS REGARDING AFLATOXIN CONTAMINATION IN FOODSTUFFS

The European Commission has carried out missions to Iran, Egypt, Turkey, China, Brazil, India, Argentina, USA, Ghana, Peru with the objective of evaluating official control systems for the prevention of aflatoxin contamination in foodstuffs originated from these countries. In addition, missions to 18 Member States (MS), with the objective of assessing controls on imported products of plant origin were carried out. The reports of these missions are available on the DG Health and Consumers Internet site at http://ec.europa.eu/food/fvo/ir_search_en.cfm.

4.2 BACKGROUND TO PRESENT MISSION

According to Article 15 (1) of Regulation (EC) No 882/2004, the Competent Authority (CA) shall carry out regular official controls on food of non-animal origin imported into the MS. These controls shall be carried out at the point of entry, the point of release for free circulation, warehouses, the premises of the importing feed and food operator, or other points of the food and feed chain as established in Article 15 (2). According to Article 16 (1) the official controls shall include at least a systematic documentary check, a random identity check and, as appropriate, a physical check.

Information of foodstuffs found to have public health implications are disseminated as alert notifications through the Rapid Alert System for Food and Feed (RASFF) to all MS and to the exporting country. From 2005 to the time of the mission 17 notifications relating to aflatoxins in hazelnuts from Azerbaijan have been notified through the RASFF. The break down of these notifications as well as the volume of imports into the EU is shown in table 1. Main importing MS

are indicated in brackets.

The mission team was informed that the annual hazelnut production in Azerbaijan is around 15,000 tonnes of which around 2,300 tonnes (hazelnut kernels, hazelnut paste and diced hazelnuts) were exported to the EU in 2008. This export volume differs from the one provided by Eurostat (see Table 1) and no explanation was given in this regard.

Table 1

Azerbaijan	Imports to EU (metric tonnes)	Number of alerts			
		2005	2006	2007	2008
Shelled hazelnuts (CN code 0802 22 00)	1,433 (DE, IT, PL)	11	5	0	1

Source: Eurostat, Comext database and RASFF database

4.3 FOOD PRODUCT INFORMATION RELATED TO PUBLIC HEALTH ISSUES

Aflatoxins are mycotoxins produced by certain species of *Aspergillus*, which develop at high temperatures and humidity levels and may be present in a large number of foods. The aflatoxin group includes a number of compounds of varying toxicity and frequency in food. Aflatoxin B1 is the most toxic compound. For safety reasons, it is advisable to limit both the total aflatoxin content (compounds B1, B2, G1 and G2) of food and the aflatoxin B1 content. In accordance with the Annex (Section 2) to Commission Regulation (EC) 1881/2006, the maximum admissible aflatoxin levels in groundnuts, nuts and dried fruit are as follows:

a) Groundnuts, nuts, dried fruit and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs:

2,0 µg/kg aflatoxin B1 content, and

4,0 µg/kg total aflatoxin content

b) Nuts and dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs :

5,0 µg/kg aflatoxin B1 content, and

10,0 µg/kg total aflatoxin content

Sampling also plays a crucial part in determining mycotoxin levels, which are very heterogeneously distributed in a consignment. Therefore, Commission Regulation (EC) No 401/2006 on the methods of sampling, and criteria for sample preparation and for methods of analysis was established to ensure that laboratories in charge of the analysis use methods of analysis with comparable levels of performance.

5 FINDINGS AND CONCLUSIONS

5.1 LEGAL REQUIREMENTS

Article 11 of Regulation (EC) No 178/2002 requires that food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto.

Article 10 of Regulation (EC) No 852/2004, in conjunction with Article 3 of the same Regulation, requires that Food business operators (FBOs) shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.

Article 10 of Regulation (EC) No 852/2004, in conjunction with Article 4.1 of the same Regulation, requires that FBOs carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in part A of Annex I.

Article 10 of Regulation (EC) No 852/2004, in conjunction with Article 4.2 of the same Regulation, requires that FBOs carrying out any stage of production, processing and distribution of food after those stages to which Article 4.1 applies shall comply with the general hygiene requirements laid down in Annex II.

Article 10 of Regulation (EC) No 852/2004 in connection with Article 5 of the same Regulation requires that FBOs shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

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

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

Article 1 of Regulation (EC) No 1881/2006 requires that the foodstuffs listed in the Annex of the same Regulation shall not be placed on the market where they contain a contaminant listed in the Annex at a level exceeding the maximum level set out in the Annex.

5.2 RELEVANT NATIONAL LEGISLATION

Findings

The main legislation in the context of this mission is as follows:

1. Decree No 609 of 24 June 1997 of the President of the Republic of Azerbaijan on import and export operations. It lays down the list of exporting goods (clause 14.4) including hazelnuts which are subject to specific documentation (e.g. registration of FBOs under State Statistic Committee, contract with importers, certificate of origin from the MED, customs declaration).
2. Law of the Republic of Azerbaijan on foodstuffs of 31 Jan 2000 as amended. It is the

framework law in relation to food safety. It contains among other thing provisions on management of foodstuffs quality and safety, foodstuffs production, storage and transportation of foodstuffs.

3. Decree No 969 of 23 October 2003 of the President of the Republic of Azerbaijan. It identifies the responsible CAs in the area of official control of foodstuffs.
4. Decree No 218 of 1 April 2005 of the President of the Republic of Azerbaijan on “regulation of controlling export of fishery and other products from the Azerbaijan to the EU” as amended by Decree No 403 of 2006. It lays down that the MED of the Republic of Azerbaijan is the CA responsible for official controls of foodstuffs intended to be exported to the EU. It also requires that FBOs willing to export to the EU must be registered (approval code number) under the above Ministry.
5. Decision No 135 of 13 July 2005 of the Cabinet of Ministers. It establishes the certification requirements of foodstuffs exported to the EU. However, as far as the quality certificate for hazelnuts intended for export to the EU from the MED is concerned this Decision has not been implemented yet. The mission team was informed that this Decision will be implemented once the above Decree No 609 be amended taking into accounts the requirements of this Decision.
6. Decision No 3276 dated on 12 Jan 2007 which are implementing rules of Decree 218 of 2005. It lays down provisions, among other things, on hygiene, HACCP and sampling regarding foodstuffs of plant origin intended to be exported to the EU. These provisions are equivalent to some aspects of Regulations (EC) No 852/2004 and Regulation (EC) No 401/2006.
7. Decision No 142 of 25 September 2007 of the Cabinet of Ministers. It lays down the requirements regarding the application of the certificates required in the above Decision No 135.

Conclusions

There is a set of legislation in the context of this mission including some provisions which are equivalent to the relevant requirements regarding Articles 4 and 5 of Regulation (EC) No 852/2004 and Regulation (EC) No 401/2006 regarding sampling. However, the national provisions regarding the quality certificate for hazelnuts have not been implemented yet.

5.3 COMPETENT AUTHORITIES

Findings

5.3.1 The State Office for Control of Consumer Market (SOCCM)

The main CA for this mission is the SOCCM. SOCCM is an executive body under the umbrella of the MED. Under the SOCCM the relevant authority responsible for official control for hazelnuts intended for export to the EU is the Consumer Commodity Expertise Bureau (CCEB), specifically the Foodstuff Safety Management and Quality Control Unit (FSMQCU).

The CCEB is responsible for the following main tasks:

- To conduct official controls on the quality and safety of foodstuffs including hazelnuts exported to the EU;
- To give the approval code numbers and compile the register of food establishments meeting the requirements of the EU;
- To withdraw the approval code numbers of food establishments not meeting the requirements and stop the export of the products to the EU;
- To carry out sampling and analysis for export purposes.

There are six regional offices of the CCEB nationwide but only two (Baku and Sheki-Zagatala) come under the scope of this mission.

There are 8 staff working in the FSMQCU central level, and communication between this Unit and the two regions concerned are held regularly. In the context of this mission official controls are always carried out by inspectors of the central office. In the Sheki-Zagatala region a new inspector has recently been recruited and this newcomer is participating in the inspections along with the inspectors from central level. The mission team was informed that the new inspector will start performing the inspections and sampling in this region at the end of 2010.

There are monitoring plans (inspection and sampling) which are drawn up by the above Unit on an *ad hoc* basis. The monitoring plan for 2008 comprised the period from 15 June to 15 September but it was extended to the end of November. During this period all authorised companies (18) were inspected and sampled for aflatoxin purposes, and as a result a number of shortcomings were identified. A deadline was given to the companies to address the deficiencies. In 2009, there was no monitoring program and no sampling was undertaken in any of the 18 authorised companies. In this year only 4 companies, which exported hazelnuts to the EU last year, have been inspected by Unit inspectors and CA stated that the remaining 14 will be inspected at the end of this year.

There is an ongoing training program as part of a twinning project which started in September 2008 and will finish in September 2010. This training is given by a consortium of the Netherlands and Latvia and supported by the European Commission. The subjects given were the Regulations (EC) No 852, 854, 178 and 882. In addition, in-service training has been organised between last year and this year concerning HACCP, ISO 9001 and 22000, risk assessment, Codex Alimentarius and analysis on mycotoxins. The mission team examined the training files of the relevant inspectors and evidence of assistance to relevant training sessions was seen. However, no training has been given in relation to Regulation (EC) No 401/2006. The CA stated that there is a training project next year in relation to the issue of aflatoxin contamination in hazelnuts. The tender will be finished in January 2010 and the CA expect to start working on it in February 2010. The aim is to conduct training for the relevant staff of the CCEB and laboratories staff regarding production, processing of hazelnuts, and in relation to official control (inspection, assessment of HACCP plan, ISO 22000). Sampling and testing following the EU requirements are also part of this project.

There is no supervision from CCEB to the 2 regional offices in the context of this mission as official controls are always carried out by inspectors of the central office. The mission team was informed that this situation will change in one year in the Sheki-Zagatala region once the inspector finishes her one-year training period. In addition, a regional laboratory will be equipped for undertaking aflatoxin analysis.

In the area of cultivation, the CA responsible for the training and guidance of good agricultural practice (GAP) is the CCEB (see point 5.4.1).

5.3.2 State Customs Committee

The State Customs Committee (SCC) is the CA who has the ultimate responsibility for releasing hazelnut consignments outside Azerbaijan in the context of this mission. This Committee has a ministerial rank and is chaired by a Chairman (Minister). Under the Chairman there are a number of units at central level and each unit has different departments. There are 13 regional offices including the autonomous areas nationwide.

The main piece of legislation for Customs is the Decree No 609. The mission team was informed that as a result of the number of non-compliant hazelnut consignments detected in the EU coming from Azerbaijan and notified through the RASFF system in 2005 the Chairman of the SCC issued an internal instruction on 19 January 2006 which was addressed to all regional customs offices. This letter instructed the regional offices to pay particular attention to the issue of aflatoxin in hazelnuts and walnuts. Further implementing instructions were sent to the regional offices indicating that each consignments of walnuts and hazelnuts had to be sampled and tested prior to export.

Customs is also responsible for rejected consignments (see also point 5.4.3). These consignments are not considered as imports.

5.3.3 Other organisations

There are also 3 other CAs involved in the context of this mission, namely the Ministry of Health (MH), the Ministry of Agriculture (MA) and the State Committee on Standardization, Metrology and Patent (SCSMP).

The MH is responsible for issuing the hygiene certificate in the context of this mission. This means that they also perform inspections, sampling and analysis of aflatoxins in hazelnuts intended to be exported to the EU. The inspection and sampling are carried out by the regional offices inspectors.

The MA is responsible for issuing the phytosanitary certificate whereas the SCSMP issues the conformity certificate which is related to equipment used in the processing companies and laboratories. The SCSMP is also responsible for the accreditation of laboratories.

In the context of this mission, the MED, the MH and the SCC are performing sampling and analyses independently and without coordination (see point 5.6). However, the mission team was informed that several meetings were held between MH, MA, SCSMP and the MED in relation to simplify the certification requirements. Some international consultants have also participated in these meetings. No minutes of these meetings were produced.

Conclusions

There are several CAs designated in the context of this mission. However, the lack of coordination and cooperation leads to an inconsistent export procedure.

Although an adequate training has been received by the MED staff no specific training on the requirements of Regulation (EC) No 401/2006 regarding sampling has been carried out.

5.4 PROCESS CONTROLS IN THE NUT PRODUCTION CHAIN

5.4.1 Hazelnut cultivation

Findings

The hazelnut growing area in Azerbaijan is the Sheki-Zagatala region which is located on the South flank of the Great Caucasus in the north-west part of Azerbaijan. The total cultivation area is 16,000 hectares (ha)

Hazelnut farmers generally have their own orchards and the size of these orchards varies from less than 2 ha to over 300 ha. All hazelnuts are purchased by the hazelnut processing companies either directly from farmers (around 90%), from middlemen, or from the local market.

The mission team met 4 hazelnut farmers who deliver hazelnuts to the processing companies visited. It was stated by the farmers that no neighbouring fields are used for plants (e.g. maize) which are known to be easily infected with *A.flavus/parasiticus* . The mission team was also informed that no pesticides are used and no irrigation is implemented in this region as there is enough rainfall during the growing season (between February and May).

The harvest period ranges from August to October. At the farmers visited, hazelnuts are harvested by shaking the trees manually. The nuts are collected on protective sheets (tents made of polypropylene). The hazelnuts are separated from their cover leaves and then left on the covered floor where the main sun-drying process takes place. Depending on the weather conditions, the total drying span can take two weeks (from 3 to 15 days).

Different sun-drying techniques (drying on the ground by means of polypropylene sheets or asphalt floor) were used. The area visited by the mission team where the nuts are sun-dried on asphalt floor was not fully protected to prevent cattle from entering (e.g. cow droppings were observed). Some of the farmers met stated that the sun-drying process finishes when the farmer considers that the hazelnuts are dry enough after breaking the kernels with the fingers. However, others stated that samples were sent to the processing companies for checking the moisture level. The records of one the processors visited showed that the moisture level varied from 8 to 22%.

The sun-dried hazelnuts are usually collected at the farms by the processors. The farmers stated that transport to the the processors happens close to the harvest.

All the farmers visited declared to have received training on GAP including the issue of aflatoxins at a workshop organised by the MED in Baku before the harvest. Leaflets, which were published on 2006, on how to prevent aflatoxin contamination in foodstuffs of plant origin were provided to the farmers.

Some general information on the issue of aflatoxins in nuts has been published by the national association of nut farmers.

Conclusions

The CCEB has taken measures to raise awareness of producers for the risk of aflatoxin contamination.

In general, the farmers visited followed the recommended practices based on GAP established in the Code of practice of the Codex Alimentarius for the prevention and reduction of aflatoxin contamination in tree nuts (CAC/RCP 59-2005).

5.4.2 *Hazelnut processors visited*

Findings

The companies willing to export to the EU must apply to the MED to get an approval code number following the national requirements of Decree 403 and Decision No 3276. Currently, there are 18 approved hazelnut processing companies to export to the EU by the MED. Three are located in Baku and the remaining 15 are in Sheki-Zagatala region. According to Decision No 3276 processing companies are required to establish procedures based on HACCP principles. The CA stated that the HACCP plans in all the 18 authorised companies have been endorsed by the CA.

The mission team visited three hazelnut processing companies out of 4 which exported hazelnuts to the EU last year and also examined inspection procedures there. All the companies were subjected to a systematic documented inspection and have food safety procedures based on HACCP principles. All these companies have got the approval code number as required by the Decree No 403.

In all hazelnut processors visited internal checks were performed with regard to moisture level (before and after drying), and a number of quality checks (e.g. rotten mouldy level, empty and damaged nuts) at reception and in the final product. In addition, one company performed semi-quantitative aflatoxin analyses of the finished product. During processing, hazelnuts are dried to moisture level of 5-6%, sorted and handpicked to remove damaged and mould affected kernels.

In the companies visited traceability is possible to the individual farmers as the processing companies are required to complete a document of origin which identifies the name of the farmers. However, the CA stated that this is not the case when hazelnuts come from middlemen or supplied from the local market (around 10% of the cases).

Conclusions

All companies visited had established procedures based on HACCP principles and established good quality controls.

Traceability is not always possible which is not in line with the Code of practice of the Codex Alimentarius for the prevention and reduction of aflatoxin contamination in tree nuts (point 33-CAC/RCP 59-2005).

5.4.3 *Non-conforming products*

Findings

As mentioned earlier, Customs is responsible for allowing the re-introduction of rejected consignments into the territory of Azerbaijan. However, there is no legal requirement from Customs to notify the return of this consignment to any CA. Therefore, no supervision can be made.

With regard to rejected consignments in the EU coming from Azerbaijan the mission team was informed by the MED that only one consignment was sent back to Azerbaijan in September 2006. In this case, the MED was aware of this rejected consignment because the company concerned applied to the MED for placing the consignment on the local market. The mission team was informed by the MED that they can also get this information when receiving the RASFF notifications. No notification from customs to the MED was done regarding this consignment. When the MED received the application, inspectors from this Ministry carried out an inspection and took samples of this consignment. The samples were sent to a private laboratory in Dubai for

aflatoxin analysis. As the results of the analysis were in compliance with the EU legislation the hazelnuts were placed on the Azerbaijani market. With regard to the inspection carried out at the company, nearly twenty shortcomings were identified mainly related to hygiene requirements. The company provided an action plan and a follow up inspection was subsequently made in January 2007.

Conclusions

Although there is no communication between Customs and MED in relation to the return of rejected consignments from the EU an adequate supervision by the MED was carried out regarding the only rejected consignment.

5.5 METHOD OF SAMPLING FOR NUT CONSIGNMENTS

5.5.1 Sampling procedure

Findings

The Decision No 3276 lays down the requirements of sampling following Regulation (EC) No 401/2006.

In 2009, the MED inspectors have not taken any samples for aflatoxin purposes. However, the mission team evaluated a sampling demonstration for a consignment of hazelnuts. The net weight of the consignment of hazelnuts was 20,000 kg (250 bags of 80 kg). Company staff took 100 incremental samples of 300 g each from 100 selected bags to produce an aggregate sample of 30 kg. The formula for the sampling of lots traded in individual bags was used. The aggregate sample was then divided into three equal laboratory samples of 10 kg each which was mixed, labelled and sealed in the presence of the MED inspectors. Two laboratory samples are taken by the MED inspectors and the remaining laboratory sample was kept by the company concerned. This is not in line with the requirements of Regulation (EC) No 401/2006 and the national provisions (Decision No 3276).

The mission team checked files of the sampling carried out by the regional health inspectors at the laboratory of the Republic Centre of Hygiene and Epidemiology. Although it was stated that the weight of the aggregate sample was 30 kg for lots more than 15 tonnes only 3 kg was taken as a laboratory sample and sent to this laboratory. This is not in line with the requirements of Regulation (EC) No 401/2006 and the national provisions (Decision No 3276).

The mission team also checked the weight of the laboratory samples at the Customs laboratory. The weight of this sample was 3 kg and only one laboratory sample was taken for lots weighing more than 15 tonnes. This is not in line with the requirements of Regulation (EC) No 401/2006 and the national provisions (Decision No 3276).

Conclusions

The sampling procedures carried out by the CAs in hazelnuts intended for export to the EU were not in line with the requirements of Regulation (EC) No 401/2006.

5.6 PROCEDURE FOR EXPORTING NUTS TO THE EU

Findings

The majority of hazelnut consignments are exported to the EU by lorry through Russia and to a lesser extent through Georgia where they are then shipped from the Batumi or Poti ports. Most of the consignments are exported to Germany, Italy and Poland and transport takes between 9 to 15 days.

According to Decrees No 135 and 403, hazelnut processing companies willing to export to the EU have to apply to the MED among other things for the quality certificate. This certificate is issued for each consignment once the analysis of the samples taken for each consignment meet the EU requirements.

There are also national provisions in place which require the hygiene certificate issued by the MH for each hazelnut consignment intended to be exported to the EU. However, this certificate is issued on the basis of the State standard which establishes a maximum level of 5 ppb for aflatoxin B1 in hazelnuts for direct human consumption which is not in line with the requirements of Commission Regulation (EC) No 1881/2006.

In addition, when hazelnut processing companies lodge a Customs declaration prior to export, customs officials following their internal instructions issued in 2006, perform also sampling and analyses for each consignment of hazelnuts. The Customs legislation, in particular the Decree No 609 does not require neither the presence of the quality certificate nor the hygiene certificate and therefore, the consignments can be exported without these certificates. For this reason, the MED has decided not to implement the requirements of the quality certificate. Moreover, the MH confirmed that no hygiene certificates have been issued in 2009 for one of the hazelnut processing companies visited and this company has exported to the EU in 2009.

As far as Customs procedures are concerned, the customs clearance take place once the hazelnuts are only tested for the levels (2 ppb) of Aflatoxin B1. This is not in line with the requirements of Commission Regulation (EC) No 1881/2006 as the total aflatoxins are not tested.

The mission team was informed that the hazelnuts are containerised at the company and a representative of Customs supervises the loading of the container and then seals the container.

Conclusions

Hazelnuts consignments are mainly shipped to the EU by lorry through Russia.

Hazelnuts consignments exported to the EU are analyzed by MH on the basis of only aflatoxin B1. Moreover, the hazelnut limit of aflatoxin B1 for direct human consumption established by this Ministry is 5 ppb. This is not in line with the requirements of Regulation (EC) 1881/2006.

Hazelnuts consignments exported to the EU are only analyzed by Customs on the basis of aflatoxin B1, which is not in line with the requirements of Regulation (EC) 1881/2006.

5.7 LABORATORY SERVICES

Findings

5.7.1 General organisation

Currently, there are 2 laboratories performing aflatoxins analyses in hazelnuts intended for export to the EU, namely the Customs laboratory and the laboratory of the Republic Centre of Hygiene and Epidemiology. There is another laboratory under the MED which is not operational yet.

5.7.2 Laboratories visited

The mission team visited the above three laboratories and a description of all of them is as follows:

Customs laboratory.

In the context of this mission, the Customs laboratory only performs analysis for aflatoxin B1. The Customs laboratory visited employs 2 staff for the analysis of aflatoxins apart from the Director. Both the Director and one of the persons involved in the analysis have received specific training in mycotoxin analysis in the EU in 2008. Training records of these staff were shown to the mission team. This laboratory is neither accredited to ISO 17025 (point 41 of CAC/GL 26¹-1997 and point 3 of CAC/GL 27²-1997) nor participated in proficiency testing schemes (point 3 of CAC/GL 27-1997) and it is not audited for the determination of aflatoxins. Although it was stated that some quality control activities are performed, the quality control scheme has not been formally established. The laboratory uses the document “GOST 30711 – 2001: Methods for the detection and determination of aflatoxin B1 and M1 content” issued by the Intergovernmental Council for Standardization, Metrology and Certification in Minsk, as standard operation procedure (SOP) for the determination of Aflatoxin B1 in hazelnuts. The analytical procedure is based on the extraction of the aflatoxin B1 from samples of 25 g in size. After addition of a solution of sodium chloride and acetone, cleanup is performed by sequential treatment with lead acetate solution, hexane, acetone and chloroform. The determination of Aflatoxin B1 is carried out by HPLC with fluorescence detection without any kind of derivatisation. The procedure uses aflatoxin B2 as internal standard. Although that SOP uses a single standard concentration in the estimation of the toxin level instead of calibration curves, the laboratory uses calibration curves built with 3 or 5 calibration points. The laboratory does not check spectrophotometrically the real concentration of the received commercial aflatoxin standard.

The laboratory has not validated the analytical procedure (point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997). The mission team was informed that the laboratory does not keep records of the raw data. This does not allow traceability to the analysis performed both for samples and quality control. Estimation of measurement uncertainty is not undertaken and the recovery factor is not reported (Annex II to Regulation (EC) No 401/2006). The mission team was informed that typical recovery range varied from 65 to 80 % for a concentration range between 3 to 20 ppb for aflatoxin B1. However, this recovery range was not fully in line with the requirements at least equivalent to those laid down in point 4.3.1 of Annex II to Regulation (EC) No 401/2006.

The grinding equipment used was not appropriate for the preparation of the samples taken from large consignments according to Regulation (EC) No 401/2006.

In 2008, 78 samples of hazelnuts were analyzed and 4 of them came from lots to be exported to the EU. None of them exceeded the EU limits for aflatoxin B1. From 2009 to the time of the mission 488 samples were tested for aflatoxin B1 of which 108 samples belonged to lots destined for export to the EU. Six of them were found to be above the EU limits.

Laboratory of the Republic Centre of Hygiene and Epidemiology

This laboratory only performs analysis for aflatoxin B1. The laboratory visited employs 5 staff for the determination of aflatoxins. This laboratory is neither accredited to ISO 17025 (point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997) nor participated in proficiency testing schemes (point 3 of CAC/GL 27-1997) and it is not audited for the determination of aflatoxins. The quality

1 Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification system.

2 Guidelines for the assessment of the competence of testing laboratories involved in the import and export control of food.

control scheme for the analysis of aflatoxin B1 has not been formally established. The laboratory uses also the document “GOST 30711 – 2001 as SOP for the determination of Aflatoxin B1 in hazelnuts. The analytical procedure is based on the extraction of the aflatoxin B1 from samples of 25 g in size. The laboratory receives normally a laboratory sample of 3 kg and grinds then 0.5 kg for analysis. According to this SOP the laboratory uses a single standard concentration for the estimation of the toxin level instead of calibration curves. The laboratory does not check spectrophotometrically the real concentration of the received commercial aflatoxin standard. This laboratory uses post column bromine derivatisation by using a Cobra cell

The laboratory has not validated the analytical procedure (point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997). Estimation of both measurement uncertainty and the recovery factor are not made (Annex II to Regulation (EC) No 401/2006). The LOQ is 5 ppb, which is above the EU legal limit for aflatoxin B1 (Regulation (EC) No 1881/2006). The performance criteria (recovery, precision) was not set up (point 4.3.1 of Annex II to Regulation (EC) No 401/2006).

The grinding equipment used was not appropriate for the preparation of the samples taken from large consignments according to Regulation (EC) No 401/2006. Some equipment (syringes) is not calibrated.

In 2008 and 2009, 146 and 66 samples of hazelnuts coming from lots to be exported to the EU were analysed respectively.

The MED laboratory

The MED laboratory has recently received some equipment in the context of this mission. The laboratory has started to implement the analytical procedure for both B1 and total aflatoxins in nuts. The mission team was informed that this laboratory will move to another premises by the end of this year.

Conclusions

At present, there are 2 laboratories performing aflatoxins analyses in hazelnuts intended for export to the EU. None of them were accredited to ISO 17025 nor participated in any proficiency testing scheme. This is not in line with point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997.

The two laboratories 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 is not in line with the requirements at least equivalent to point 4.3.1 of Annex II to Regulation (EC) No 401/2006.

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 appropriate for the preparation of the samples taken from large consignments according to Regulation (EC) No 401/2006.

The LOQ for aflatoxin B1 in one of the laboratory visited is higher than the EU legal limit for aflatoxin B1 (Regulation (EC) No 1881/2006).

5.8 RESPONSE TO RASFF NOTIFICATIONS

Findings

The Azerbaijan Ministry of Foreign Affairs receive the RASFF notifications through the Azerbaijan embassy in Brussels from the Commission services who in turn submits this information to the Cabinet of Ministers. In the context of this mission the RASFF notifications reached the relevant CAs such as Customs, the MH, the MED, the MA and the Ministry of Environment.

For those processing companies notified through the RASFF system in 2005 and 2006, an awareness campaign on the issue of aflatoxins in nuts was undertaken by the MED once this Ministry was nominated by means of Decree No 403 as a CA in the context of this mission in 2006.

With regard to the company which was notified through the RASFF system on 18 September 2008 from the Commission services, the Ministry of Foreign Affairs was informed on 2 October 2008 and passed this notification on to the Cabinet of Ministers two days after who in turn passed this notification to the relevant CAs on the 6 October 2008. The CCEB of the MED received this information two days after and contacted the company concerned the following day by fax. The company was requested to provide clarifications on the contaminated consignment which was sampled as part of the market control by one MS. The hazelnut consignment consisted of one lot of 20 tonnes which was shipped to the EU through Georgia on 27 December 2007. The consignment was not sent back to Azerbaijan as the product was already on the EU market. A report of the investigation was sent from the MED to the Cabinet of Ministers on 11 November 2008.

Conclusions

RASFF notifications have reached the relevant CA and adequate investigations were carried out.

6 OVERALL CONCLUSIONS

Since the RASFF notifications in 2005 and 2006, the CA has raised awareness of all stakeholders. Hazelnut farmers and processing companies have generally implemented GAP and good manufacturing practice (GMP). However, the official control system set up for hazelnuts intended for export to the EU is not adequate due to the lack of cooperation and coordination between the CAs, the important deficiencies identified in relation to laboratory performance and sampling, and the limited knowledge on the EU requirements.

7 CLOSING MEETING

A closing meeting was held on 25 November with the central competent authority, MED and representatives of Customs were also present. At this meeting, the main findings and conclusions of the mission were presented by the inspection team.

The representatives of the MED and Customs offered initial comments but they did not express any major disagreement with these findings and conclusions.

8 RECOMMENDATIONS

To the competent authorities of Azerbaijan.

An action plan in response to the recommendations should be forwarded to the Commission within 25 days of receipt of the report. This action plan should clearly set out the manner and deadline by which the competent authorities will address each of the following recommendations:

N°.	Recommendation
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.
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.
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).
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).
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).
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.
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.
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).

N°.	Recommendation
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.

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

http://ec.europa.eu/food/fvo/ap/ap_az_2009-8167.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
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. 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. 2076/2005	OJ L 338, 22.12.2005, p. 83-88	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
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. 315/93	OJ L 37, 13.2.1993, p. 1-3	Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food
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. 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

Legal Reference	Official Journal	Title
Dec. 2006/504/EC	OJ L 199, 21.7.2006, p. 21-32	2006/504/EC: Commission Decision of 12 July 2006 on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins