EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2010-8594 - MR FINAL

FINAL REPORT OF A MISSION

CARRIED OUT IN

IRAN

FROM 11 TO 20 OCTOBER 2010

IN ORDER TO ASSESS THE CONTROL SYSTEM IN PLACE TO CONTROL AFLATOXIN CONTAMINATION IN PISTACHIO NUTS INTENDED FOR EXPORT TO THE EUROPEAN UNION AND TO FOLLOW UP THE RECOMMENDATIONS OF MISSION DG SANCO 7670/2005

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

Executive Summary

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in the Islamic Republic of Iran from 11 to 20 October 2010.

The objective was to assess the control systems in place to control aflatoxin contamination in pistachio nuts intended for export to the European Union (EU) and the action taken by the competent authorities (CAs) in response to the recommendations made by the FVO in report SANCO 7670/2005.

No major changes have been made in the responsibilities for controls on pistachio exports to the EU. Since the last mission progress has been made on adopting new requirements and procedures for official controls, in particular regarding sampling of exports to the EU, registration of food establishments, food hygiene requirements and HACCP. Tangible progress has been made on implementing good practices in pistachio cultivation and processing.

Pistachios for export to the EU market could still originate from farms that are not implementing good agricultural practices (GAP) and do not apply the principles of integrated pest management (IPM). The level of HACCP implementation by the pistachio processors exporting to the EU is low.

Despite all the efforts made, the number of consignments of pistachios not complying with the EU limits on aflatoxins, whether presented in Iran for export to the EU or at EU borders for import, is still high, adding up together to over 20 % (2009 data). The current system of sanctions against exporters who try to export consignments that are not in compliance with the legal requirements on aflatoxins is not effective, as it takes no account of the pre-export rejection rate.

Considerable improvements have been made since the last mission at all the laboratories visited regarding their quality management system and quality controls. However, accreditation of all official laboratories is still lacking. In addition, certain aspects identified in the laboratories' performance still do not comply with the criteria established by Regulation (EC) No 401/2006.

Overall, good procedures are in place for official controls on pistachios intended for export to the EU. Improvements have been made since the last mission to rectify deficiencies in the procedures. However, there are still deficiencies, particularly in laboratory accreditation and application of the criteria established by Regulation (EC) No 401/2006. Although good progress has been made since the last mission on implementation of GAP, IPM and Good Manufacturing Practice (GMP) in pistachio cultivation and processing, further efforts are needed to reduce the number of consignments of pistachios intended for export to the EU which do not comply with the EU limits on aflatoxins.

This report contains recommendations to the CAs of the Islamic Republic of Iran with the aim of addressing the shortcomings identified.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AOAC	Association of Official Analytical Chemists
BC	Blue Corridor
CA	Competent Authority
CAC/RCP	Codex Alimentarius Committee/Recommended Code of Practice
CCA	Central Competent Authority
CN	Combined Nomenclature
EU	European Union
FCL	Food Control Laboratory
FDCL	Food and Drug Control Laboratory
FDO	Food and Drug Office
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice
GMP	Good Manufacturing Practice
GSP	Good Storage Practice
HACCP	Hazard Analysis and Critical Control Points
HPLC	High Performance Liquid Chromatography
IPA	Iran Pistachio Association
IPM	Integrated Pest Management
IPRI	Iran Pistachio Research Institute
ISIRI	Institute of Standards and Industrial Research of Iran
ISO	International Organisation for Standardisation
MoA	Ministry of Agriculture of Jihad
MOHME	Ministry of Health and Medical Education
MS	Member State
NSPC	National Supreme Pistachio Council
RASFF	Rapid Alert System for Food and Feed
SANCO (DG)	Health and Consumers Directorate-General
SOP	Standard Operating Procedure
TC	Third Country
U	Measurement uncertainty

1 Introduction

The mission took place in the Islamic Republic of Iran (hereinafter referred to as 'Iran') from 11 to 20 October 2010 in order to assess the control systems in place to prevent aflatoxin contamination in pistachio nuts intended for export to the EU. The mission team consisted of 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 annual mission programme in order to follow up developments in Iran since the previous FVO mission (SANCO 7670/2005).

During the mission the inspection team was accompanied by the representative of the central competent authority (CCA), the Ministry of Agriculture of Jihad (MoA).

An opening meeting was held on 11 October 2010 with the CCA (MoA), including the representatives of the Ministry of Health and Medical Education (MOHME), the Institute of Standards and Industrial Research of Iran (ISIRI), the Iran Customs Agency, the Iran Port Authority, the Iran Chamber of Commerce, Industry and Mines, Iran Pistachio Association (IPA) and Kerman Chamber of Commerce. At this meeting, the objectives of and itinerary for the mission were confirmed.

2 Objectives Of The Mission

The **objectives** of the mission were to:

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

– assess compliance with conditions in Commission Regulation (EC) No 1152/2009 on special conditions governing certain foodstuffs imported from certain third countries (TC) due to contamination risks of these products by aflatoxins;

– follow up recommendations made in the previous report (SANCO 7670/2005).

In terms of **scope**, the mission reviewed the controls in place on production and exports, including the national legislation in place, organisation of the competent authorities (CA) and their controls and enforcement capability.

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

Competent authority/ies		Comments
Central Competent Authorities	3	MoA MOHME Iran Customs Agency
Regional/local Competent Authorities	2	Food and Drug Office (FDO) of the MOHME, Kerman FDO of the MOHME, Rafsanjan
Laboratories	3	Food and Drug Control Laboratory (FDCL),

		Tehran Food Control Laboratory (FCL), Kerman FCL, Rafsanjan
PRODUCERS		
	5	One pistachio orchard in Rafsanjan Four pistachio orchards in Kerman
PROCESSORS		
	5	Three pistachio processors in Rafsanjan Two pistachio processors in Kerman
POINTS OF EXPORT		
	1	Kerman customs office
OTHER SITE VISITS/MEETINGS		
	1	Chamber of Commerce in Kerman

3 LEGAL BASIS FOR THE MISSION

3.1 LEGAL BASIS FOR THE MISSION

The mission was carried out 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 which stipulates that Community controls in TCs may verify the compliance or equivalence of TC legislation and systems with Community feed and food law and Community animal health legislation. These controls must have particular regard to the assurances which the TC can give regarding compliance with, or equivalence to, Community requirements.

3.2 LEGAL STANDARDS

Article 11 of Regulation (EC) No 178/2002 stipulates 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 stipulates that as regards the hygiene of imported food, the relevant requirements of food law referred to in Article 11 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of the Regulation.

Annex to Regulation (EC) No 1881/2006 sets out maximum levels for mycotoxins in foodstuffs.

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

Reference is also made to the following Codex Alimentarius standards:

Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005, Rev.1-2006).

Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (Codex Alimentarius CAC/GL 26-1997).

Guidelines for the Assessment of the Competence of testing laboratories involved in the import and export control of food (Codex Alimentarius CAC/GL 27-1997).

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

4 BACKGROUND

4.1 FVO MISSIONS TO THIRD COUNTRIES REGARDING MYCOTOXIN CONTAMINATION IN FOODSTUFFS

The European Commission carries out missions to the main exporting countries to evaluate their official control systems for preventing aflatoxin contamination in foodstuffs originating from those countries. This is the fourth mission to Iran concerning aflatoxins in pistachio nuts. The reports on earlier missions are available on DG SANCO's website at:

http://ec.europa.eu/food/fvo/ir_search_en.cfm .

4.2 BACKGROUND TO THE MISSION

Notifications concerning foodstuffs found to have public health implications are disseminated to all MSs and to the exporting country via the Rapid Alert System for Food and Feed (RASFF). In the case of pistachios, the notifications indicate mycotoxin contents exceeding the EU limits of 8 ppb for aflatoxin B1 and 10 ppb for total aflatoxins in nuts for direct human consumption. Since the previous FVO mission (SANCO 7670/2005), some 625 alerts relating to aflatoxins in pistachios from Iran have been issued via the RASFF (234 in 2006, 126 in 2007, 158 in 2008, 57 in 2009 and 50 during the first eight months of 2010). The breakdown of these alerts and the volume of imports into the EU are shown in Table. The biggest importing Member States are indicated in brackets.

Regulation (EC) No 1152/2009 imposes specific import conditions on products from certain TCs where the risk of contamination is considered greatest. These specific conditions relate to mycotoxin contamination, including checks on the aflatoxin content of pistachio nuts originating in or consigned from Iran and intended for import into the EU. Under Regulation (EC) No 1152/2009, pistachios exported to the EU have to be accompanied by a health certificate issued by the MOHME confirming that the consignment was sampled and analysed for aflatoxins in accordance with Commission Regulation (EC) No 401/2006. MSs are required to perform documentary checks and further sampling and analysis of 50 % of the consignments for aflatoxin B1 and total aflatoxins at the point of entry since 2010 (before 2010, sampling and analysis frequency of 100 % was applicable). Any non-compliance found results in rejection of the consignment from entering the common market and, subsequently, in return to the place of origin or another TC or destruction of the consignment.

	Imports to the EU (metric tonnes)		Number of RASFF notifications				
	2008	2009	2006	2007	2008	2009	2010 (8 months)
Pistachios (CN code 0802 50 00)	26 600 (BE, NL, DE)	18 458 (DE, BE)	234	126	158	57	50

Source: Eurostat, Comext database

In view of the number of alerts, the FVO decided to undertake a mission with the abovementioned objectives.

The report on mission SANCO 7670/2005 contained recommendations to the CAs of the country. The action plans subsequently received were considered satisfactory.

5 Findings And Conclusions

5.1 Relevant national legislation

Legal requirements

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

This mission covered the specific standards for the admissible levels of aflatoxins established in Regulation (EC) No 1881/2006 (as last amended) setting maximum levels for certain contaminants (including mycotoxins) in foodstuffs.

Regulation 401/2006 (as amended) lays down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.

Findings

The following changes have been made to the relevant national legislation since the previous FVO mission (SANCO/7670/2005):

- Iranian standard No 12004 on sampling methods for the official control of mycotoxins in foodstuffs is based on Commission Regulation 401/2006. The mission team was informed that Commission Regulation 178/2010 amending the abovementioned Regulation has not yet been incorporated into the abovementioned standard. According to the representatives of the Institute of Standards and Industrial Research of Iran (ISIRI), the abovementioned national standard is being revised and the new version will be adopted by mid-November 2010. However, the mission team saw evidence that Regulation (EU) No 178/2010 has been translated into Farsi and made available to FDO inspectors. In addition, staff responsible for official sampling under the abovementioned Regulation received training in September 2010 in both regions visited.[1]
- The Iranian Customs Tariff codes for the various types of pistachio for export have been amended. Instead of the single code 08025000, the following five-code system is now used:
  - Code No 08025010 for ‘Different varieties of open in-shell pistachios’;
  - Code No 08025020 for ‘Different varieties of closed in-shell pistachios’;
  - Code No 08025030 for ‘Pistachio kernels’;
  - Code No 08025040 for ‘Pistachio kernels without endocarp’ (blanched, whole pistachio kernels) and ‘Pistachio kernel slivers’ (blanched pistachio kernel slivers);

1 In their response to the draft report the Competent Authority noted that the national standard of “Sampling method of tree kernels” has been passed by the final Commission of ISIRI (standard is based on the requirements of Regulation (EC) No 178/2010).

– Code No 08025050 for 'Other pistachio products'.

- Directive No PEI/CRV1/0040 of the MOHME from 2006 establishes the requirements for licensing food processors. Among other things, they are required to comply with general food hygiene requirements.
- The Decision of the National Supreme Pistachio Council of 27 September 2010 requires that all consignments intended for export to the EU should be certified against the aflatoxin limits set in Regulation (EC) No 165/2010 (aflatoxin B1: 8 ppb and total aflatoxins: 10 ppb). Until September 2010, certification was based on the former aflatoxin limits set in Regulation (EC) No 1881/2006 (2 ppb for B1 and 4 ppb for total aflatoxins).

In addition to this legislation, the following guidelines are relevant to this mission:

- ISIRI No 8914 from 2006 on the 'Code of practice for establishing a HACCP system in pistachio processing establishments';
- Good Agricultural Practice Guidelines on pistachio cultivation (last amended in 2009);
- ISIRI No 8689 on the „Tree nuts-Code of hygienic practice

No changes have been made to the national legislation with regard to the maximum limits for aflatoxins in pistachios for the domestic market. The limits for pistachios for direct human consumption are 5 ppb for aflatoxin B1 and 15 ppb for total aflatoxins.

Conclusions

Since the last mission progress has been made on adopting new requirements and procedures for official controls: new legislation, standards and guidelines have been introduced covering sampling for exports to the EU, registration of food establishments, food hygiene requirements and HACCP.

5.2 COMPETENT AUTHORITIES

Legal requirements

Article 46(1)(b) of Regulation (EC) No 882/2004 stipulates that Community controls must have particular regard to, *inter alia* , the organisation of the TC's CAs, their powers and independence and the authority they have to enforce the applicable legislation effectively.

Article 46(1)(c) of Regulation (EC) No 882/2004 stipulates that Community controls must have particular regard to the training of staff in the performance of official controls.

Findings

5.2.1 Competent Authorities

Since mission SANCO 7670/2005 the following changes have been made to the responsibilities for supervision and inspection of cultivation, processing and export of pistachios:

- The National Supreme Pistachio Council (NSPC) has been established as a nationwide coordinating body for pistachio-related issues. Its main task is coordination between the different ministries, research bodies and entities involved in production and export of pistachios. The NSPC has the same powers to the Council of Ministers as a Minister and its decisions are legally binding.

- There has been some restructuring within the MoA with regard to pistachio-related issues. The Pistachio Focus Group is now the main body responsible within the Ministry.
- Since the last mission ISIRI has delegated its sampling responsibilities for aflatoxin controls to seven private companies in Iran, which (as a pre-requisite) have to be certified as complying with the ISO 17020 standard. The mission team was informed that, the FDO has delegated its pistachio sampling responsibilities to one of the private contract companies which itself has 3 branches in Tehran, Kerman and Rafsanjan. Each of the above mentioned branches are also under the supervision of the local FDO offices. The mission team was informed that in Rafsanjan 100 % of sampling is conducted by a private company, whereas in Kerman 100 % is conducted by the FDO.
- ISIRI is the CA for controls on the physical parameters of the nuts exported.

The other responsibilities have remained unchanged since the last mission (SANCO 7670/2005), as follows:

- The MoA, via its provincial departments, is responsible for supervision of pistachio growing and harvesting, for promotion of good agricultural practice (GAP) for pistachio cultivation, for training and for dissemination of information to pistachio growers and processors.
- ISIRI is responsible for development and publication of national standards, e.g. on pistachio cultivation and processing, and sets the standards applicable to pistachio quality, sampling and analysis.
- The MOHME's main responsibilities include sampling of pistachios for export to the EU by provincial FDO inspectors and analysis by three laboratories, namely the FDCL in Tehran plus two other laboratories in Rafsanjan and Kerman. All three laboratories are also responsible for issuing the health certificate necessary before pistachio consignments can be released for export to the EU. Health inspectors check basic hygiene requirements on the premises when sampling pistachio consignments for export to the EU. The FDCL administers the decisions on suspension of health certificates, as described in Section 5.5.

5.2.2 Customs authorities

In the field covered by this mission the customs authorities are responsible for customs clearance of consignments for export to the EU and of consignments that are rejected at EU borders and returned to Iran.

5.2.3 Other organisations

The following other organisations are relevant to this mission:

- The Iran Pistachio Research Institute (IPRI) is responsible for pistachio research and for training stakeholders nationwide. The mission team was informed that the IPRI has undertaken some 225 research projects on cultivation and processing of pistachios to date, 50 of them related to aflatoxin contamination. According to the IPRI, it takes an average of four years from the beginning of a project to implementation of its outcome.
- IPA was established in 2007 as part of the Iran Chamber of Commerce, Industry and Mines, a non-governmental organisation. It is an umbrella organisation for pistachio growers, processors and exporters and represents the sector in the NSPC.

Conclusions

Responsibilities for official controls in the field covered by this mission are clearly defined. Some changes have been made since the last mission.

5.3 Controls along the pistachio nut production and processing chain in Iran

Legal requirements

Article 46(1)(e) and (b) of Regulation (EC) No 882/2004 stipulates that Community controls must have particular regard to, *inter alia*, the existence and operation of documented control procedures and control systems based on priorities and the CA's authority to enforce the applicable legislation.

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

Article 10 of Regulation (EC) No 852/2004, in conjunction with Article 4(1) of the same Regulation, requires FBOs carrying out primary production and the associated operations listed in Annex I to the same Regulation to 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 FBOs carrying out any stage of production, processing and distribution of food after those stages to which Article 4(1) applies to comply with the general hygiene requirements laid down in Annex II to the same Regulation.

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

Article 10 of Regulation (EC) No 852/2004, in conjunction with Article 6 of the same Regulation, requires every FBO to notify the appropriate CA of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.

The Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005, Rev.1-2006) sets out recommended practices based on good agricultural practice (GAP), good manufacturing practice (GMP) and good storage practice (GSP).

Findings

5.3.1 Pistachio nut cultivation

Pistachios are currently cultivated in Iran on approximately 440 000 ha, of which 300 000 ha are in Kerman province. Approximately 200 000 farmers are involved, most of whom maintain small orchards. The mission team was informed that in Kerman province implementation of GAP is currently supervised by public or private advisors in approximately 50 % of the area cultivated (150 000 ha). According to the CA, in the remaining 50 % GAP principles are followed in half of the orchards, to which the information is usually passed on by other farmers. Of the remaining 25 % of the orchards, some 15 % are not bearing nuts. Integrated pest management (IPM) covers about 40 % of the area cultivated (120 000 ha). The CA informed the mission team that pistachios for

export to the EU could originate from farms that are not participating in the GAP and IPM schemes.

The mission team visited five pistachio nut farms: one in Rafsanjan and four in Kerman province. All the farms visited were in the GAP supervision scheme. They were found to follow GAP principles, such as early picking of pistachio nuts, short harvesting period, periodic irrigation depending on the season and on the availability of water, pruning of pistachio trees, use of sheets during harvesting for collection of the nuts that fall from the trees during the hand-picking and use of organic manure in trenches covered by soil. The farmers stated that they use insecticides three or four times a year, depending on the need. The mission team also observed that records of all farming activities were kept by the farmers visited. The farmers informed the mission team that nuts are hand-picked on all the farms and transported to the processing plants within 24 hours at the latest. In most cases, nuts are delivered directly from the orchard to the processors.

The mission team was informed that public or private supervisors usually visit farms at least once a month. However, if necessary, visits can be made more frequently in order to provide know-how on proper and timely application of insecticides, irrigation or harvesting. The mission team also observed that some of the farms visited received additional information on GAP from the processors, in particular on the harvesting time in order to reserve a slot for quick delivery of the produce from the farm to the processor for drying and sorting.

The farmers and representatives from the CA informed the mission team that the IPRI also plays a major role in delivering know-how on GAP via the mass media, training sessions, leaflets and on-site visits. Most of the measures applied to reduce the risk of aflatoxin contamination, such as early harvesting, use of flood irrigation or use of organic manure and other fertilisers in trenches, are based on IPRI 50 research studies (see also point 5.2.3). Farmers met during the mission stated that information on new developments in GAP and the right harvesting time is communicated to them by the IPRI, generally via the mass media.

5.3.2 Pistachio nut processing

There are approximately 1 300 pistachio processors in Iran. They cover some 950 semi-mechanised and 900 fully-mechanised processing lines. The mission team was informed that 95 % of pistachios exported to the EU are processed in 70 large terminals: 54 in Kerman, 12 in Rafsanjan and 4 in the rest of the country.

The mission team visited three processing plants in Rafsanjan and two in Kerman. GMP principles were followed in all two wet and three dry terminals visited, such as separation of floating and sinking nuts using chlorinated fresh water, quick-drying nuts to a moisture level of 5 % and sifting out pistachios suspected of being contaminated with aflatoxins. At three of the terminals visited, routine internal controls for aflatoxins were conducted on the incoming nuts or on nuts ready for dispatch.

The mission team observed that some of the general hygiene requirements established in the Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005, Rev.1-2006) were not followed in some of the facilities visited, such as keeping birds out of the sorting and storage area and not using pallets for storage of pistachio bags.

The processors visited informed the mission team that traceability to the individual farmer is generally lost during sorting in facilities that receive nuts from more than one orchard. In two of the terminals visited, traceability to individual orchards or small groups of orchards was possible.

ISIRI informed the mission team that a research project to analyse whether pistachios are becoming contaminated with aflatoxins during transport to EU ─ one of the recommendations made in the

previous inspection report (SANCO 7670/2005) ─ has not yet been undertaken, mainly due to difficulties with finding partners amongst exporters and importers in the EU.

5.3.3 Non-conforming products

According to the MOHME, in 2009 some 1 108 applications were made to export pistachios to the EU. Out of these, 179 lots were found not to comply with the EU aflatoxin limits and were, therefore, not granted a health certificate. This gives a rejection rate of 16 %. Out of the 929 lots exported to the EU, some 45 were rejected after the aflatoxin controls at EU borders, which corresponds to a rejection rate of approximately 5 %. In all, some 21 % of consignments presented for export in Iran or exported to the EU failed to comply with the EU limits on aflatoxins. In 2010, by the time of the mission, 775 applications were made to export pistachios to the EU. Out of these, 114 lots were found not to comply with the EU aflatoxin limits and were, therefore, not granted a health certificate. This gives a rejection rate of 14,7 %. Out of the 661 lots exported to the EU, some 50 were rejected after the aflatoxin controls at EU borders, which corresponds to a rejection rate of approximately 7,5 %.

The procedure for consignments rejected from the EU has changed since the last mission and is now as follows: once the consignment arrives back in Iran, a sample is taken by the FDO to check whether the consignment can be imported into Iran or needs decontamination (sorting) prior to release. According to the FDO, a consignment can be released by the customs authorities before the results of the analysis are available. However, it remains under the supervision of the FDO until the results of the analysis are available. According to the FDO, all rejected consignments go through a sorting procedure irrespective of the level of aflatoxin contamination. After sorting, a sample is taken by the FDO and, if necessary, the process is repeated. According to the FDO, this procedure can be repeated a maximum of three times. If the results are still not satisfactory after the third round of processing, the pistachios are either used for oil production or destroyed. However, the CA stated that this has never happened.

The mission team was informed that decontaminated nuts can be sold on the domestic market or exported to any country outside the EU. The mission team saw evidence of a case in Rafsanjan where a consignment rejected by one EU MS was sent back to the exporter's facilities, re-sampled and then re-exported to a non-EU country.

The mission team was informed that consignments that fail the FDO certification process for export to the EU are treated like consignments that have been rejected at the EU border. These consignments can be resorted, re-sampled and sold on the domestic market or exported to any country outside the EU.

The mission team noted that the FDOs visited receive information on consignments rejected by the EU, but which were not sent back to Iran, from the RASFF contact point only every three or every six months. In the case of rejected consignments that are returned to Iran, the FDO is informed by the customs authorities upon arrival of the consignments at the Iran border or directly by the exporters.

5.3.4 Additional private controls

The CA informed the mission team that there is no legal obligation for exporting companies to have a HACCP system in place. According to the CAs, the HACCP system is generally implemented by pistachio processors at the request of trading partners. In Kerman, only six of the 54 processors exporting their produce to the EU had put in place HACCP procedures and another four or five

were in the process of developing a HACCP system. In Rafsanjan, only one of the 12 processors exporting their produce to the EU had put in place HACCP procedures and one more was in the process of developing such procedures. The mission team was informed that currently no external private controls on pistachio production and exports are in place in Iran.

The new 'Blue Corridor' (BC) project is currently in the preparatory phase. It is owned and coordinated by the Iran Pistachio Association. The idea behind the project is to introduce pre-export inspection of lots by an independent inspection body, sealing and tracing lots up until the point of export and granting a BC inspection certificate to the lots. The project has yet to start.

Conclusions

Since the last mission good progress has been made on implementation of GAP and IPM in pistachio cultivation. However, pistachios for export to the EU could still originate from farms that are not participating in the GAP and IPM schemes.

The GMP and GSP principles established in the Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005, Rev.1-2006) were generally implemented in all the processing facilities visited, although some minor shortcomings were identified.

Research on pistachio cultivation is continuing and has produced some very good results. However, no research has been conducted on transport conditions. Therefore this recommendation made in the previous report (SANCO 7670/2005) has not been addressed.

The number of consignments of pistachios not complying with the EU limits on aflatoxins, whether presented in Iran for export to the EU or at EU borders for import, is still high, adding up together to over 20 %.

There are procedures in place for non-conforming products.

The number of processors of pistachios intended for export to the EU who have implemented HACCP is low. This is not in line with the requirements Article 5 of Regulation (EC) No 852/2004 in conjunction with Article 10 of the same Regulation.

No external private controls on pistachio production and exports are in place in Iran.

5.4 Method of sampling pistachio nut consignments

Legal requirements

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

Findings

5.4.1 Sampling procedure

Sampling of pistachio consignments to be exported to the EU is undertaken by FDO inspectors in the provinces or by private companies (see Section 5.2.1). The FDO in Rafsanjan informed the mission team that private companies responsible for sampling for the purpose of certification by the MOHME work under the supervision of the FDO. Approximately 10 % of the sampling performed

by private companies is supervised at random by the FDO. Evidence of such supervision was provided to the mission team, including checklists completed by the FDO and evidence of non-compliance identified and of enforcement action taken against the private company in the form of a warning.

The mission team observed two sampling exercises performed on lots of 8 tonnes (160 bags of 50 kg each) and 25 tonnes (500 bags of 50 kg each) by two different teams from Kerman FDO at two exporters' facilities. In the case of the 8-tonne lot, 80 incremental samples of 200 g each were taken from every second bag. In the case of the 25-tonne lot, 100 incremental samples of 200 g each were taken from every fifth bag. After sampling, all the bags were labelled and sealed by the inspectors. In both cases, the incremental samples were mixed and separated into two laboratory samples. Samples were packed into non-transparent plastic bags, then sealed, labelled and delivered to the laboratory by the inspectors. If requested by the representative of the processor, counter-samples are taken by the inspectors and kept in the processor's facilities.

Conclusions

The two sampling exercises observed at the exporters' facilities met the requirements of Regulation (EC) No 178/2010.

Procedures are in place to supervise sampling activities carried out by private companies.

5.5 Procedure for exporting pistachio nuts to the EU

Legal requirements

Article 46(1)(b) of Regulation (EC) No 882/2004 stipulates that Community controls must have particular regard to, *inter alia*, the organisation of the TC's CAs, their powers and independence and the authority they have to enforce the applicable legislation effectively.

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

Article 3 of Regulation (EC) No 1152/2009 requires that consignments of foodstuffs referred to in Article 1 of the Regulation may be imported into the EU only in accordance with the procedures laid down in the same Regulation.

Findings

No changes have been made to the procedure for exporting pistachios to the EU since the last mission (SANCO 7670/2005), except that the certification procedure may now include sampling by private companies. According to the customs authorities in Kerman, some 90 % of customs clearance is already completed in the province and only 10 % at the point of export. In the Kerman customs office visited, changes have been made to the export documentation since the previous mission, in particular:

- the customs export permit now contains the lot number of the consignment concerned;
- the correct laboratory name is now included on health certificates issued by the MOHME.

However, the health certificate issued by the MOHME still does not include a reference to a specific EU MS. Instead, a general reference to the EU is given.

According to the report on the last mission (SANCO 7670/2005), based on a Decision of the Pistachio Committee covering the period from 6 July to 6 October 2005, exporters who exceeded a rejection rate of 10 % for all their consignments shipped to the EU were suspended from export for three months. According to the NSPC, this Decision was taken as a general legal basis for applying a similar rule in subsequent years. The NSPC informed the mission team that this measure was last applied in 2006. The CA informed the mission team that this measure is applied to individual exporters regularly if the rejection rate for their consignments exceeds 10 %. This measure can also be applied as a general emergency measure in the event of a substantial increase in the number of rejections at EU borders. The mission team noted that the system takes no account of pre-export rejections by the MOHME. Based on 2009 data, approximately 75 % of all rejections are pre-export rejections and another 25 % occur at EU borders. No other sanctions are in place for exporters who try to export consignments that are not in compliance with the legal requirements on aflatoxins.

Conclusions

The system for exports of pistachios to the EU is clearly regulated and is under the control of the MOHME and customs authorities. Most of the deficiencies identified by the previous mission have been rectified (see Section 5.8 'Follow-up to previous mission'), except that health certificates still do not contain details of the place and country of destination.

The current system of suspension of exporters is not effective, as it fails to take into account the pre-export rejection rate. No other sanctions are in place for exporters who try to export consignments to the EU that are not in compliance with the EU requirements on aflatoxins.

5.6 Laboratory services

Legal requirements

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

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

Points 41 and 42 of Codex Alimentarius Guidelines CAC/GL 26-1997 for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems also apply.

Findings

Currently, there are three public laboratories performing official analyses for aflatoxins in pistachios intended for export to the EU, namely the FDCL in Tehran and the FCLs in Kerman and Rafsanjan.

5.6.1 Laboratories visited

The mission team visited the three above-mentioned laboratories to check the performance of analyses and reporting of results for both aflatoxin B1 and total aflatoxins. They are also issuing official health certificates, as requested by the EU legislation.

Regarding the number of samples analysed in the course of this mission, the mission team was given the following figures for 2010: the FDCL analysed 28 samples, five of which were found to exceed the level of 2 ppb for aflatoxin B1 and/or 4 ppb for total aflatoxins. The FCL in Kerman analysed 579 samples, of which 72 were found to exceed those levels and, finally, the FCL in Rafsanjan analysed 167 samples, of which 37 exceeded the same levels.

The mission team found that none of these laboratories was accredited to internationally recognised quality control standards. The three laboratories had a quality manager and quality manual in place. This mission found that the three laboratories had sufficient and well-trained staff and that the premises and equipment were fit for purpose.

The three laboratories used the same analytical procedure, which was method 999.07 as described in the Official Methods of Analysis of the AOAC (2005). This procedure was based on extraction, with methanol, of the toxins present in a slurry formed by a 1:1.5 mixture of pistachios in the shell and water in the FDCL and FCL at Kerman and a 1:1 mixture in the FCL at Rafsanjan. This was cleaned up by immunoaffinity columns and the toxins content was determined by HPLC with bromide post-column derivatisation using a Kobra® cell, followed by fluorescence detection. All three laboratories had standard operating procedures (SOPs) for the different stages of the analytical procedure and use of the related equipment. All three used aflatoxin standards in solid form supplied by two different companies. The FDCL used calibration curves built on each day of analysis with five levels ranging from 0.45 to 8.18 ppb for aflatoxin B1 and 1.08 to 19.64 ppb for total aflatoxins. The FCLs in Kerman and Rafsanjan used calibration curves also built on each day of analysis with six levels, ranging from 0.38 to 12.3 ppb and from 0.2 to 6.4 ppb for aflatoxin B1 and total aflatoxins respectively.

The three laboratories expressed the results for aflatoxins by reference to the edible part of the pistachios. However, both the FDCL and the FCL in Kerman used a factor of two for the ratio between the kernel and the edible part. This was not based on any traceable test. The FCL in Rafsanjan showed the mission team some recent data where checks produced ratios of 1.75, 1.83 and 1.91 for 'round', 'jumbo' and 'long' pistachios respectively. Besides that, the FDCL was found not to have incorporated the conversion factor into the formula which was included in the SOP, although it was incorporated correctly in the Excel sheet for ratios calculations.

All three laboratories had carried out some estimates of the expanded measurement uncertainty (U) as the standard deviation of their internal reproducibility and using a k factor of 2 in order to obtain a 95 % interval of confidence. These estimates were based on their own quality control data. However, neither the FDCL nor the FCL in Kerman had the corresponding SOP in place and the FCL in Rafsanjan had given no information about the frequency and purposes of its estimates in the SOP. None of the three laboratories used the estimated U values in the evaluation of their results nor reflected them in their analytical reports.

The three laboratories participated regularly in international proficiency tests with satisfactory z-scores of less than +/- 2. The three laboratories used reference materials and had established quality control measures covering recovery and precision, with adequate use of control charts. However, none of them had any SOP or written instructions about performance and the frequency of these activities, the acceptance or rejection criteria and the corrective action to be taken in the event of deviation or non-conformity.

The results of the analyses of aflatoxins reported by the three laboratories were corrected for recovery. The mission team detected some miscalculations in the recovery factor applicable to the value for total aflatoxins at the FCL in Rafsanjan. The analytical reports were not in line with the EU requirements because they did not incorporate the U value and contained no information about the manner of reporting and the level of recovery. The mission team noted that in their reports all three laboratories used 'ND' (not detectable) for results below the limit of quantification, but failed

to give details of the values for the Limit of Detection or the Limit of Quantification.

Regarding participation in proficiency tests and provision of reference material, all three laboratories expressed concern about the difficulties with obtaining material which had to be shipped in frozen or refrigerated condition because of delays in transportation, at customs posts, and in delivery, all of which makes the properties of the material unreliable.

The mission team obtained evidence of internal audits performed in the FDCL and the FCL in Rafsanjan but not in the FCL in Kerman. External audits had also been performed in the FCLs in both Kerman and Rafsanjan but not in the FDCL. The FDCL played the role of national reference laboratory giving technical advice to the other two laboratories, performing audits regularly and providing them with reference material.

Conclusions

There have been improvements since the last mission in the quality management systems and quality controls at all the laboratories visited. However, certain aspects identified in the laboratories' performance still do not comply with the criteria established by Regulation (EC) No 401/2006, in particular with regard to the reporting of recovery and measurement uncertainty.

Still no official laboratories have obtained accreditation under officially recognised programmes to demonstrate compliance with the general quality criteria for testing laboratories such as those laid down in ISO 17025.

5.7 Response to RASFF notifications

Legal requirements

Point 6 of Codex Alimentarius Guidelines CAC/GL 25-1997 covers exchanges of information between countries on rejections of imported food.

Findings

There have been some changes in the RASFF procedure in Iran since the previous mission (SANCO 7670/2005). According to the CAs, the FDCL has internet access to the EU's RASFF database. According to the FDCL, FDOs receive a summary of the RASFF alerts relating to exporters from their region every three months during the peak season and after six months in other periods.

However, as mentioned in the report on the previous mission (SANCO 7670/2005), none of the CAs follows up individual rejections at EU borders at exporter level.

Conclusions

The current procedure does not allow fast and effective action to be taken regarding exporters involved in the RASFF.

5.8 Follow-up to previous mission

Findings

The report on mission DG(SANCO)/7670/2005 identified a number of shortcomings. The table set out below lists the recommendations made then and indicates how they have been addressed by the CAs.

Recommendations by mission DG(SANCO)/7670/2005	Follow-up during mission DG(SANCO)/8594/2010
(1) The Competent Authorities should ensure the application of GAP and GMP principles identified to be effective to avoid or reduce aflatoxin contamination in pistachios by all operators concerned as soon as possible.	Partly addressed. GAP and GMP principles were followed by the farms and processors visited. However, pistachios for export to the EU could still originate from farms that are not participating in the GAP and IPM schemes (see Section 5.3.1).
(2) The Competent Authorities should continue the HACCP project in 2006 and widen the project's scope in so far as it should address small scale farmers and processors.	Not addressed. There has been very little progress with implementation of HACCP by pistachio nut processors exporting their produce to the EU (see Section 5.3.4).
(3) The Competent Authorities should consider the accreditation of public laboratories according to ISO 17025 for the analysis of aflatoxins in pistachios.	Not addressed. See Section 5.6.
(4) The Competent Authorities should ensure that all Health Certificates contain details of the place and country of destination.	Not addressed. The health certificate issued by the MOHME still does not include a reference to a specific EU MS. Instead, a general reference to the EU is given (see Section 5.5).
(6) The Competent Authorities should consider communicating the list of exporters temporarily suspended from export of pistachios to the EU to Commission Services.	Partly addressed. The last list was communicated to the Commission in 2006.
(7) The Competent Authorities should ensure that sampling of pistachio consignments to be exported to the EU is carried out in a uniform way.	Addressed. The sampling operations observed met the requirements of Regulation (EC) No 178/2010.
(8) The Competent Authorities should consider undertaking research in order to determine if pistachios are becoming contaminated with aflatoxins during transport to the EU.	Not addressed. No research has been done on transport conditions (see Section 5.3.2).

6 Overall Conclusions

Good procedures are in place for official controls of pistachios intended to be exported to the EU. Improvements have been made since the last mission to rectify deficiencies in the established procedures. However, there are still deficiencies, particularly in laboratory accreditation and in application of the criteria established by Regulation (EC) No 401/2006. Although good progress has been made since the last mission on implementation of GAP, IPM and GMP in pistachio cultivation and processing, further efforts are needed to reduce the number of consignments of pistachios intended for export to the EU which do not comply with the EU limits on aflatoxins.

7 Closing Meeting

A closing meeting was held on 20 October 2010 with the CCA, the MoA. Representatives of the MOHME, the Iran Customs Agency, the Iran Port Authority, ISIRI, the IPRI and the Iran Chamber of Commerce, Industry and Mines were also present. At this meeting, the main findings and preliminary conclusions of the mission were presented by the mission team.

The representatives of all the authorities made initial comments but expressed no major disagreement with the findings and conclusions.

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.

N°.	Recommendation
1.	Ensure that GAP and IPM principles are implemented in all farms which produce pistachio nuts for export to the EU in line with Codex Alimentarius Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005, Rev.1-2006).
2.	Ensure that food business operators exporting pistachio nuts to the EU implement standards at least equivalent to those required by Article 5 of Regulation (EC) No 852/2004 on food safety procedures based on HACCP principles.
3.	Ensure that all health certificates contain details of the place and country of destination, as previously recommended in the report on mission SANCO 7670/2005.
4.	Ensure that laboratories involved in official controls apply the principles of internationally recognised quality assurance techniques (such as ISO 17025) and are evaluated and accredited under officially recognised quality management and assurance programmes to ensure these laboratories provide reliable analytical results.

N°.	Recommendation
	(Point 41 of CAC/GL 26-1997 and point 3 of CAC/GL 27-1997).
5.	Consider undertaking research in order to determine whether pistachios are becoming contaminated with aflatoxins during transport to the EU, as previously recommended in the report on mission SANCO 7670/2005.
6.	Consider introducing sanctions against exporters who present export consignments to the EU that do not comply with the EU requirements on aflatoxins.
7.	Consider introducing a RASFF follow up procedure that allows fast and effective action to be taken against exporters involved in the RASFF.

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

http://ec.europa.eu/food/fvo/ap/ap_ir_2010-8594.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. 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. 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
Reg. 1152/2009	OJ L 313, 28.11.2009, p. 40-49	Commission Regulation (EC) No 1152/2009 of 27 November 2009 imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC