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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate F - Food and Veterinary Office

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FINAL REPORT OF A MISSION
CARRIED OUT IN THE ISLAMIC REPUBLIC OF IRAN
FROM 21 TO 30 NOVEMBER 2005
TO ASSESS THE FACILITIES AND MEASURES IN PLACE FOR THE
CONTROL OF AFLATOXIN CONTAMINATION IN PISTACHIOS INTENDED FOR
EXPORT TO THE EUROPEAN UNION

Please note that factual errors in the draft report, identified by the Authorities of the Islamic Republic of Iran, have been corrected in the text of this final report. Clarifications, provided by the Authorities of the Islamic Republic of Iran, are given as footnotes, in italics, to the relevant part of this final report.



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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

AOAC	Association of Analytical Communities
CRM	Certified Reference Material
EU	European Union
FAPAS	Food Analysis Performance Assessment Scheme
FDCL	Food and Drug Control Laboratory Tehran
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Point
HPLC	High Performance Liquid Chromatography
IAC	Immuno-Affinity Column
IAS	Iranian Accreditation System
INSN	Iranian National Standards Number
IPRI	Iranian Pistachio Research Institute
ISIRI	Institute of Standards and Industrial Research of Iran
KFCL	Kerman Food Control Laboratory
LOD	Limit of Detection
LOQ	Limit of Quantification
MA	Ministry of Jihad-e-Agriculture
MH	Ministry of Health and Education
MS	Member States
PAO	Pistachio Affairs Office
RASFF	Rapid Alert System for Food and Feed
RFCL	Rafsanjan Food Control Laboratory
SOP	Standard Operating Procedure
TLC	Thin Layer Chromatography

EXECUTIVE SUMMARY

The mission was carried out as part of the planned Food and Veterinary Office mission programme and in agreement with the Authorities of the Islamic Republic of Iran to assess the facilities and measures in place for the control of aflatoxin contamination in pistachios intended for export to the European Union. Despite previous FVO missions to the Islamic Republic of Iran (SANCO 1492/1998 and 3157/2001), a rising number of rapid alert notifications had been noted, concerning aflatoxin contaminated pistachios.

Responsibilities were clearly defined between the Ministry of Health and Education (MH) and the Ministry of Jihad-e-Agriculture (MA) and a good legal framework is in place for controls on pistachio exports to the EU. Research on the subject of aflatoxin contamination in pistachios has revealed a number of measures, which were demonstrated to be efficient to reduce or eliminate the problem. Producing and processing companies visited had implemented these measures to various extents with good results. However, competent authorities do not enforce GAP and GMP principles systematically in this industry and RASFF notifications are not followed up at the exporters concerned.

Two samplings were demonstrated by inspectors of the MH and evaluated by the mission team, of which 1 was found to be in line with Commission Directive 98/53/EC. Up to now, inspectors were not provided with specific and uniform written instructions on the application of this Directive. Furthermore, training of inspectors and use of uniform equipment was found to be deficient, resulting in one sampling demonstrating improper execution of the aforementioned Directive.

Improvements in the area of export of pistachios to the EU have been noted, with a clear procedure in place and supervised by the MH and customs. The documentation accompanying lots exported provides for indirect traceability and health certificates issued by the MH are not in all cases in line with Commission Decision 2005/85/EC.

Improvements were also noted with regard to the public laboratories responsible for aflatoxin analysis which can now adequately undertake routine aflatoxin analysis for this purpose. However, none of these laboratories is accredited according to ISO 17025, not all of them participate regularly in international proficiency tests and the use of certified reference material is not common.

Overall, there is a good framework control system in place for exporting pistachios to the EU. Improvements since last mission SANCO 3157/2001 in the areas of laboratories and regarding the export procedure have been noted. Examples of GAP and GMP principles identified in Iran have been demonstrated to the mission team as to be efficient for the control of aflatoxin contamination in pistachios. However, only a small number of operators apply these principles. A significant reduction of the numbers of pistachio consignments not complying with EU limits for aflatoxins can only be achieved by uniform application of these principles by all operators and their enforcement by the MH. Further minor shortcomings were identified in the areas of sampling, laboratories, health certification and research.

The report provides a number of recommendations to the competent authorities of the Islamic Republic of Iran to address the noted deficiencies.

1. INTRODUCTION

The mission took place in the Islamic Republic of Iran from 21 to 30 November 2005. The mission team comprised 2 inspectors from the Food and Veterinary Office (FVO) and one national expert.

The mission was undertaken as part of the FVO's planned mission programme and in agreement with the competent authorities of Iran.

The mission team was accompanied during the whole mission by representatives from the central competent authority, the MA.

An opening meeting was held on 21 November at the premises of the MH, in Tehran. During this meeting, the objectives of and itinerary for the mission were confirmed by the mission team.

2. OBJECTIVES OF THE MISSION

The objective of the mission was to assess the facilities and measures in place to control aflatoxin contamination in pistachios for export to the European Union (EU). The scope of the mission comprised of an examination of the complete production chain, from pistachio cultivation to the export of pistachios to the EU.

In pursuit of this objective, the following visits were carried out and meetings held with:

COMPETENT AUTHORITY VISITS			Comments
Competent authority	Central	1 1 1	Ministry of Jihad-e-Agriculture Ministry of Health and Medical Education Institute of Standards and Industrial Research of Iran (ISIRI)
	Provincial	5	Yazd Ministry of Jihad-e-Agriculture and Ministry of Health and Education Kerman Ministry of Health and Education Governor of Kerman province Hormozgan customs authorities
	Local	3	Governor of Rafsanjan Rafsanjan and Bandar Abbas customs authorities
LABORATORY VISITS			Comments
		4	Laboratories of the Ministry of Health and Education in Tehran, Kerman and Rafsanjan and central ISIRI lab
		2	Private laboratories, both approved by ISIRI, one by the Ministry of Health and Education
FOOD PROCESSING ESTABLISHMENTS			Comments
Pistachio Plantations		5	In Kerman and Yazd provinces
Processing Establishments		6	Provinces of Kerman, Yazd and Tehran
OTHER SITE VISITS/MEETINGS			
Chambers of commerce/ Exporter meetings		3	Kerman, Rafsanjan and Tehran
Green corridor project		1	Kerman
HACCP project		1	Kerman

3. BASIS AND LEGAL FRAMEWORK FOR THE MISSION

The mission was carried out in agreement with the MA and under the general provisions of Community legislation. The relevant legal framework for this mission is as follows:

- Council Regulation (EEC) No 315/93¹ of 8 February 1993 laying down Community procedures for contaminants in food,
- Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs² as amended,
- Council Directive 85/591/EEC³ of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption,
- Council Directive 89/397/EEC⁴ of 14 June 1989 on the official control of foodstuffs,
- Council Directive 93/99/EEC⁵ of 29 October 1993 on additional measures concerning the official control of foodstuffs,
- Commission Directive 98/53/EC⁶ of 16 July 1998 laying down sampling methods and the methods of analysis for the official control of the levels for certain contaminants in foodstuffs as amended,
- Commission Decision 2005/85/EC⁷ of 26 January 2005 imposing special conditions on the import of pistachios and certain products derived from pistachios originating in, or consigned from Iran.

4. BACKGROUND

4.1. Overview of previous missions regarding aflatoxin contamination in foodstuffs

The European Commission has carried out missions to Egypt, Turkey, China, Brazil, Argentina and India with the objective of evaluating official control systems for the prevention of aflatoxins contamination in foodstuffs originated from these countries. In addition, missions to 16 Member States (Austria, Belgium, Czech Republic, France, Germany, Greece, Hungary, Italy, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Slovak Republic, Spain and the UK) 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 Consumer Protection Internet site at http://europa.eu.int/comm/food/fvo/index_en.htm.

¹ OJ L 37, 13/02/1993, p. 0001 - 0003

² OJ L 77, 16/03/ 2001, p. 0001 - 0013

³ OJ L 372, 31/12/1985, p. 0050 - 0052

⁴ OJ L 186, 30/06/1989, p. 0023 - 0026

⁵ OJ L 290, 24/11/1993, p. 0014 - 0017

⁶ OJ L 201, 17/07/1998, p. 0093 - 0101

⁷ OJ L 30, 03/02/2005, p. 0012 - 0018

4.2. Background to present mission

Competent Authorities of the EU Member States (MS) are obliged to carry out routine sampling and analysis of products originated from third countries at points of entry or on the marketplace. 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.

Alert notifications were issued concerning aflatoxin levels in pistachios imported from the Islamic Republic of Iran during the previous years as follows:

- in 2003, 489 consignments,
- in 2004, 485 consignments, and
- in 2005, 425 consignments until mission date.

Based on this continuing high number of rapid alerts, a mission to the Islamic Republic of Iran was planned to be undertaken during 2005. Previous FVO mission SANCO 3157/2001 revealed shortcomings in the area of structure of competent authorities, control monitoring undertaken on aflatoxin levels for the domestic market, public laboratories for health certification of pistachios, export procedure and concerning the causal dependence between storage and transport conditions and aflatoxin levels found in pistachios.

According to FAOSTAT data for 2003, Iran is the largest producer of pistachios, followed by Syria, the USA and Turkey. It is also the largest exporter of this commodity in the world. Figures for 2004 are not yet available from FAOSTAT. Estimates show that the 2004 harvest in the USA revealed a much larger quantity of pistachios, turning the USA into the second largest producer worldwide.

Table 1: Main producer and exporter of pistachios in 2003

Country	Production (mt)	Global export (mt)	EU exports (mt)
Iran	275,000	184,946	43,959
USA	53,980	23,770	21,948
Syria	50,000	3,012	83
Turkey	90,000	1,038	697

(Source: FAOSTAT 2005)

EUROSTAT data display that Iran exported 48,809 metric tons of dried pistachios to the EU in 2004 compared to 43,959 metric tons in 2003. Bandar Abbas is the main port used for shipping the products to the major importing countries within the EU, such as Spain and Germany. The usual mode of transport between loading of the goods from the point of processing and arrival in Europe is ambient containerised shipment.

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 aflatoxins group includes a number of compounds of varying toxicity and frequency of occurrence 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. Maximum limits for aflatoxins in food were fixed in legislation taking into account the known possible effects of sorting, mixing or of other physical treatment methods to reduce the aflatoxin content of the nuts. In accordance with Commission Regulation (EC) No 466/2001, the maximum admissible aflatoxin levels in various nuts, groundnuts, dried figs and products thereof intended for human consumption are as follows:

- a) Nuts, groundnuts, dried figs and processed products:
2 µg/kg aflatoxin B1 content, and
4 µg/kg total aflatoxins content
- b) Nuts and dried fruit subject to sorting or other physical treatment:
5 µg/kg aflatoxin B1 content, and
10 µg/kg total aflatoxins content

In addition, sampling plays a crucial part in determining aflatoxin levels, which are very heterogeneously distributed in a consignment of the product. Therefore, in Commission Directive 98/53/EC a sampling procedure and general criteria were fixed to ensure methods of analysis with comparable levels of performance.

5. MAIN OBSERVATIONS

5.1. Relevant national legislation

Since mission SANCO 3157/2001 a number of changes regarding legislation, legislative procedures and additional standards were noted by the mission team:

(1) Article 10 of the by-law (secondary legislation) of the executive law on foodstuffs, cosmetics and hygienic products of 1st July 1968 allows private laboratories to perform analysis for official purposes after approval by the Department of Food and Drug control laboratories (FDCL) of the Ministry of Health, excluding those for EU exports.

(2) The subgroup “Analysis and certification” of the Pistachio committee of the President’s office has on 16 July 2005 implemented a decision on the handling of pistachio consignments rejected at EU borders and returned to Iran (description of the procedure under 5.5).

(3) With effect of 6 July until 5 October 2005, a new measure regarding issuance of health certificates was introduced. According to the measure, issuance of health certificates will be suspended for a period of 3 month in cases, where exporters exceed a rejection rate of 10% at EU borders, based on all their EU exports, within the preceding period of 3 month. At the beginning of each period, a list of exporters concerned is communicated to all stakeholders involved within Iran.

(4) In March 2006 new legislation will come into force, demanding all food operators to comply with certain hygiene requirements in order to obtain a production license, necessary for example for the export of pistachios to the EU.

(5) Iranian National Standards Number (INSN) 5925 – “Maximum limits of mycotoxins in food and feed stuffs”, allowing a maximum level of aflatoxin B1 and total aflatoxin of 5 and 15 ppb respectively in pistachios.

- (6) INSN 2581 – “Code of practice for sampling of agricultural products for aflatoxin analysis”.
- (7) INSN 6872 – “Determination of aflatoxins by HPLC and immuno affinity clean-up”.
- (8) INSN 2380 – “Code of practice for the processing of pistachios from harvesting to packaging”.

5.2. Competent Authorities

Since mission SANCO 3157/2001 no major changes have been introduced with regard to the supervisory and inspection responsibilities to be carried out in the area of cultivation, processing and exporting of pistachios. The mission team gathered the following additional information:

- *Ministry of Jihad-e-Agriculture*

The Pistachio Affairs Office (PAO) is responsible for coordinating the “Ministry of Jihad-e-Agriculture Pistachio Committee”, which has expanded the number of working groups since last mission. This Committee and its working groups is the main forum for technical discussions and decision-making. Via the provincial departments of the Ministry, supervision of pistachio growing and harvesting is carried out and training courses and dissemination of information is organised.

In 2003, the PAO set up a project on the implementation of the Hazard Analysis and Critical Control Points (HACCP) principles in orchards and processing companies. So far, only a small number of operators have participated and implemented the guidance provided. Details of the project are to be found in chapter 5.3.3.

- *Ministry of Health and Medical Education*

Main responsibilities include sampling of pistachios for EU export by provincial health inspectors and analysis performed by 3 laboratories, namely the central Food and Drug Control laboratory (FDCL) in Tehran, and 2 laboratories in Rafsanjan and Kerman. The FDCL and the Rafsanjan laboratory are also responsible for issuing the health certificate necessary to release pistachio consignments for EU export. Health inspectors check basic hygiene requirements at the premises when sampling pistachio consignments for EU export. The FDCL administers the decision on the suspension of issuance of health certificates as described under point 8 of chapter 5.1.

- *Institute of Standards and Industrial Research of Iran*

No change with regard to the responsibilities hold by ISIRI was noted by the mission team.

- *Iran’s Pistachio Research Institute (IPRI)*

The Institute is part of the Ministry of Agriculture and apart from research into the area of pistachio cultivation is responsible for training of public and private entities and individuals as well as promotion of Good Agricultural Practice (GAP), mainly via mass media and its own website. No specific research has been undertaken regarding the impact of transport conditions on the aflatoxin content in pistachio, but 2 studies were in progress simulating ship transport conditions..

5.3. Process controls in the pistachio production chain

5.3.1. *Pistachio cultivation*

The area cultivated in Iran for pistachio production is 427.000 ha, of which 78% are located in the province of Kerman, 8% in Yazd and 6% in Khorasan province. Further 8 provinces are also cultivating pistachios to a small amount. The average share of fertile trees is around 75%, fertility starts after 10 – 12 years until 30 years of age.

There are approximately 200.000 farmers involved, which manage field sizes from less than 1 ha to more than 600 ha. Traditionally, harvesting starts in September, depending on the maturity of the nuts and runs until end of October of each season. Nuts are handpicked and transported to the processing plants within 1 – 2 days⁸.

Research was undertaken in the area of pistachio cultivation by IPRI in order to establish the causal dependencies between farming conditions and aflatoxin content in pistachios. IPRI concluded that a) early harvesting of pistachios, b) obeying density limits of trees in pistachio farms, c) transport of harvested pistachios in aerated crates, d) sorting out of floating nuts at terminals (proven to contain large amounts of aflatoxins) and e) separation of stained nuts are the most important steps for the avoidance or reduction of aflatoxins.

The mission team visited 5 orchards, 3 in the province of Kerman and 2 in the province of Yazd. All of the orchards visited applied principles such as:

- proper pruning of trees
- fertilizer application buried
- periodic irrigation
- picking of pistachios before achieving full maturity (harvest brought forward by one month as advised by the MA) in order to reduce early split nuts
- reduced harvesting times by increasing workforce and
- avoidance of collecting nuts from the ground by using single sided sheets.

The farming activities are supervised by local staff of the MA, specifically during harvesting and evidence of promotion of Good Agricultural Practice (GAP) principles and training given to farmers was provided to the mission team. The last 3 of the aforementioned principles were introduced only recently by the farms visited, but the farmers visited reported a reduced rate of early split nuts and subsequently less product losses due to aflatoxin contaminated nuts.

5.3.2. *Pistachio processors visited*

There are approximately 800 pistachio processors in Iran. They process the complete harvest each season, which varies between 150,000 250,000 metric tons. The process of producing dried pistachios is separated into wet and dry processing. Wet processing describes the cleaning of nuts at reception, mechanically dehulling, separation of light weight nuts from normal weight nuts by means of air flow or in a water floatation tank, and final mechanical and/or sun-drying. Dry processing describes cleaning, sorting and grading to various extents and bagging of the final product.

⁸ *In their response to the draft report the Iranian authorities noted that due to developments in recent years the time for transporting pistachios has been reduced to less than 12 hours.*

The mission team visited 6 companies processing and exporting pistachios to the EU, where the following observations were made:

- (1) All processors visited were in general very well aware of potential aflatoxin contamination
- (2) Separation of incoming nuts was based on visual and/or analytical checks, and on areas and farms of origin and subsequently separately processed at 3 processors
- (3) Use of water floatation devices to sort out light weight nuts at 3 processors
- (4) Use of chlorinated fresh water for the above at 2 processors
- (5) Removal of pistachio hulls at all premises
- (6) Mechanical drying, combined with sun drying at 4 processors
- (7) Improved sorting during processing based on visual checks at 5 processors

However,

- (8) implementation of the aforementioned measures had started recently, depending on resources available and quality standards of the individual companies visited,
- (9) efforts to separate aflatoxin contaminated pistachios by handpicking or mechanical sorting varied widely in the companies visited; in one example, the mission team found the final product to be of significantly lesser quality,
- (10) no evidence was found of MH inspectors or any other official body checking the application of neither the measures mentioned under points 1 – 7 nor those measures identified by IPRI,
- (11) no evidence was found that MH inspectors check the application of Codex Alimentarius guides CAC/RCP 59 – 2005⁹ or CAC/RCP 6 – 1972¹⁰,
- (12) it was demonstrated that traceability of the final product is limited to the production region due to the various lot sizes produced by farms and subsequent mixing of pistachios at the processing stage. Furthermore, control on the origin of pistachios purchased on the market is limited, especially in the case of dry processing companies buying from intermediaries.

5.3.3. *Public/Private projects*

Currently there are 2 projects running aiming to avoid or reduce aflatoxin contamination in pistachios.

The HACCP project funded by the MA, and implemented under the responsibility of the PAO, started in 2003. It aims to avoid or reduce aflatoxin contamination by identifying Critical Control Points (CCP) in individual orchards and processors. Research undertaken in the framework of the project highlighted a number of measures, which could prevent or reduce aflatoxin contamination. The most effective measures were identified as:

- Visual inspection and separation of nuts at reception
- Sorting out of floater nuts by use of a floatation device
- Drying of pistachios, intensified visual inspection and sorting of dried pistachios before bagging

Since start of the project, 11 companies have participated. For each of the companies a HACCP plan is set up by a team of the MA, containing a number of CCPs and Standard Operating procedures (SOP). Although the CCPs established address at least the

⁹ CAC/RCP 59 – 2005: Code of practice for the prevention and reduction of aflatoxin contamination in tree nuts

¹⁰ CAC/RCP 6 – 1972: Recommended international code of hygienic practice for tree nuts

aforementioned measures, they are lacking of clear defined and measurable critical limits and monitoring steps. In addition, setting up HACCP systems would require operators to comply with GMP (Good Manufacturing Practices) beforehand.

The MA presented the project to the mission team, showing clearly the effectiveness of the measures in so far as the average aflatoxin contamination found in the final product was generally reduced to levels below the official EU limits. However, continuation of the project depends on funds which have to be made available by the MA for 2006. Furthermore, at the moment no plans are in place to extend the programme to include small farms and processors.

The Green Corridor Project (GCP) is an initiative set up in 2004 by private entities and companies in order to establish GAP and Good Manufacturing Practice (GMP) throughout the production chain of pistachios and to reduce the rejection rate of pistachio consignments at EU borders. In order to become an approved participant in the project, farmers and processors have to fulfil certain prerequisites regarding GAP and GMP, described in the “Main Operational Procedures”, including minimum size of operations. Furthermore, the manual contains SOPs regarding production and processing of pistachios, addressing the measures and criteria mentioned under 5.3.2 and further rules contained in the relevant Codex guides. Project participants are obliged to follow the SOPs, monitored by resident GCP inspectors. Disregard of the rules would lead to immediate exclusion from the project. Funding of the project is based on contributions of its participants, which pay a fee of 0,01 € per kilogram of pistachios produced/processed and/or exported.

To verify the effectiveness of the project, in 2004 29 pistachio consignments were closely followed throughout the production chain until arrival at the destination by carrying out aflatoxin analysis. When released for export in Iran, aflatoxins analysis undertaken within the framework of the project showed that 2 of the consignments were contaminated with aflatoxins. However, official sampling and analysis did not reveal any aflatoxin contamination and the export went ahead. On arrival at the destination 2 of the 29 consignments (7%) were rejected. The project continues in 2005, now including 21 processing plants and orchards across 9 regions. Due to the fact that export of pistachios of the current season had just begun, no results concerning rejection rates were available yet.

5.3.4. *Export*

Approximately 90% of all consignments exported to the EU are shipped via Bandar Abbas by sea transport, the remaining 10 – 12 % are exported overland by truck. All exports are containerized and transported under ambient temperature conditions. Usually pistachios are bagged in 50 kg polyethylene or polypropylene bags. In relation to the previous mission SANCO 3157/2001 the following change has been put in place:

- Pistachio consignments can be containerized at the exporter premises and released by Rafsanjan customs, currently applied in 60% of all EU exports from this region

5.4. Method of sampling of pistachio consignments

5.4.1. Sampling procedure

Sampling of consignments to be exported to the EU is undertaken by the inspectors of the MH in the provinces, and to a very limited extent by staff of 1 private laboratory (see 5.6.2). For sampling of consignments to be exported to non-EU countries, INSN 5197 is applicable. It reflects Commission Directive 98/53/EC in so far as the principles for taking incremental samples, producing aggregate samples and dividing into sub-samples are similar. However, for EU exports, only the provisions of the mentioned Commission Directive are applied.

The mission team evaluated 2 samplings, performed by health inspectors of Rafsanjan and of Tehran province. In summary, it noted:

- To take samples, all bags are placed separately on the ground or on pallets, and opened for inspection; bags are speared from the top by staff of the premises under supervision of the inspector and are closed and sealed afterwards.
- Consignments usually consist of 20 – 25 tons of pistachios. Inspectors explained that, as a rule of thumb, usually every third bag is sampled, resulting in samples sizes of at least 30 kg.
- A sampling protocol is being produced, containing information such as lot number, date and place of sampling, and responsible inspector.
- Inspectors avail of equipment, such as spears, sample bags, forms and seals for sampling. Official seals applied by inspectors of the MH vary in appearance and materials used. In case of lead seals applied, the imprint of the inspectors' number on the seal is not readable.
- Training for inspectors is provided as “training-on-the-job” approach. No formalized training on the application of Commission Directive 98/53/EC was given to newcomers. Furthermore no written instruction is in place for inspectors outlining the sampling and calculation of sampling frequency. Individual handwritten tables are used to decide upon sample size and number of bags to be sampled.
- Mixing of samples before division into 3 x 10 kg sub-samples was in 1 case done while bagged.

5.5. Procedure for exporting pistachios to the EU

Since mission SANCO 3157/2001 there are now 3 ways for exporting pistachios to the EU.

- In Rafsanjan province, consignments are containerized at the exporters' facilities and sealed and released by Rafsanjan customs.
- Non-containerized consignments are loaded onto lorries, sealed by customs in the region of production, distributed by road to the point of export, containerized and sealed and released by customs.
- Consignments arrive at the point of export, are containerized under the supervision of customs and sealed and released.

The export procedure at customs in Rafsanjan was assessed by the mission team and consists of the following steps:

- presentation of commercial registration, ISIRI conformity certificate of quality standards, analytical report of MH concerning aflatoxin analysis, bill of lading to customs by the exporter;

- customs check the documents presented and transfer the data into the ASYCUDA system (electronic database and interface for customs affairs);
- identity check by customs officers, application of seal and documentation of analytical report, seal number and container number on export permit;
- final documentary check and issuance of export permit by customs.

Once the export is released, the exporter has to submit a container number to the MH in order for them to issue the required health certificate. It was explained by exporters and customs to the mission team that the consignment concerned has sometimes already left the country before the certificate arrived at the exporter. However, the health certificate is based on the analytical report of the MH, which has to be presented by the exporter to customs in order to achieve the export permit.

Four observations were made by the mission team concerning the export of pistachios to the EU.

- At the port of Bandar Abbas (Shahid Rajaee port) 2 dedicated warehouses are now in use for the reception, containerization and intermediate storage of pistachio consignments, until loading onto ships can be performed
- Evidence was provided by the port authority that pistachios are usually stored at the quayside warehouses for not longer than 8 days until loading takes place, the journey by ship to the EU commonly takes 15 days.
- Customs export permit does not contain the lot number of the consignment concerned. However, it contains the number of the analytical report of the MH, which is linked to the consignment, necessary for the export to be released.
- Although the export permit contains the country of destination, the health certificate issued by the MH does not. In addition, the correct laboratory name is not included in health certificates issued by the central FDCL laboratory as required by Commission Decision 2005/85/EC Annex I.

Between 21 April 2004 and 01 August 2005 health certificates required for EU exports were issued only for those consignments where the aflatoxin level was below the limit of detection (LOD). Because this measure did not show any effect on the rejection rate of pistachio consignments at EU borders, it was withdrawn with effect of 01 August 2005. Now consignments are exported to the EU when complying with EU aflatoxin limits for direct human consumption.

Concerning the procedure for handling of pistachio consignments rejected at EU borders and returned to Iran, the decision of 16 July 2005 allows for consignments not exceeding national aflatoxin limits to undergo the common import procedure. Once passed, the pistachios can be used for the domestic market or can be resorted at the exporters' premises and exported to EU or non-EU countries. If the aflatoxin content is between 20 and 35 ppb for B1 and total aflatoxin respectively, it can be exported to those countries allowing the marketing of such products. Finally, if the aflatoxin levels are above 20/35 ppb then the consignments can be transported to free-zones, where they can be resorted, sampled and exported in accordance with their aflatoxin level after resorting. Until the mission date, no consignments have undergone this procedure.

5.6. Laboratory services

5.6.1. Public laboratories

The inspection team visited three public laboratories under supervision of the MH, the FDCL in Tehran, the food control laboratory of the Medical University of Rafsanjan (RFCL), and the food control laboratory of the Medical University of Kerman (KFCL), who are responsible for performing official analysis of aflatoxins of pistachio consignments intended for export to the EU.

Two of these laboratories, FDCL and RFCL, are also issuing the official health certificates as requested by Commission Decision 2005/85/EC, and FDCL is issuing health certificates on behalf of KFCL.

FDCL is also responsible for assessing public and private laboratories regarding the application of required analytical procedures and basic quality requirements.

None of the public laboratories visited are accredited to ISO 17025¹¹. Some principles, such as SOPs for performing the analyses, validation of methods, quality control charts, logbooks and training records are well installed. Laboratory quality managers are not assigned, though there is a nominated person for quality assurance at central FDCL level. Internal audits and management reviews are not carried out, but FDCL inspects the laboratories in Rafsanjan and Kerman on a regular basis.

All laboratories visited use slurry sample preparation, and an internationally published method (AOAC 999.07) consisting of immunoaffinity cleanup (IAC) and High Performance Liquid Chromatography (HPLC) with fluorescence detection and Kobra cell for determination of aflatoxin B1, B2, G1, G2.

The laboratories participate in the Food Analysis Performance Assessment Scheme (FAPAS) with favourable results, though the FDCL did not participate in the 2005 rounds due to administrative problems and lack of funding. The KFCL participated only once in 2003 and once in 2005. Certified reference materials (CRM) were available only in the RFCL, but not yet used.

Results reported by the three laboratories are corrected for recovery. The results of the FDCL were not adjusted for the edible part. During the visit to the KFCL in Kerman, which uses the same Excel software for calculation, it was shown that this error has already been corrected. None of the laboratories have calculated measurement uncertainty and hence do not report them.

The KFCL used the lot numbers of the pistachio consignments instead of unique numbers for identification of samples in the laboratory.

Sampling and analysis of consignments intended for export to non-EU countries is the responsibility of ISIRI. The central ISIRI laboratory in Karaj was visited. This laboratory is not accredited to ISO 17025, but seeking accreditation in the near future. A quality manager is assigned and most of the necessary quality procedures are in place.

¹¹ ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories

The ISIRI laboratory also uses the AOAC method described above. However, it was reported by ISIRI, that the RFCL and KFCL were using a thin layer chromatography (TLC) method and were advised in November 2004 to implement the HPLC method.

Table 2 provides a summary of the performance criteria of the laboratories visited.

5.6.2. Private laboratories

On request by the MA, the mission team visited 2 private laboratories. One laboratory is accredited to ISO 17025 by the Iranian Accreditation System (IAS) and a German accreditation body (DAP) and participates regularly in international proficiency tests. It is approved by FDCL for sampling of consignments intended for export to the European Union, and for analysis of products for the local market. The number of consignments sampled for EU export was 8 in the period 2003/2004, and 9 in the period 2004/2005. The laboratory is also approved by ISIRI for sampling and analysis of consignments intended for non-EU export. The laboratory was well organized and capable of analysing large numbers of samples for a wide range of mycotoxins.

The other private laboratory visited, part of a pistachio export company, is approved by ISIRI for analysis of non-EU exports until January 2006. It is currently in progress to achieve accreditation to ISO 17025 by IAS.

5.7. Follow-up of RASFF notifications

In April 2005, the PAO proposed to the MH the setting up of a database about pistachio consignments rejected at EU borders and expressed concerns about the continuing high number of rejections. As mentioned under 5.1 (8), the FDCL of the MH introduced a new procedure concerning the suspension of issuing health certificates for EU exports of pistachios which became effective for the period of 6 July to 6 October 2005 for the first time. Under this decision, 14 exporters were suspended from exporting to the EU for three month.

Apart from the aforementioned action, no follow-up of individual rejections at EU borders is performed by the competent authorities at exporter level.

5.8. Domestic aflatoxin monitoring system for pistachios

The mission team could not identify any change regarding monitoring of aflatoxin content in pistachios destined for the domestic market since last mission.

6. CONCLUSIONS

6.1. Relevant national legislation

- (1) National legislation in place provides for sufficient legal powers necessary to ensure that only those pistachios complying with the EU aflatoxin limits for direct human consumption are exported to the EU.
- (2) The temporary suspension of the issuance of health certificates for exporters with a high number of rejections of pistachio consignments at EU borders can reduce the overall

figure of rejected consignments. However, the list of suspended exporters is communicated only within Iran, which does not allow EU customs authorities to verify the proper functioning of the measure implemented.

6.2. Competent Authorities

(3) Official control responsibilities with regard to the subject of the mission are clearly allocated between the MA and the MH. They largely remain unchanged since the previous mission.

(4) Research on the prevention of aflatoxin contamination in pistachios is ongoing. There is good communication and organisation in place in order to transfer research knowledge into practice. Currently, research regarding potential causes of contamination of pistachios during sea transport to the EU has not been undertaken.

6.3. Process controls in the pistachio production chain

(5) Pistachio producers visited are well aware of relevant GAP principles and research findings, related to the aflatoxin prevention in pistachios during cultivation.

(6) Pistachio processors visited were also well aware of relevant GMP principles and research findings. However, because of the large number of processors and exporters of pistachios in Iran, and the lack of routine inspections by the MH regarding GMP, these principles are not uniformly applied.

(7) Furthermore, only those few companies working fully in accordance with GMP principles provide traceability of pistachios to the areas of cultivation or to individual farmers. For all other companies buying pistachios on the market, control on the quality of pistachios is limited, particularly due to the lack of traceability.

(8) It was demonstrated that the principles and measures of the HACCP and GCP projects can efficiently reduce or avoid aflatoxin contamination in pistachios. However, continuation of the HACCP project 2006 depends on the availability of funds provided by the MA. Furthermore, both projects have not yet addressed the issue of standard GAP and GMP application in small scale farmers and producers.

6.4. Method of sampling for pistachio consignments

(9) Sampling, as demonstrated in 2 different regions, was found to be in compliance with Commission Directive 98/53/EC in one region. While samplings observed by the mission team were in line with Commission Directive 98/53/EC, the lack of written instructions regarding the application of Commission Directive 98/53/EC and the lack of formalized trainings could result in different performance levels.

Table 2: Laboratory performance

Laboratory Item	FDCL Tehran	RFCL Rafsanjan	KFCL Kerman	ISIRI Karaj	Private Lab #1 Tehran	Private Lab #2 Tehran
Milling	Slurry	Slurry	Slurry	Slurry	Slurry / Dry milling	Slurry
extraction method	AOAC 999.07	AOAC 999.07	AOAC 999.07	AOAC 999.07	AOAC 999.07	AOAC 999.07
determination by	HPLC-FLD/Kobra cell	HPLC-FLD/Kobra cell	HPLC-FLD/Kobra cell	HPLC-FLD/Kobra cell	HPLC-FLD/Kobra cell	HPLC-FLD/Kobra cell
aflatoxin standard	Sigma crystal	Sigma crystal	Sigma crystal	R-Biopharm liquid	R-Biopharm crystal	R-Biopharm liquid
Validation	+	+	+	+	+	+/-
recovery (%)	+	+	+	+	+	+
CV (%)	+	+	+	+	+	+
calibration curve	+	+	+	+	+	+
range (µg/kg)	+	+	+	+	+	+
calibration level	+	+	+	+	+	+
LOD	+	+	+	+	+	-
LOQ	+	+	+	+	+	+
measurement uncertainty	-	-	-	-	+	-
use of CRM	-	+/-	-	-	+	-
proficiency tests	+/-	+	+/-	+	+	+
internal audits	-	-	-	-	+	+
ISO 17025 accreditation	No	No	No	No	yes (IAS, DAP)	in progress (IAS)
additional remarks	Analytical results not adjusted to edible part. No proficiency tests performed in 2005. FDCL does regular internal inspections in RFCL and KFCL labs.	CRM available, but not yet used. Internal inspections by FDCL.	Proficiency tests not regularly performed. No unique sample no. used in lab. Internal inspections by FDCL. Health certificates issued by FDCL.	ISIRI Karaj does annual internal checks at ISIRI labs in Kerman and Rafsanjan (not visited); HPLC is reported to be implemented.		

- + in accordance with ISO 17025 criteria
- +/- partially in accordance with ISO 17025 criteria
- not in accordance with ISO 17025 criteria

6.5. Procedure for exporting pistachios to the EU

(10) The system for the export of pistachios to the EU is clearly regulated and under control by the MH and customs authorities. A number of changes were made, addressing the shortcomings identified on the previous mission, which facilitate the swift export of pistachio consignments to the EU.

(11) The export permit does not contain the lot number of the consignment concerned and thus traceability is only possible indirectly via the associated analytical report.

(12) Health certificates of the MH do not always contain all information required by Commission Decision 2005/85/EC Annex I. In some cases this is the lack of identification of the laboratory performing analysis and in other cases lack of detail on the point of import into the EU. This latter point in particular allows for the possibility rejected lots being resubmitted for import at another EU port.

(13) According to the Pistachio Committee of the President's office of 16 July 2005, pistachio consignments rejected at EU borders and returned to Iran can be subjected to sorting, re-sampled and exported to the EU when complying with the applicable aflatoxin limits.

6.6. Laboratory services

(14) Since mission SANCO 3157/2001 the analytical capabilities of the public laboratories of the MH visited by the mission team have improved, particularly in the application of a uniform analytical method. All public laboratories were assessed as to be adequate to undertake routine aflatoxin analysis for export purposes.

(15) Deficiencies found by the mission team related to lack of laboratory accreditation according to ISO 17025, and the lack of use of certified reference materials. One laboratory participates regularly in international proficiency tests.

6.7. Follow-up of RASFF notifications

(16) Follow-up of individual rejections at exporter's premises by the competent authorities is not performed, but could speed up the implementation of GAP and GMP principles identified to be efficient to reduce or avoid aflatoxin contamination.

6.8. Domestic aflatoxin monitoring system in pistachios

(17) No change since last mission.

6.9. Overall Conclusion

(18) Overall, there is a good framework control system in place for exporting pistachios to the EU. Improvements since last mission SANCO 3157/2001 in the areas of laboratories and regarding the export procedure have been noted. Examples of the application of certain GAP and GMP principles have been demonstrated to the mission team as to be efficient for the control of aflatoxin contamination in pistachios. However, only a small number of operators apply these principles. A significant reduction of the

number of pistachio consignments not complying with EU limits for aflatoxins can only be achieved by uniform application of these principles by all operators and their enforcement by the MH. Further minor shortcomings were identified in the areas of sampling, laboratories, health certification and research.

7. CLOSING MEETING

A closing meeting was held on 30th November 2005 with the competent authorities. At this meeting, the main observations and initial conclusions were presented by the mission team. Representatives of the competent authorities accepted the main observations and initial conclusions without major objections. Representatives of the MH indicated further changes to be made in the near future, such as producing a draft on sampling of pistachios to be exported to the EU and the implementation of regulations regarding hygiene requirements and GAP. Exporter representatives, present during the closing meeting, and competent authority representatives voiced their concerns about Regulation (EC) No 882/2004¹² 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, specifically regarding chapter 4.

8. RECOMMENDATIONS

To the Competent Authorities of the Islamic Republic of Iran

The Competent Authorities should address the shortcomings and deficiencies, stated above in section 6, in order to improve the official control system of the foodstuffs concerned intended for export into the EU, in particular:

- (1) The Competent Authorities should ensure the application of GAP and GMP principles identified in Iran to be effective to avoid or reduce aflatoxin contamination in pistachios by all operators concerned as soon as possible.
- (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.
- (3) The Competent Authorities should consider the accreditation to ISO 17025 of official control laboratories for the analysis of aflatoxins in pistachios to ensure the equivalence to Article 12.2 of Regulation 882 (as derogated by Article 18 of Regulation 2076/2005 of 5 December 2005¹³ 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) and to ensure these laboratories provide reliable analytical results.

¹² OJ L 165, 30/04/2004. Corrected and re-published in OJ L 191, 28.5.2004, p. 0001-0052

¹³ OJ L 338, 22/12/2005, p. 0083-0088

- (4) The Competent Authorities should ensure that all health certificates contain the information as required by Commission Decision 2005/85/EC Annex I, specifically details of the laboratory which performed the analysis and the place and country of destination.
- (5) The Competent Authorities should consider communicating the list of exporters temporarily suspended from export of pistachios to the EU to Commission services.
- (6) The Competent Authorities should ensure that sampling of pistachio consignments to be exported to the EU is carried out in a uniform way.
- (7) The Competent Authorities should consider undertaking research in order to determine if pistachios are becoming contaminated with aflatoxins during transport to the EU.

An action plan in response to these recommendations should be produced by the competent authorities, which provides detailed information of the actions that will be taken and proposes deadlines by which these actions will be completed **within 2 months of receipt of the final report.**

9. ADDENDUM

In their response to the draft report the competent authorities of the Islamic Republic of Iran provided corrections and clarifications on the text. A number of comments provided, indicated planned actions to be undertaken as follows.

Recommendation 1

The competent authorities indicated that legal and operational steps have been taken to systematically enforce GAP and GMP principles in pistachio orchards and processing plants as of March 2006.

Recommendation 2

The competent authorities indicated that the extension of the HACCP program and its general implementation in the provinces of Kerman, Yazd, Fars, Semnan and Khorasan will begin in March 2006.

Recommendation 3

The competent authorities indicated that plans are in place for the official control laboratories to achieve accreditation in accordance with ISO 17025 within 2 – 3 years. It is planned to improve the quality assurance system within the laboratories and that all 3 laboratories will participate in FAPAS proficiency tests in 2006. Regarding measurement uncertainty it was indicated that it will be calculated by all 3 laboratories and included in the analytical reports. Finally, it was indicated that a unique sample identification code will be used in the KFCL laboratory.

Recommendation 4

The competent authorities indicated that the name of the laboratory having performed the analysis will be included in the health certificates.