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FINAL REPORT OF A MISSION
CARRIED OUT IN
INDIA
FROM 01 TO 12 OCTOBER 2009

IN ORDER TO ASSESS THE CONTROL SYSTEM IN PLACE TO CONTROL AFLATOXIN
CONTAMINATION IN PEANUTS INTENDED FOR EXPORT TO THE EUROPEAN UNION
AND TO FOLLOW UP THE RECOMMENDATIONS OF MISSION DG SANCO 7633/2005

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 an endnote.

Executive Summary

This report describes the outcome of a mission carried out by the Food and Veterinary Office in India, from the 1 to 7 October 2009.

The objective was to evaluate the facilities and measures in place for the control of aflatoxin levels in groundnuts intended for export to the European Union and to follow up on the recommendations of FVO mission 7633/2005.

The provisions relating to groundnuts which are subject to export to the EU are laid down in national provisions (Trade Notice). Following an increase in the number of RASFF alerts relating to aflatoxins in groundnuts this trade notice has been strengthened in June 2009 with additional requirements regarding the approval of companies exporting, and of the procedure for the export of groundnuts and groundnut products.

The principle changes to the export provisions are that since June 2009 it is mandatory for all groundnut processing units for human consumption to have HACCP certification in place, and that there are additional controls in the export procedures.

There is a move to the construction of newer processing facilities for kernels for human consumption, with automated processing and the use of electronic sorting equipment.

The sampling procedure observed is satisfactory and the analysis for mycotoxins within the required parameters. At present there is no standard method for grinding or validation of the homogeneity of ground samples and some deficiencies were noted in the examined methods..

At the port of export the formal instructions issued by the Indian Government for customs used the incorrect TARIFF code, requiring certification only for in-shell peanuts and not kernels or peanut products.

Regarding the follow up of the previous mission SANCO 7633/2005 two recommendations are fully addressed and two are in the course of being actioned.

Overall the Indian competent authorities and industry have made significant efforts to improve the controls and conditions for peanut production and export in India, including a positive response to recommendations in the previous report. Some continuing improvements are required to ensure full compliance with the APEDA trade notice.

The report provides a number of recommendations to the Indian Authorities to address the noted deficiencies.

Table of Contents

1	<u>INTRODUCTION</u>	1
2	<u>OBJECTIVES OF THE MISSION</u>	1
3	<u>LEGAL BASIS FOR THE MISSION</u>	1
4	<u>BACKGROUND</u>	2
4.1	<u>OVERVIEW OF PREVIOUS MISSIONS REGARDING AFLATOXIN CONTAMINATION IN FOODSTUFFS</u>	2
4.2	<u>BACKGROUND TO PRESENT MISSION</u>	2
4.3	<u>FOOD PRODUCT INFORMATION RELATED TO PUBLIC HEALTH ISSUES</u>	2
5	<u>FINDINGS AND CONCLUSIONS</u>	3
5.1	<u>LEGAL REQUIREMENTS</u>	3
5.2	<u>NATIONAL LEGISLATION</u>	3
5.3	<u>COMPETENT AUTHORITIES</u>	4
5.3.1	<u>AGRICULTURAL AND PROCESSED FOOD PRODUCTS EXPORT DEVELOPMENT AUTHORITY (APEDA)</u>	4
5.3.2	<u>CUSTOM AUTHORITIES</u>	4
5.3.3	<u>INDIAN OILSEEDS AND PRODUCE EXPORT PROMOTION COUNCIL (IOPEPC)</u>	4
5.3.4	<u>DIRECTORATE OF GROUNDNUT RESEARCH (DGR)</u>	4
5.4	<u>PROCESS CONTROLS IN THE GROUNDNUT PRODUCTION CHAIN</u>	5
5.4.1	<u>GROUNDNUT CULTIVATION</u>	5
5.4.2	<u>GROUNDNUT PROCESSORS VISITED</u>	5
5.5	<u>METHOD OF SAMPLING FOR GROUNDNUT CONSIGNMENTS</u>	6
5.5.1	<u>AUTHORISED COMPANIES</u>	6
5.5.2	<u>SAMPLING PROCEDURE</u>	7
5.6	<u>PROCEDURE FOR EXPORTING PEANUTS TO THE EU</u>	7
5.7	<u>LABORATORY SERVICES</u>	9
5.7.1	<u>LABORATORIES VISITED</u>	9
5.8	<u>RESPONSE TO RASFF NOTIFICATIONS</u>	12
5.9	<u>FOLLOW-UP TO MISSION 7633/2005</u>	12
6	<u>OVERALL CONCLUSIONS</u>	14
7	<u>CLOSING MEETING</u>	14
8	<u>RECOMMENDATIONS</u>	14
	<u>ANNEX 1 - LEGAL REFERENCES</u>	15

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AOAC	Association of Official Analytical Chemists
APEDA	Agricultural and Processed Food Products Export Development Authority
CCA	Central Competent Authority
CRM	Certified Reference Material
DGR	Directorate for Groundnut Research
EC	European Commission
EDI	Indian Customs Electronic Data Interchange System
EU	European Union
FAPAS	Food Analysis Performance Assessment Scheme
FTE	Full Time Equivalent
FVO	Food and Veterinary Office
HACCP	Hazard Analysis and Critical Control Point
HPTLC	High Performance Thin Layer Chromatography
IOPEPC	Indian Oilseeds and Produce Exporter Promotion Council
ISO	International Organization for Standardization
LC-MS/MS	Liquid Chromatography/Mass Spectrometer/Mass Spectrometer
LIMS	Laboratory Information Management System
LOD	Limit of Detection
MS	Member States
NABL	National Accreditation Board for Testing and Calibration Laboratories
RASFF	Rapid Alert System for Food and Feed
SOP	Standard Operating Procedure
TLC	Thin Layer Chromatography
UV	Ultra-Violet

1 INTRODUCTION

The mission took place in India from 1 to 7 October 2009. 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 Indian authorities.

The mission team was accompanied during the whole mission by representatives from the central competent authority (CCA) the Agricultural and Processed Food Products Export Development Authority (APEDA) and representatives from the Indian Oilseeds and Produce Export Promotion Council (IOPEPC).

An opening meeting was held on the 1st October at the premises of APEDA. Representatives from APEDA, IOPEPC, and the EU Delegation in India were present. During this meeting, the objectives of and itinerary for the mission were finalised and confirmed by the mission team.

2 OBJECTIVES OF THE MISSION

The objectives of the mission were:

- To verify whether the facilities and measures were in place to control aflatoxin contamination in peanuts for export to the European Union (EU).
- To follow-up on action taken by the Indian authorities in response to recommendations made by the FVO in the previous report (SANCO 7633/2005).

In pursuit of these objectives, the visits were carried out in accordance with the itinerary agreed between APEDA and the FVO of the European Commission and were as follows

Competent authority visits			Comments
Competent authority	Central	2	APEDA, IOPEPC
	Local	1	Customs offices in Ghandidham
Laboratory visits			Comments
		2	Laboratories authorised by APEDA
Food processing establishments			Comments
Harvesting Areas		2	Peanut fields, State of Gujarat
Processing Establishments		4	State of Gujarat

3 LEGAL BASIS FOR THE MISSION

The mission was carried out in agreement with the competent authority APEDA and under the general provisions of Community legislation, in particular:

– Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal

health and animal welfare rules.

4 BACKGROUND

4.1 OVERVIEW OF PREVIOUS MISSIONS REGARDING AFLATOXIN CONTAMINATION IN FOODSTUFFS

The European Commission has carried out missions to Iran, Egypt, Turkey, China, Brazil, India, the USA, Argentina, Peru and Ghana with the objective of evaluating official control systems for the prevention of aflatoxin contamination in foodstuffs originating from those countries. In addition, missions to assess controls on imported products of plant origin have been carried out in 18 Member States (MS): Austria, Belgium, Bulgaria, the Czech Republic, France, Germany, Greece, Hungary, Italy, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Romania, the Slovak Republic, Spain and the UK. The reports on these missions are available on the DG Health and Consumers website at:

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

4.2 BACKGROUND TO PRESENT MISSION

According to Eurostat exports of peanuts from India to the EU were approximately 25,000 tonnes, (see details below). The number of RASFF notifications has increased from 6 in 2006, 19 in 2007, 15 in 2008 and at the date of the mission in September 2009 19 have been received.¹

	2007	2008
Shelled Groundnuts CN code 12022000	5,991(UK, BE, DE)	23,148 (UK, BE, DE)
Groundnuts in shell CN code 12021090	1,263 (UK, PL, NL,)	1,484 (UK, DE, BE)
Peanut butter CN code 20081110	26(UK)	60 (UK)

Source: Eurostat, Comext database.

4.3 FOOD PRODUCT INFORMATION RELATED TO PUBLIC HEALTH ISSUES

Aflatoxins are mycotoxins produced by certain species of *Aspergillus*, which develop at high temperatures and humidity levels and may be present in a large number of foods. The 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 Regulation (EC) No 1881/2006, the maximum admissible aflatoxin levels in groundnuts, nuts and dried fruit are as follows:

¹ Please note that following the mission 11 of these alerts have been withdrawn by the reporting Member State due to a misinterpretation of the legal provision pertaining to the reporting to the RASFF system.

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

2 µg/kg aflatoxin B1 content, and

4 µg/kg total aflatoxins content

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

8 µg/kg aflatoxin B1 content, and

15 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 Regulation (EC) No 401/2006, a sampling procedure and general criteria are established to ensure methods of analysis with comparable levels of performance.

5 FINDINGS AND CONCLUSIONS

5.1 LEGAL REQUIREMENTS

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

Article 10 of Regulation (EC) No. 852/2004, in conjunction with Article 4.1 and Annex I, Part A of the same Regulation, requires that food business operators carrying out primary production shall comply with general hygiene provisions held in the annex.

Article 10 of Regulation (EC) No. 852/2004 in connection with Article 5 of the same Regulation requires that every food business operator shall put in place a procedure based on HACCP principles.

Regulation (EC) No 401/2006 provides methods of sampling and analysis for the official control of mycotoxins in foodstuffs.

5.2 NATIONAL LEGISLATION

Findings

The provisions in national legislation pertaining to competent authorities for peanut production and export control remain unchanged from the previous mission in 2005.

The principle changes to the export provisions are made in an APEDA trade notice (APEDA/Q/2009) of June 2009, amended in August 2009. It is clarified that it is now mandatory for all peanut processing units and exporting warehouses to be registered with APEDA and HACCP certified and for additional controls in the export procedure (see section 5.5).

Conclusions

The main legislation regarding responsibilities remains unchanged, but there are stricter controls now imposed by a new trade notice

5.3 COMPETENT AUTHORITIES

Findings

5.3.1 *Agricultural and Processed Food Products Export Development Authority (APEDA)*

The structure of Competent Authorities remains substantially unchanged since the previous mission in 2005, and responsibilities remain the same.

APEDA is a statutory body under the Ministry of Commerce and Industry (MOC&I (Govt of India)) and was established by an Act of the Indian Parliament in 1986. It is funded by the MOC&I (Govt of India) and has no income from private sources. APEDA was established to further develop the Indian agricultural commodities and processed foods, and to promote their exports.

APEDA has its headquarters in New Delhi and 5 regional offices. Under the Director's remit there are several divisions of which the quality division comes under the scope of this mission. This division is responsible, among other things, for aflatoxin control.

5.3.2 *Custom authorities*

Customs belong to the Ministry of Finance and they are responsible for the application of the Customs Act, 1962.

The customs office visited has an electronic data interchange system called EDI on which customs data concerning each consignment are entered. Customs clearance takes place only after the export certificate has been issued by APEDA.

The mission team visited the customs office of the port of Kandla in Gujarat Province, where the majority of consignments of Indian groundnuts are shipped to the EU. The port is located in the Gulf of Kutch in Gujarat.

5.3.3 *Indian Oilseeds and Produce Export Promotion Council (IOPEPC)*

IOPEPC was previously known as IOPEA, and is referred to as such in the previous report. It was a private trade association, but is now an Export Promotion Council, recognized by the Ministry of Commerce and Industry, responsible for promotion of the export of oilseeds. Within the scope of this mission, IOPEPC is the liaison with APEDA with regard to registration of peanut processors and for the issuing of export certificates.

IOPEPC is responsible for the organising of training/awareness programmes for the farmers and processors for control of aflatoxins and improvement in hygiene standards. To this extent some nine training programmes were implemented in the period 2006-2009, in all the main production areas. These covered both production practices and processing practices and were thus aimed primarily at farmers and processing companies. APEDA were also present at these training courses, as were representatives of the Directorate for Groundnut Research (DGR).

5.3.4 *Directorate of Groundnut Research (DGR)*

Previously known as the National Research Centre for Groundnut (and referred to in the previous report as such) this is an agricultural research centre based in Gujarat that has undertaken research on peanuts, including research specific to aflatoxin control in groundnut production. Evidence of research papers published or presented at international symposia that related to mycotoxin control was presented.

In addition to research projects that influence the development of GAP the DGR has produced

booklets that are disseminated to the industry entitled 'Safeguard Groundnut from Aflatoxin Contamination'. The leaflet covers basic practices during groundnut growing, harvesting and processing to reduce aflatoxin formation.

Members of the DGR are also involved in the committees that undertake the inspection and approval of export facilities.

Conclusions

The responsibilities of CAs remains unchanged and is clearly defined in both legislation and the Trade Notice

There are changes to the name of both IOPEPC and the DGR but responsibilities remain unchanged.

5.4 PROCESS CONTROLS IN THE GROUNDNUT PRODUCTION CHAIN

Findings

5.4.1 Groundnut cultivation

In India, there are approximately 8 million hectares being cultivated with groundnuts. The states of Gujarat, Andhra Pradesh and Karnataka are the main producing regions which account for approximately 68% of the total production. The state of Gujarat is the main producing region with 2.12 million tonnes in 2008 accounting for 36% of total production. The size and operation of farms remains substantially unchanged from the last mission, although APEDA cited there was a move towards the use of contract farming.

There are two main crops in India, namely the winter crop and the summer crop. Sowing of the winter crop is carried out in April and May while harvesting takes place in October and November after approximately 100-120 days. Sowing of the summer crop (during monsoon) is undertaken in January and February while harvesting takes place in May and June after 90-110 days. As the period from sowing to harvesting is lower in the summer crop, the productivity during this crop is lower than the winter crop. The mission team visited the production region of Gujarat prior to the beginning of the winter crop harvest.

The mission team visited two farms of less than 6 hectares. Both had irrigation facilities and showed a consistent mature plant with no signs of moisture stress. Although harvesting had not begun due to a late harvest period the process of harvesting was described as follows; whilst harvesting the plants are turned manually. Then, pods were exposed to the sun for drying periods of 5 to 8 days. Threshing stage takes place at farmer level to clean and sort the groundnuts. Sorted groundnuts are then packaged in jute bags to be transported to groundnut processing facilities.

At present traceability is not always possible as groundnuts can be purchased from intermediate traders. In some processors visited a traceability procedure was possible and APEDA are currently trialling a computer system to facilitate traceability.

5.4.2 Groundnut processors visited

The new export procedure defines that all peanut/ peanut product processors are certified to having followed HACCP principles. Peanut shelling and grading units are encouraged to implement HACCP principles.

The mission team visited 4 groundnut processing units. All were approved by APEDA for export

and demonstrated that they had been subject to visits and assessment by a panel of the approval committee; including staff from APEDA, IOPEPC and the DGR. There are 5 facilities approved for the export of peanut kernels for human consumption, with 6 under the process of approval.

Once in-shell groundnuts have been shelled, groundnut kernels are subjected to a sorting and grading process by mechanical and visual inspection where groundnuts are handpicked or subject to mechanical sorting to remove damaged and mould affected kernels. Kernels are passed through metal separators prior to bagging. Groundnut kernels rejected during the selection and sorting process are clearly marked and used for the production of oil. Bags for final products used include 25 kg (for bird feed) and 50 kg jute bags (for human consumption).

Hygienic conditions in all the visited premises were good and there is a concerted move towards the upgrading of processing facilities to produce a more mechanised grading and sorting process. The use of large mechanical sorting machinery using two colour selection is more frequent, either in addition or replacing hand picking/ sorting. There was no research presented to indicate which process was the most efficient at removing aflatoxin affected groundnuts.

The companies exporting also demonstrated the export procedure in line with the APEDA instruction, as exports for human consumption must take place directly from the processing company.

At present traceability to the farmer is not possible in many cases as the in shell nuts are sold to intermediaries or to shelling plants on the open market. At present APEDA is working on the development of a traceability system, currently trialled in the eight main processors, and it was stated that the processors were encouraged to use contract farming.

One processor undertook analysis of production regions at the beginning of the season to identify the regions with the least problems, best quality and least aflatoxin levels.

Conclusions

Farms are generally small to medium sized but as peanuts are sold on the open market traceability is not always possible.

Farms visited exhibited no problems and the farmer was aware of general practices to control aflatoxin production. Ongoing education programmes are in place covering practices that affect aflatoxin production

Producers are all certified to HACCP by private accreditation bodies. Hygiene conditions were good and processing is been modernised for sale of kernels for human consumption

There is a satisfactory system of approval in place for producers and warehouses, based on assessment by a committee under the responsibility of APEDA and IOPEPC.

5.5 METHOD OF SAMPLING FOR GROUNDNUT CONSIGNMENTS

Findings

5.5.1 Authorised companies

Based on the new Trade Notice APEDA/Q/2009 of the 22 nd June 2009 and associated procedural document, sampling must be performed by authorised private companies (laboratories) which in turn will also be responsible for undertaking analysis of aflatoxins. Certification including analytical certificate and 'stuffing certificate' are also required for all exports to the EU

Currently there are 12 private laboratories authorised by APEDA for undertaking sampling (details

under the laboratory section).

5.5.2 *Sampling procedure*

There are three different sampling procedures depending on the intended use of the groundnuts (human consumption or bird feed, or bird feed with destination in the UK). In all cases, the sequence of sampling starts with a request of the exporting company to the authorised laboratory to sample the consignment for export. Staff from the designated laboratory are then required to take a sample according to procedure detailed in the Trade Notice. For human consumption the sampling takes place only at the producing premises, whilst for feed the sampling may be done at warehouses near the port.

According to the Trade Notice, sampling of groundnuts and groundnut products intended for human consumption or to be subjected to sorting or other physical treatment shall be carried out only at the warehouse of the processing units, this instruction was widely known and observed in the visited establishments and the instructions given follow Commission Regulation (EC) No 401/2006.

The mission team evaluated a sampling procedure conducted by the regional staff of the main laboratory in one of the processors, the product being for human consumption. The staff had a written procedure for the sampling, and this was also copied into local languages. The staff were experienced in conducting sampling and had undergone training conducted by the laboratory centrally. The staff ensured the lot was defined and took samples from the opened filled bags using metal sample spears. The procedure followed exceeded the requirements of Regulation (EC) No401/2006 as a larger sample was taken than was needed. A procedure of quartering and mixing was then followed to provide a homogenous sample. 3 lots of 10 Kg were then double bagged in first an opaque cloth bag and then a plastic bag which was sealed and labelled. The samples and associated documentation was then sent, usually by courier for analysis at the central laboratory. Documentation contains a clear indication of the intended use of the lot.

Following the sampling the bags are then sown shut and sealed with a continuous string attached to each bag to ensure lot integrity is maintained.

For groundnuts intended for use as bird feed, the Trade Notice lays down that sampling shall be carried out either at the warehouse of the processing unit or at the warehouse of the exporter. Intended use must be mentioned on each bag as follows: “for animal and bird consumption only” and the size of each bag is 25 kg. The sampling procedure described in APEDA documentation is correctly described but states that it is only for the export to the UK, the same procedure is also described by the sampling laboratory.

For other MS for Bird Feed the method was described by the sampling laboratory as being taking a 10Kg sub-sample from a 30Kg sample to give two homogenised sub-samples. This method appears to be an amendment of the method described in Regulation EC (No) 401/2006 for nuts for further processing, although in this case a 30Kg sample should be homogenised.

Conclusions

There are three different sampling procedures depending on the intended use. Staff are well trained and instructions are available.

The method of sampling for human consumption and for Bird feed sent to the UK are correct, but the method for birdfeed to other EU MS is not in line with Regulation (EC) No 152/2009 laying down the method of sampling and analysis for the official control of feed. This is being incorporated in the APEDA trade notice (APEDA/Q/2009) amended in August 2009.

The sampling staff from one laboratory had not got suitable sampling equipment to provide a fully representative sample, whilst the other did.

5.6 PROCEDURE FOR EXPORTING PEANUTS TO THE EU

Findings

The new Trade Notice APEDA/Q/2009 provides for an improvement in the system of approval and export of peanuts and peanut products to Europe. Associated documentation describes the procedure for the granting of recognition certificates to peanut processing units, peanut shelling units and storage facilities .

	2008-9	2009-10 (to date)
For human consumption		
Total sampled	65 consignments	20 consignments
Rejected	8 consignments	0 consignments
For bird feed		
Total sampled	1104 consignments	103 consignments
Rejected	241 consignments	12 consignments

(Indicative figures from the main laboratory conducting sampling.)

Recognition procedures for groundnut processors

The new export procedure laid down in Trade Notice APEDA/Q/2009 also requires that all groundnut processing units are assessed and approved for export. The procedure involves firstly the submission of a written application for all peanut processing units to APEDA. Documentation for the submission is available on the APEDA website. Following the submission all are visited by a committee of officials from APEDA, IOPEPC, DGR and state governments. The documentation in the Trade Notice includes an evaluation fiche that identifies the areas that need to be assessed. The committee may make recommendations for improvements to be made. Although this is not submitted in writing, evidence was found of email communication of any deficiencies, and of the submission of the evaluation outcome to APEDA. In one case a revisit was made by the committee to verify the actions required. The certification of a HACCP system is required as part of this evaluation for peanut processing units.

At the time of the mission five facilities were approved by APEDA for the export of food grade kernels for direct human consumption.

There is also a requirement for the granting by APEDA of a recognition certificate for all storage warehouses ('Godowns') and peanut shelling/ grading units. The application and certification is administered by IOPEPC and is subject to an annual fee and an inspection visit of 10% of the warehouses annually. Documentation provided to the mission team included a thorough checklist for use during inspection.

In both cases the recognition certificate is valid for a period of one year. The list of approved facilities and approved laboratories is maintained on the APEDA website.

Following the sampling procedure described in section 5.4.2 the certificate is sent by the laboratory to the regional laboratory office that conducted the sampling. Results are usually received in 4-5 days. In the case of non-compliance the results have to be sent to the National Referral Laboratory (NRL) and APEDA as well as the company.

The staff of the laboratory sampling office are then responsible for the supervision of the loading of the container to ensure that the lot loaded is that sampled. There is a separate document ' container stuffing' that confirms this and gives the container number. The container can then proceed to the

port for export.

Customs procedures

A legal person on behalf of the exporter presents the declaration to customs offices along with the relevant documents (shipping bill, invoice, aflatoxin certificate and stuffing certificate, purchase order etc). This data is input in to the computer system. Customs staff have a publication ('Indian Trade Classification (Harmonised System) Classification of Export and Import Items') that lists all export requirements in place. The computer system is not able to identify these export requirements. At present this export book contains the instruction ' Export to EU permitted subject to compulsory registration of contractor with APEDA along with control / aflatoxin certificate given by laboratories nominated by APEDA.' The relevant TARIFF code however is given as 12021000, which is for in shell nuts only. It does not list any requirement for 12022010 (peanut kernels) which are the main export commodity, or for peanut products/ peanut butter etc.

During the closing meeting the mission team was shown a letter sent to the customs authorities in July 2009 that identified the above problem and asked it to be rectified. To date no response had been received and an undertaking was made at the final meeting to follow up on this.

Conclusions

All consignments of peanuts or peanut products are required to follow the APEDA export procedure. This provides for an export control system that offers good control over the exported lots.

All documentation examined at the exporters for lots exported to Europe contained all the required documentation as above.

Customs staff at the point of export check that the required APEDA documentation is being included in the export documentation. At present the book used to identify the required controls has incorrect TARIFF coding which means that checks are not in compliance with the APEDA requirements.

5.7 LABORATORY SERVICES

Findings

Based on the requirements established in the export trade notice and on the basis of an established laboratory approval procedure, aflatoxin analysis must be performed by authorised private laboratories. Currently there are 12 private laboratories authorised by APEDA for undertaking aflatoxins analysis, in addition to the nominated NRL. These 12 laboratories are accredited to ISO 17025 by the National Accreditation Board for Testing and Calibration Laboratories (NABL) as required by the new Trade Notice APTN. Details of the current status of accreditation, and of the scope of accredited methods is available on their website www.nabl-india.org

All authorised laboratories have also been recognised under the APEDA scheme for laboratory recognition which was established in 2003, and the current version was updated in January 2008. The procedure requires submission of details of equipment, staff, and quality procedures and requires an on-site assessment by APEDA staff. Based on this scheme, the recognition is granted for a period of one year. Details of the approval procedure are also available on the APEDA website www.apeda.com as are the relevant Trade notices.

According to information in the Pre-Mission Questionnaire there is now a designated NRL; the Indian Institute of Integrative Medicine based in Jammu Tawi. This laboratory will play a role as of

the new harvest period in the checking of documentation, the counter analysis of some samples, method development and validation, training and the production of statistical summaries from the results of all laboratories.

5.7.1 *Laboratories visited*

The mission team visited two laboratories authorized under the above procedure, both in Mumbai. The first laboratory visited in Mumbai is an independent private laboratory established in 1964. The core activity is inspection, monitoring and trade and shipment of agricultural products and a number of other materials, such as pharmaceuticals, petrochemicals and metals. The central chemical laboratory for testing of agricultural products is located in Mumbai where 20 chemists and 10 technicians are working, sampling is undertaken by regional offices, of which there are four based in the peanut growing region. The laboratory is accredited in accordance with ISO/IEC 17025:2005 by NABL in the fields of chemical, biological and mechanical testing. The recent certificate of accreditation was issued in July 2008 and is valid until July 2010. A quality handbook is available and internal audits are performed and documented regularly. In June 2008 the laboratory was recognized by APEDA for export testing covering chemical and microbiological analysis of oilseeds (ground nuts) and nine other food commodities, in line with the approval procedure described above.

Concerning peanuts the scope of accreditation covers the determination of aflatoxins using AOAC methods 968.22 and 970.45 with a range of testing between 0.5 and 1000 µg/kg. Concerning food, feed and agricultural products the scope of accreditation covers aflatoxin determination using LC-MS/MS based on AOAC method 990.33 with the same before mentioned range of testing. Samples are taken all over India by own personnel following written detailed protocols according to European requirements as laid down in Commission Regulation (EC) No 401/2006 for groundnuts intended for human consumption or according to specific UK requirements if the groundnuts are intended for bird feed. The samples are shipped by courier generally within 24 hours to the laboratory. Upon receipt each sample is recorded and gets an internal laboratory code. A LIMS system is recently not available, but will be installed in December 2009. Source and origin of the sample is unknown to the laboratory personnel who perform the aflatoxin analysis. Only kernels are analysed which are crushed from 10 kg bags. The grindings takes place portion wise into a metal container which is not suitable to hold the whole 10 kg. At the time of the mission no homogeneity testing had been conducted but evidence of this was handed to the mission team later in the mission, and appeared satisfactory. All analyses so far were performed based on the above AOAC methods by HPTLC/densitometry. Fourteen samples and 5 standards are analysed in one batch. Up to three batches can be analysed per day. The batches contain either a 2 µg/kg spike with aflatoxin B1 or a blank. A calibration curve is produced with each batch covering the range between 1 and 10 µg/kg. Calibration of the HPTLC system is performed twice a month using caffeine. Certified standards have a purity of >98% and are stored properly. Working standards are checked twice a month by UV. A comprehensive validation was performed for aflatoxin levels between 0.5 and 5 µg/kg.

Currently the laboratory is switching to an LC-MS/MS based method using up-to-date analytical instrumentation. The analytical method is based on AOAC method 990.33. Three transmissions are recorded for identification, quantification and confirmation. The performance of the mass spectrometer is checked daily with triazophos and is properly documented. Instrumentation, calibration, documentation, and quality control procedures were found to be adequate for both analytical procedures.

Participation in one international proficiency test applying HPTLC as well as LC-MS/MS and one national inter-laboratory test was successful. A number of deficiencies were noted with respect to infrastructure, laboratory environment, grinding, calculation and reporting of measurement

uncertainty. The decision limit $cc\alpha$ was not estimated in respect of the maximum level, but on the lowest standard. Recovery and expanded measurement uncertainty are not given in the report. The laboratory recognised the shortcomings in the laboratory environment and informed the mission that they will move to a new build facility by March 2010.

During the visit to the second laboratory the staff were just moving from an old location to a new building and only part of the equipment was installed. The laboratory is accredited by NABL for the determination of aflatoxins in nuts and other food items by TLC with a range of testing between 1 $\mu\text{g}/\text{kg}$ and 1000 mg/kg as well as LC-MS/MS with a range of testing between 0.5 $\mu\text{g}/\text{kg}$ and 1000 mg/kg . The recent certificate of accreditation was issued on September 2008 and is valid until August 2010. In June 2009 the laboratory was recognized by APEDA for export testing covering chemical and microbiological analysis of oilseeds (ground nuts) and nine other food commodities. The APEDA approval relates to groundnuts intended for human consumption as well as for bird feed. So far, the laboratory has only performed aflatoxin analyses of groundnuts intended for bird feed which started in 2006. Since then, the number of samples tested is as follows 102 (2006-2007), 290 (2007-2008), 297 (2008-2009) and 253 (2009-till date).

Out of the total of 76 technical personnel that is working in the laboratory, 6 persons are involved in the preparation and extraction of aflatoxins and 5 persons are operating the mass spectrometers.

Sampling is performed locally in Gujarat by in-house trained personnel as per the method for bird feed. The samples are then sent to the laboratory in Mumbai by courier where they are coded manually and transferred to the responsible analytical unit. An SOP for sampling, sampling preparation and analysis for aflatoxins is available. The analytical procedure is a modification of AOAC methods 968.22 and 990.33. Grinding is performed portion wise into a small metal container which is not able to hold 10 kg. The demonstrated equipment which is intended for use for extraction and homogenization of samples for human consumption consists of a plastic bucket with several plastic scoops and was found to be insufficient for this purpose. Validation of the grinding procedure by homogeneity testing had not been conducted. The analytical determination is no longer performed by TLC but only by LC-MS/MS using one transition for quantification and two transitions for confirmation. LOD and LOQ are calculated on a signal to noise ratio of 3:1 and 9:1, respectively resulting in 0.15 and 0.50 $\mu\text{g}/\text{kg}$ for aflatoxins B1, B2 and G1. Respective data for G2 could not be supplied. Linearity is checked by a seven point calibration curve. The sequence of samples injected is documented in a logbook and the analytical data are backed up to a server weekly. Documentation regarding handling of reference standards, regular calibration of balances and performance checks of the mass spectrometer was found to be sufficient. The laboratory participated in a self-organized national proficiency test with two other Indian laboratories for detection of aflatoxin B1 in a spiked peanut product (10 $\mu\text{g}/\text{kg}$) with reasonable results.

Besides the before mentioned shortcomings regarding the extraction and homogenization a number of further deficiencies were noted with respect to laboratory environment, reporting of results, documentation and traceability. Although working with harmful solvents, such as benzene and chloroform, fume hoods were not available for aflatoxin analysis. The responsible laboratory manager indicated that all SOPs as well as the respective validations were sent to the NRL by July/August 2009 for approval and a "verbal approval" by the NRL was received in-between. A proof for this procedure could not be given. The SOP does not give details concerning the LC-MS/MS parameters, such as type of column and MS/MS settings. The validation of the method is only based on two concentration levels performing a threefold and a twofold analysis of spiked materials, respectively as well as a fivefold injection of the same sample. Estimation of the expanded measurement uncertainty is not available. The report of the analysis only refers to AOAC as method of analysis without any further specification and does neither give the recovery nor the expanded measurement uncertainty. The traceability of a groundnut sample received in the laboratory some 7 days before could not be demonstrated.

As the laboratory was not fully operational and a number of requested documents could not be provided during the time of the mission, a detailed evaluation was not possible.

Conclusions

There are 12 designated private accredited laboratories located in different regions through an APEDA approval system. Accreditation to ISO 17025 is a prerequisite for approval.

There is now a designated NRL. Whilst its role is defined it will only become fully operational with the new harvest (November 2009)

There is currently no standardized method of sample preparation and no evidence of the homogeneity of prepared samples. Laboratories visited did not have the capability to grind 10kg in one go.²

In the first laboratory visited the analysis has been undertaken to produce dependable results, but a number of deficiencies were noted with respect to infrastructure, laboratory environment, grinding, calculation and reporting of measurement uncertainty.

The second laboratory visited was not fully operational and as requested documentation could not be provided during the time of the mission, as the laboratory was in the process of shifting the laboratory facility to a more spacious location, it was not possible to reach a conclusion on its compliance.

5.8 RESPONSE TO RASFF NOTIFICATIONS

Findings

APEDA is the responsible authority receiving RASFF notifications concerning aflatoxins contamination in groundnuts exported to the EU. APEDA has provided evidence of follow-up in relation to the above RASFF notifications

In response to the increasing rapid alert notifications, the mission team was informed that investigations are conducted by APEDA/ IOPEPC and evidence was provided of communication and of visits to companies affected by RASFF notifications. In one case export approval was temporarily suspended.

Conclusions

Thorough investigations are carried out by APEDA/IOPEPC and evidence of corrective actions been taken was noted.

5.9 FOLLOW-UP TO MISSION 7633/2005

The FVO undertook a mission in India in 2005 with similar objectives. The report contained a number of recommendations to the Indian authorities:

² The Competent Authority of India added that the NRL is in the process of harmonization of method of sample grinding to be followed by the authorized laboratories to ensure homogeneity of groundnut samples.

RECOMMENDATION OF SANCO 7633/2005	RESPONSE FROM INDIAN AUTHORITIES	FOLLOW UP IN MISSION SANCO 2009-8148
Ensure that the additional export procedures proposed by the Indian authorities and detailed in the findings of this report are implemented at all stages, prior to the recommencement of exports to the EU of groundnuts for human consumption; in particular that all bags of groundnuts are clearly labelled with intended use, including a clear statement on the export certificate.	The competent authority i.e. APEDA, would ensure the implementation of the additional requirements as mentioned in the Trade Notice dated 5th July 2005. The recognition certificate to the processing units would be issued only when they comply with the requirements as mentioned in the Trade Notice of 5th July 2005. However, it may be noted that system of “each bag labelled with intended use” and “export certificate” exists as per the procedures.	The trade notice as described was implemented in 2005 but is superseded now by the notice of 2009 which provides a more thorough control system than that in 2005. This system is seen as operating effectively.
Ensure that all groundnut processing units exporting to the EU implement standards at least equivalent to Article 3 of Council Directive 93/43/EEC on food safety procedures based on HACCP principles	All the Groundnut processing units for human consumption have been advised about HACCP certification. The certification is a long process, and once they implement the HACCP system, it would be informed to EU Authorities	All processing facilities exporting to the EU are HACCP certified and this is verified by the inspection committee as part of the approval process.
Ensure that adequate sampling equipment is available to those with responsibility for sampling so as to be in line with Commission Directive 98/53/EC for sampling of groundnuts for aflatoxins analysis	Adequate sampling equipment is available with the persons responsible for sampling. In case they are not available with any particular persons, it would be ensured that they have it	The staff of the main laboratory have been equipped with full sampling spears that allow access to all parts of a 50Kg bag, ensuring a representative sub-sample distribution. The second laboratory visited only had plastic scoops which are not considered adequate.
Ensure that the deficiencies noted in the designated laboratory with responsibility for sampling and analyses of groundnuts destined for the EU are corrected	Deficiencies noted for correction. More frequent audit of the units would be carried out for quality control implementation.	Main performance issues have been rectified, and the environmental conditions will improve following the proposed move to a new building in 2010.

Conclusions

Two of the recommendations made in the last report have been fully implemented, two are partially implemented with satisfactory action ongoing.

6 OVERALL CONCLUSIONS

Overall the Indian competent authorities and industry have made significant efforts to improve the controls and conditions for peanut production and export in India, including a positive response to recommendations in the previous report. Some continuing improvements are required to achieve

full compliance

7 CLOSING MEETING

A closing meeting was held on 07 October 2009 at the premises of APEDA in New Delhi. Representatives from APEDA, IOPEPC, and the EU Delegation in India were present. At this meeting, the main observations and initial conclusions were presented by the mission team. They provisionally accepted the observations and initial conclusions presented during that meeting with some general comments.

8 RECOMMENDATIONS

To the Competent Authorities of India

Nº.	Recommendation
1.	Should consider to provide guarantees that the system put in place for ensuring that products are in line with Community requirements applies to all relevant commodities to be exported to the EU (e.g. Revision of TARIFF codes).
2.	Ensure that adequate sampling equipment is available to those with responsibility for sampling so as to be in line with Commission Regulation (EC) No 401/2006 for sampling of groundnuts for aflatoxin analysis.
3.	Ensure that the deficiencies noted regarding sample preparation in laboratories to produce a fully homogenised sample are corrected to offer equivalent guarantees to the requirements of Commission Regulation (EC) No 401/2006.
4.	Ensure that deficiencies in the laboratory performance are rectified to ensure the performance criteria established in Commission Regulation (EC) No 401/2006 are met.
5.	Ensure that the method of sampling for bird feed destined for EU countries other than the UK is line with the requirements of Regulation (EC) No 152/2009.

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

http://ec.europa.eu/food/fvo/ap/ap_in_2009-8148.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
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. 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. 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. 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. 152/2009	OJ L 54, 26.2.2009, p. 1-130	Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed