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FINAL REPORT OF A MISSION
CARRIED OUT IN INDIA
FROM 7 TO 17 NOVEMBER 2005
TO ASSESS THE FACILITIES AND MEASURES IN PLACE FOR THE
CONTROL OF AFLATOXIN LEVELS IN GROUNDNUTS INTENDED FOR
EXPORT INTO THE EUROPEAN UNION
AND
TO FOLLOW UP ON THE RECOMMENDATIONS MADE IN THE REPORT
SANCO/7075/2004

Please note that factual errors in the draft report have been corrected. Clarifications provided by the Indian authorities are given as footnotes in bold, italic, type, to the relevant part of the report.



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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

AOAC	Association of Official Analytical Chemists
APEDA	Agricultural and Processed Food Products Export Development Authority
APTN	APEDA Trade Notice No QMC/GMC/055/2005
CCA	Central Competent Authority
CRM	Certified Reference Material
DGFT	Directorate-General for Foreign Trade
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
HPLC	High Performance Liquid Chromatography
HPS	Hand-Picked and Selected
HPTLC	High Performance Thin Layer Chromatography
IOPEA	Indian Oilseeds and Produce Exporters' Association
ISO	International Organization for Standardization
LC-MS/MS	Liquid Chromatography/Mass Spectrometer/Mass Spectrometer
LOD	Limit of Detection
MS	Member States
NABL	National Accreditation Board for Testing and Calibration Laboratories
NRCG	National Research Centre for Groundnuts
PFA	Prevention and Food Adulteration Act and Rules
QEL	Quality Evaluation Laboratory of the Spices Board
RASFF	Rapid Alert System for Food and Feed
SOP	Standard Operating Procedure
TEU	Twenty foot equivalent units or one small container, the shipping industry's standard unit of measure

EXECUTIVE SUMMARY

This report describes the outcome of a mission carried out by the Food and Veterinary Office in India, from 7 to 17 November 2005.

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 7075/2004 on the control of Sudan dyes and aflatoxins in spices also for export to the European Union (EU).

The provisions relating to groundnuts which are subject to export to the EU are laid down in national provisions. Following an increase in the number of RASFF alerts relating to aflatoxins in groundnuts this trade notice has been strengthened in July 2005 with additional requirements regarding the export of groundnuts and groundnut products.

The principle changes to the export provisions are that since July 2005 it is mandatory for all groundnut processing units wishing to export groundnuts for human consumption to the EU to be assessed and approved. In addition, other important changes include the provision that the export certificate and all bags of groundnuts are clearly labelled with the intended use so as to prevent supply of birdfeed as food at the point of entry to the Community.

Those premises visited have initiated requests for recognition for export of groundnuts for human consumption to the EU. However, not all the premises visited have food safety procedures based on HACCP principles.

Investigations carried out by the Agricultural and Processed food Products Export Development Authority (APEDA) have indicated that the supply of birdfeed as food by importers at the point of import to the EU rather than the control systems in place were primarily responsible for the rise in RASFF alerts concerning aflatoxins.

The sampling procedure observed was not adequate to produce a representative sample of the whole consignment as required by sampling Commission Directive 98/53/EC. The designated laboratory visited was adequately staffed and equipped to carry out its functions, although a number of deficiencies were noted.

An adequate framework of controls has been proposed by the Indian authorities, which if implemented should ensure that consignments are adequately labelled with intended use, and that they comply with EU legislation. However, some deficiencies were noted concerning the sampling procedure, the laboratory visited and the food premises visited. With regard to the follow up, recommendations made in the last report have been adequately addressed. However, a number of minor deficiencies were noted in the laboratory visited and in the sampling procedure for aflatoxins in spices

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

1. INTRODUCTION

The mission took place in India from 7 to 17 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 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 Exporters Association (IOPEA). For the follow up mission, representatives of the Spices Board accompanied the mission team.

An opening meeting was held on the 7th November at the premises of APEDA regional office in Mumbai. Representatives from APEDA, IOPEA, the Spices Board 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 groundnuts 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 7075/2004) on the mission carried out in February 2004.

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

COMPETENT AUTHORITY VISITS			Comments
Competent authority	Central	1	APEDA, the Spices Board
	Local	2	Customs offices in Mumbai and Mundra
LABORATORY VISITS			Comments
		1	Private laboratory authorised by APEDA (Mumbai)
		1	Quality Evaluation Laboratory of the Spices Board (Cochin)
FOOD PROCESSING ESTABLISHMENTS			Comments
Harvesting Areas		3	State of Gujarat
Processing Establishments		3	State of Gujarat
Warehouse		1	State of Maharashtra
OTHER SITES			
Research facilities		1	Visit to National Research Centre for Groundnuts in the state of Gujarat

3. BASIS AND LEGAL FRAMEWORK FOR THE MISSION

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

The relevant legal framework for this mission is as follows:

- Council Directive 89/397/EEC^{1,2} of 14 June 1989 on the official control of foodstuffs;
- Council Directive 93/99/EEC³ of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs;
- Regulation (EC) No 178/2002⁴ 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;
- Council Regulation (EEC) No 315/93⁵ of 8 February 1993 laying down Community procedures for contaminants in food;
- Commission Regulation (EC) No 466/2001⁶ of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs;
- Council Directive 85/591/EEC⁷ of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption;
- Commission Directive 98/53/EC⁸ 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;
- European Parliament and Council Directive 94/36/EC⁹ of 30 June 1994 on colours for use in foodstuffs;
- Commission Decision 2005/402/EC¹⁰ of 23 May 2005 on emergency measures regarding chilli, chilli products, curcuma and palm oil repealing Commission Decision 2004/92/EC¹¹.

¹ Legal acts quoted in this report refer, where applicable, to the last amended version.

² OJ L 186 of 30 June 1989, p. 0023-0026. Repealed by Regulation (EC) No 882/2004 from 1 January 2006.

³ OJ L 290 of 24 November 1993, p. 0014-0017. Repealed by Regulation (EC) No 882/2004 from 1 January 2006

⁴ OJ L 31 of 01 February 2002, p. 0001-0024

⁵ OJ L 37 of 13 February 1993, p. 0001-0003

⁶ OJ L 77 of 16 March 2001, p. 0001-0013

⁷ OJ L 372 of 31 December 1985, p. 0050-0052. Repealed by Regulation (EC) No 882/2004 from 1 January 2006

⁸ OJ L 201 of 17 July 1998, p. 0093-0101

⁹ OJ L 237 of 10 September 1994, p. 0013-0029

¹⁰ OJ L 135 of 28 May 2005, p. 0034-0036.

¹¹ OJ L 27 of 30 January 2004, p. 0052-0054

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 and Argentina 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.

4.2. Background to present mission

According to Article 4 of Council Directive 89/397/EEC Member States (MS) are obliged to carry out routine sampling and analysis of foodstuffs originated from third countries at points of entry or on the marketplace. The same provision is set out in Article 3 of Regulation (EC) No 882/2004¹² which will repeal the above Council Directive and will be applicable from 1 January 2006. Information of foodstuffs found to have public health implications are disseminated as alert notifications through the Rapid Alert System for Food and Feed (RASFF) to all MS and to the exporting country.

From March 2004 to the time of the mission 29 notifications relating to mycotoxins in groundnuts and groundnut products (peanut butter, peanut candy) from India have been notified through the Rapid Alert System for Food and Feed (RASFF) which are broken down as follows: 23 alerts in 2004 (22 at the point of entry and 1 at the market control) and 6 alerts at the point of entry until November 2005. All of them were notified by 4 MS of which the United Kingdom (UK) notified 25.

In view of the increasing number of notifications in 2004, the FVO decided to undertake a mission with the above-mentioned objectives. In addition, a follow up of the recommendations made in the report SANCO 7075/2004 with regard to Sudan dyes adulteration as well as aflatoxins in spices will be made.

According to the World Bank document "Global Agricultural Trade and Developing Countries"¹³ India accounts for 23 percent of worldwide production. It is the second largest groundnut producer and the fourth largest exporting country in the world. In contrast, India devotes more than 60 percent of its production to crushing groundnuts for oil and meal. In 2004, India produced circa 6 million tonnes of groundnuts of which 0.7% were exported to the EU. The main ports used for shipping the groundnuts to the EU are Mumbai, Mundra and Kandla. The usual mode of transport between loading of the goods at the point of processing and arrival in Europe is ambient containerised shipment. The amount of groundnuts imported from India in 2004 and 2005 are shown in the table below (in tonnes); the main importing MS are indicated in brackets.

¹² 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. OJ L 165 of 30 April 2004, p. 0001-00141. Corrected and re-published in OJ L 191 of 28 May 2004.

¹³ 2005 The International Bank for Reconstruction and Development / The World Bank, ISBN 0-8213-5863-4, p. 215 - 235

	2004	2005
Groundnuts in shell CN code 12021090	2,130 (UK, BE, DE)	1,748 (UK, BE, DE)
Shelled Groundnuts CN code 12022000	38,937 (UK, PL, NL,)	15,381 UK, NL, PL
Peanut butter CN code 20081110	20.8 (UK)	42.3 (UK, PL)

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 Commission Regulation (EC) No 466/2001, the maximum admissible aflatoxin levels in groundnuts, nuts and dried fruit are as follows:

- 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 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

The provisions relating to groundnuts which are subject to export to the EU are laid down in the Director General of Foreign Trade (DGFT)¹⁴ Public Notice No 68 dated on 3

¹⁴ *In their response to the draft report the Indian Authorities noted that according to a new DGFT Public Notice dated on 9 January 2006 issued by the DGFT “groundnut products” have also been included.*

February 1999. The provisions establish that exports of groundnuts (not groundnut products) are allowed subject to compulsory registration of exporters with APEDA, and certificate of analysis (issued by private laboratories authorised by APEDA) indicating that the consignment complies with Community legislation. Following the rise in RASFF notifications for aflatoxins in groundnuts and groundnut products (peanut butter, peanut candy), APEDA has issued an additional Trade Notice No QMC/GMC/055/2005 (APTN) in July 2005 which is entitled “Regulation of export of groundnuts and groundnut products to the EU to control of aflatoxins”.

The principle changes to the export provisions are that since July 2005 it is now mandatory for all groundnut processing units wishing to export groundnuts for human consumption to the EU to be assessed and approved under the “Procedure for grant of recognition certificate to groundnut processing units for export of groundnuts for human consumption”. In addition, other important changes include the provision that the export certificate and all bags of groundnuts and cartons/packaging of groundnut products are clearly labelled with the intended use so as to prevent supply of birdfeed as food at the point of entry to the Community.

The Prevention of Food Adulteration Act and Rules, 1954 as amended (PFA) are directly applicable to India and set a limit for total aflatoxin in foodstuffs of 0.03 mg/kg. The PFA is the framework law related to foodstuffs applicable within the domestic market.

Legislation requiring Customs to implement export control procedure coming under the scope of this mission is also laid down in the DGFT Public Notice No 68 dated on 3 February 1999.

5.2. Competent Authorities

5.2.1. Agricultural and Processed Food Products Export Development Authority (APEDA)

APEDA is a statutory body under the Ministry of Commerce and Industry (MoC) and was established by an Act of the Indian Parliament in 1986. It is funded by the MoC 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 is responsible for 15 food commodities including groundnuts. All exporters of these 15 products are required to be registered with APEDA.

APEDA, which employs around 100 staff, has its headquarters in New Delhi and 5 regional offices, namely Bangalore, Hyderabad, Mumbai, Kolkata and Guwahati. 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 aflatoxins control.

5.2.2. Custom authorities

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

The mission team met Customs Commissioner at Mumbai and the Assistant Customs Commissioner at Mundra.

The two customs offices visited have 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. In addition, operators can make the declaration for exported goods through Customs' website.

The mission team visited the port of Mundra, in particular the Container Terminal where the majority of consignments of Indian groundnuts are shipped to the EU. The port is located in the Gulf of Kutch in Gujarat. The Container terminal, which is managed by a private company, comprises 2 berths having a total Quay length of 632 meters. It is the third largest in container throughput in India as it handles around 1.2 million TEUs per annum.

5.2.3. Other organisations

5.2.3.1. Indian Oilseeds and Produce Exporters' Association (IOPEA)

IOPEA is a private trade association for oilseeds which was established 50 years ago. It consists of more 250 members spread across India. Within the scope of this mission, IOPEA is the liaison with APEDA with regard to registration of groundnut export contracts destined for EU. A Memorandum of Understanding (MoU) between APEDA and IOPEA laying down the procedure to be followed for exports of groundnuts to the EU was signed in April 1999. The role of each is described in this MoU. In addition, the new Regulation (APTN) clearly describes the functions of IOPEA which are summarised as follows:

- IOPEA shall receive and process the application for issue of the certificate of export and submit to APEDA with clear recommendations to issue the export certificate.
- IOPEA will provide to APEDA, a monthly statement of exports made by the processors/exporters.
- IOPEA shall organise training/awareness programmes for the farmers and processors for control of aflatoxins and improvement in hygiene standards.

5.2.3.2. National Research Centre for Groundnuts (NRCG)

The NRCG was established on 1 October 1979. The Institute, which was set up by the Indian Council of Agricultural Research, is the main research body for conducting and coordinating groundnut research in India. It is located near Junagadh within the Gujarat region.

The NRCG performs its research activities through 11 scientific sections such as Genetic resource, Plant Breeding, Agronomy, Microbiology and Plant Pathology. The NRCG employs 100 staff, 40 of whom have scientific background. The main focus is on 3 areas of research, crop improvement, crop production and crop protection as well as consultancy. Research in these three areas were presented to the mission team such as development of high yield varieties (crop improvement), factors limiting groundnuts production identified (crop production) and management of aflatoxin contamination. In addition, some research undertaking concerning mapping different productions systems for mycotoxin risks and developing farm-worthy technologies (at soil, plant and storage level) to produce "safe to eat groundnut".

Some activities relating to aflatoxins control are carried out at farmer level by means of leaflets and pamphlets. In addition, workshops are conducted by the NRCG annually.

The mission team was informed that aflatoxin contamination in groundnuts in India is produced mainly by the fungus *Aspergillus flavus*. Some factors during the pre-harvest (e.g infestation of insect-pest, disturbances in soil-water-nutrient balance during the crop growth) and post-harvest stages (e.g. stacking the harvested plants under high humidity conditions) are the main contributors to the entry of the fungi in the pods.

5.3. Process Controls in the groundnut production chain

5.3.1. Groundnut cultivation

In India, there is approximately 8 million hectares being cultivated with groundnuts. About 80% of this area falls in the states of Gujarat, Andhra Pradesh, Tamil Nadu and Karnataka, which account for 84% of the total production. The state of Gujarat is the main producing region with 1.65 million tonnes in 2004 accounting for 30% of total production. As the major area under groundnut is rain dependent and is cultivated mostly by the resource of small farmers, the average national productivity of groundnut is quite low (938 kg/ha).

There are two main crops in India, namely the winter crop and the summer crop. Sowing of the winter crop is carried out in December/January while harvesting takes place in April/May after approximately 110-130 days. Sowing of the summer crop (during monsoon) is undertaken in June/July while harvesting takes place in October/November 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. In 2004, APEDA commissioned a private company to conduct crop estimation for groundnut in Gujarat. A brief summary of this study is as follows: 66% of the farmers hold less than 5 hectares land. In addition, 88% of the farmers adopted single crop pattern and cultivated only groundnuts while about 14% adopted mixed cropping pattern mainly with cotton. The remaining 4% adopted both mixed and single cropping pattern.

The mission team visited three farms of less than 6 hectares. Groundnut harvesting starts with digging and turning of the plants 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 units.

5.3.2. Groundnut processors visited

The mission team visited 3 groundnut processing units. All three companies produced hand-picked and selected (HPS) groundnuts, while one of the companies shelled, and two blanched groundnuts. All of them have applied for recognition of groundnut processing units under APEDA's procedure. Responsibilities for implementing food hygiene currently rest with the establishments concerned. The 3 companies visited have implemented general hygiene requirements while one of them has been certified against HACCP principles by a recognised private certification agency. A number of points were noticed by the mission team relating to hygiene in one of the facilities visited such as the potability of the water used to increase moisture content, the point at which this water is

added in shelling area (potential for contamination), and the poor separation of the clean area from the shelling area¹⁵.

Trucks are used for delivering harvested groundnuts to the processors premises. On arrival and according to the processors quality requirements, each truck load is checked for physical quality parameters such as size, moisture (< 7%) and damage prior to unloading the groundnuts from the suppliers.

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 to remove damaged and mould affected kernels. Final HPS groundnuts are passed through metal detectors prior to bagging. When groundnuts are intended for human consumption the sorting process takes place twice. 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).

Processors keep all information relating to the products received on file, including seller of the product, analytical data at reception, and other commercial information.

The mission team also visited a warehouse in Mumbai. This warehouse had a storage capacity of 1950 m² and also the possibility of cleaning and sorting groundnuts. The company's food safety systems were based on HACCP principles and were certified by a private company. Loading of consignments for export was also possible at this warehouse, in which case the export procedure outlined in 5.5 below applies.

5.4. Method of sampling for groundnut consignments

5.4.1. Authorised companies

Based on DGFT Public Notice No 68 dated on 3 February 1999 and the new Trade Notice APTN, sampling must be performed by authorised private companies (laboratories) which in turn will also be responsible for undertaking analysis of aflatoxins.

Currently there are 8 private laboratories authorised by APEDA for undertaking sampling. The method of sampling described in Annex III of this Trade Notice APTN follows the provisions of sampling detailed in Commission Directive 98/53/EC. In this regard, all designated laboratories are required to develop and validate their method of taking samples to comply with the above mentioned sampling Directive. The authorised laboratories will submit to APEDA and IOPEA a monthly statement of samples tested and containers loaded.

5.4.2. Sampling procedure

There are two different sampling procedures depending on the intended use of the groundnuts (human consumption or bird feed). In both cases, the sequence of sampling

¹⁵ *In their response to the draft report the Indian Authorities noted that since the mission it has been ensured that the water is potable and that the shelling area is under the proper hygiene conditions according to their new provisions.*

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 Trade Notice APTN.

For groundnuts intended for direct human consumption, Annex III of Trade Notice APTN lays down that sampling shall be carried out following Commission Directive 98/53/EC.

As no consignments of groundnuts intended for human consumption have been exported to the EU since July 2005, the mission team evaluated a sampling demonstration of a consignment of shelled groundnuts destined for non-EU countries consisting of 740 bags of 25 kg each (total weight 18.5 tonnes) stored in a private warehouse in Gandhidham. Staff from the laboratory took incremental samples of 400 g by hand from 100 selected bags to produce an aggregate sample of 40 kg. However, as not all the bags were accessible the distribution of incremental samples was not completely random. No sampling equipment (e.g. a sampling spear) was used during the procedure. The aggregate sample was mixed and then divided by quartering in 4 portions of 10 kg each. The first 10 kg are used for physical tests such as moisture content. For the remaining 3 parts of 10 kg each, samples are collected in cloth bags and subsequently labelled and sealed. The mission team was informed that this type of sampling can usually take up to 3 hours. A sampling protocol is then produced containing information such as lot number, date and place of sampling, intended use, packing (25 or 50 kg) and name of buyer and seller. Samples are then transferred to the laboratory by courier, where homogenisation takes place.

According to Trade Notice APTN, 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. Intended use must be mentioned on each bag as follows: “groundnuts or groundnut products intended for direct human consumption or as an ingredient in foodstuffs” or “groundnuts to be subjected to sorting or other physical treatment before human consumption or use as an ingredient in foodstuffs”. The size of each bag will be 50 kg and sampling will be carried out as detailed by sampling Commission Directive 98/53/EC.

For groundnuts intended for use as bird feed, Trade Notice APTN 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 will be 25 kg. Samples will be taken from 10% of the bags selected at random.

5.5. Procedure for exporting groundnuts to the EU

Since 1999, the responsible authority for export of groundnuts is the APEDA. Prior to the new Trade Notice APTN the export procedure required exporters to request one of the designated laboratories authorised by APEDA to take samples and perform analysis for aflatoxins. If the laboratory analysis found the samples were within the specified limits, the authorised laboratory would issue an aflatoxin certificate to the exporter. Then the exporter applied to APEDA through IOPEA to issue the export certificate along with a printed copy of the aflatoxins certificate. Export certificates were issued by APEDA on the basis of the recommendation made by IOPEA but importantly did not indicate intended use. Additionally, exports of groundnuts were not labelled with intended use as there was no requirement as such. For groundnut products destined for the EU there was

no requirement concerning sampling and analysis for aflatoxins and therefore, no aflatoxin certificate was issued.

Based on the information provided by the laboratory visited (see table 1 below) all export control certificates in 2004 for groundnuts for human consumption indicated 100% compliance with EU legislation. However, results from MS import controls indicated high levels of rejection of these consignments. The competent authority in India indicated that the variance between their export control results and MS was due to importers in MS switching the intended use from bird feed to human consumption (groundnuts for human consumption attracting a higher price per tonne). As indicated in 5.5 all consignments of groundnuts are accompanied by two documents, export certificate issued by APEDA and an aflatoxin certificate issue by the one of the designated laboratories. However, as there is no Community Decision imposing special conditions for the import of groundnuts from India there was no obligation by the importer to present the original certificate of results indicating the level of aflatoxins and as the export certificate did not indicate the intended purpose imports of birdfeed as food was possible.

Table 1

	2004	2005
<u>For human consumption</u>		
Total sampled	47	3
Rejected	0 (0%)	3 (100%)
<u>For bird feed</u>		
Total sampled	1,303	340
Rejected	30 (2.30%)	38 (11.18%)

Information received by the mission team from an importing MS, which includes Container number, port of export and aflatoxin certificate issued by the designated laboratory, indicated that the switch of supply of birdfeed to food explained by the Indian authority was occurring.

The Indian authorities have taken action to address this problem by amending the export procedure. This new procedure (Trade Notice APTN), which will also cover groundnut products, requires that both the export certificate and individual bags are clearly labelled with intended use so as to prevent supply of birdfeed as food at the point of entry to the Community. There have been no consignments exported for the purpose of human consumption to the EU since July 2005, and exports are not expected to recommence until the new system of recognition and labelling have been fully implemented.

New recognition procedures for groundnut processors

The new export procedure will also require that all groundnut processing units are assessed and approved for export. The procedure involves the submission of a request either to APEDA, or at any of its regional offices. Under this recognition procedure, APEDA will organize inspection of the groundnut processing unit by means of an assessment committee. This committee will consist of representatives from different organisations, namely APEDA (2 representatives: the regional manager and an officer from central level), IOPEA, NRCG, State Agricultural Department wherever the processing unit is located and a representative from either the Directorate of Marketing

and Inspection under the Ministry of Agriculture or the Bureau of Indian Standards or the Export Inspection Agency. The recognition shall be granted on the basis of general hygiene requirements as described in the procedure. However, there is a no legal requirement that these food premises implement food safety systems based on HACCP principles. The mission team was informed that 5 out of the 13 exporters have applied for recognition for this procedure. However, none of them have been inspected yet by the assessment committee. The CCA indicated that no exports of groundnuts for human consumption will take place until the new procedures are fully in place (expected in January 2006).

Customs procedures

A person authorised by the exporter presents the declaration to customs offices along with the relevant documents (shipping bill, invoice, purchase order). Declaration can be done by entering data on the consignment into the customs EDI system. Then the data is assessed by the customs assessing officer. At this stage, the staff here also check whether the commodity is subject to any specific requirement such as export certificate issued by APEDA with regard to groundnuts. Details of the export requirements are detailed in the customs handbook for classification of export and import items. After this assessment the documents are countersigned by the assistant commissioner. Once the final assessment of the documents has taken place, the examination of goods as well as the physical verification of documents is also carried out by the customs officers and then they give a "Let Export Order" on duplicate copies of shipping bill. The goods thereafter remain in the customs area until they are loaded into the container under customs supervision.

5.6. Laboratory services

Based on DGFT Public Notice No 68 dated on 3 February 1999 and Trade Notice APTN, aflatoxins analysis must be performed by authorised private laboratories. Currently there are 8 private laboratories authorised by APEDA for undertaking aflatoxins analysis. These 8 laboratories are accredited to ISO 17025 by the National Accreditation Board for Testing and Calibration Laboratories (NABL) as required by new Trade Notice APTN.

All authorised laboratories have also been recognised under APEDA scheme for laboratory recognition which was established in January 2003. Based on this scheme, the recognition is granted for a period of one year.

5.6.1. Laboratory visited

The laboratory visited is one of the 8 designated private laboratories for the analysis of aflatoxins in groundnuts. The laboratory, which employs 180 staff, has several divisions of which the organic testing division comes under the scope of this mission. The division concerned has 20 employees 5 of whom have university degree. The head of this division has received training in the area of aflatoxins, which took place in May 2005 at the Central Science Laboratory in the UK, under the Directorate General for Trade's (European Commission) initiative for training developing country laboratory experts.

The laboratory was re-accredited in July 2005 for three additional years to ISO 17025:1999 by the NABL, for the chemical testing of Aflatoxins. The analytical method was based on the use of HPTLC – Densitometry and an SOP was available.

The mission team examined the organisation chart, the list of staff, both NABL and internal audits reports, some relevant SOPs, calibration records, data from the validation

study performed in August 2005 and some examples of analytical reports issued by the Laboratory. In general, the laboratory followed good practice. However, a number of points were noted by the mission team during the evaluation. These included the fact that some equipment (semiautomatic sample application device) was not being calibrated for accuracy. The Laboratory has not taken part in any international proficiency test for Aflatoxins and has undertaken only limited inter-comparison studies with another national laboratory. With regard to reporting of results neither the recovery factors nor the measurement of uncertainty are included. The laboratory also indicated that the infrastructure and environment were inappropriate, and that they will move to another purpose built location in one year¹⁶.

In the new Trade Notice APTN the criteria for the acceptance of a lot or sub lot and the recovery calculation and reporting of results as stated in Commission Directive 2003/121/EC¹⁷, which amends sampling Commission Directive 98/53/EC, are not included.

A summary of the performance of the laboratory visited is detailed in the table 2

Table 2: Summary of Laboratory performance

LABORATORY	Laboratory visited
ACCREDITATION TO ISO 17025	Yes
ACCREDITATION BODY	National Accreditation Board for Testing and Calibration Laboratories (NABL)
Scope of Accreditation	Aflatoxin in Groundnut Seeds : 0.1 – 1000 ppb
REFERENCE OF THE METHOD	AOAC Official Method 968.22 (17 ed.)
MILLING	Dry
Extraction solvent	Chloroform
Determination by	Densitometry – CAMAG Scanner II
Aflatoxin standard	Commercial / crystal. FERMENTEK (Israel)
Validation	YES. LOD : 0.1 ppb for each Aflatoxin
Calibration curve	5 points calibration
Range	0.5 – 20.0 ppb
Recovery (%)	The rates were in accordance with the performance criteria of Dir. 98/53/EC, except slight deviations for B2 and for G1 at the level of 2.0 ppb and for B1 at the level of 100 ppb. Analytical results were not corrected for recovery
Precision (%)	Repeatability was checked at three levels: 1.0 ppb, 4.0 ppb and 10.0 ppb. The rates were in accordance with the performance criteria of Dir. 98/53/EC
Measurement uncertainty	No measurement uncertainty data were presented
Aflatoxin reference materials	Not available
Internal Audits	Yes
Additional remarks	Neither the recovery factors nor the measurement uncertainty are included in the analytical report

¹⁶ *In their response to the draft report the Indian Authorities noted that the laboratory would be moving to a much bigger site by late 2006 and the site plan was also shown to the EU Mission.*

¹⁷ OJ L 332 of 19 December 2003, p. 0038-0040. Commission Directive 2003/121/EC of 15 December 2003 amending Directive 98/53/EC laying down the sampling methods and the methods of analysis for the official control of the levels for certain contaminants in foodstuffs.

5.7. Response to RASFF notifications

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 for those concerned companies. Following a review of the entire export procedure including sampling and analysis, and the issue of export certificates the CA found that source of the problem lay with importers who were circumventing the export procedures by misdeclaring consignments for import (see Table 1).

In response to the increasing rapid alert notifications, the mission team was informed that since July 2005, no consignment of groundnuts for human consumption has been shipped to the EU. In addition, an exporter, which has been notified several times through the RASFF system, has been suspended for its activities.

5.8. Follow-up to mission 7075/2004

The FVO undertook a mission in India in February 2004 with the objectives of evaluating the control systems in place to control Sudan dyes adulteration in foodstuffs, in particular related to chilli and chilli products, and assessing the control systems in place to prevent aflatoxins contamination in spices intended for export into the EU. This report made a series of recommendations that required attention by the Indian authorities.

The recommendations, the response of the competent authority and the follow up on current situation are summarised in the following table:

Table 3

RECOMMENDATION OF SANCO 7075/2004	RESPONSE FROM INDIAN AUTHORITIES	FOLLOW UP IN MISSION SANCO 7633/2005
Modify the instructions laid down in the circular from the Spices Board to ensure controls are in line with the requirements set down in Commission Decision 2004/92/EC repealing Commission Decision 2003/460/EC, regarding the investigation of Sudan II, Sudan III and Sudan IV.	In pursuance of the Commission Decision 2004/92/EC all consignments of chilli products for export to destinations in the EU are subject to mandatory sampling and analysis of the samples for Sudan I – IV, in addition to Aflatoxin with effect from 15.3.2004.	In line with the requirements set down in Commission Decision 2005/402/EC all consignments of chilli, chilli products and curcuma are subject to mandatory sampling and analysis of the samples for Sudan I – IV, in addition to Aflatoxin with effect from 16.04.2005.
Ensure that the Spices Board representatives and staff involved in the sampling procedure are suitably qualified and experienced staff, in particular in areas related to food hygiene and technology so that the controls and sampling procedure can be carried out adequately.	Spices Board continue to use the services of competent external professional agencies to undertake the sampling work. Notwithstanding, Spice Board employees engaged in supervision/monitoring (See Footnote 9, page 11 of report) have since been given training in sampling methods and procedures.	Training in sampling procedure conforming to sampling Commission Directive 98/53/EC has been carried out in June 2004 and June 2005. However, regarding sampling for aflatoxins in spices, in particular whole chilli the 10 kg of aggregate sample is not homogenised (ground) and therefore, only 200 g are ground for the analysis which is not in line with Annex I of Commission Directive 98/53/EC.

RECOMMENDATION OF SANCO 7075/2004	RESPONSE FROM INDIAN AUTHORITIES	FOLLOW UP IN MISSION SANCO 7633/2005
<p>Improve communication between the competent authorities involved on the controls at points of export and reinforce controls at export point to ensure that consignments of spices intended for export to EU are adequately monitored.</p>	<p>Customs authorities have been instructed not to clear shipment of chilli and chilli products for export unless a certificate from the Spices Board to the effect that the consignment was subjected to mandatory sampling is produced for verification. The capacity of the Quality Evaluation Laboratory (QEL) of the Spices Board to test sample for the substances in question have been doubled and samples from consignments meant for export to EU are tested immediately on receipt to allow Spices Board to effectively intervene in case a sample is found to be non-compliant.</p>	<p>Instructions from the Spices Board relating to export procedure for chilli, chilli products and curcuma have been circulated to Customs authorities as evidenced by a number of circulars provided to the mission team. Customs releases consignment of spices intended for export into the EU on the basis of analytical report from the Spices Board.</p>
<p>Reinforce controls at all possible stages of the food chain to reduce aflatoxin contamination in spices intended for export to EU.</p>	<p>Controls are in place at all possible stages of the food chain to reduce aflatoxin contamination in spices intended for export to the EU. (See Footnote 11, page 19 of report).</p> <p>The QEL of the Spices Board has been equipped with instruments which have single digit ppb detection levels for analysis of for Sudan I – IV and Aflatoxin.</p>	<p>The spices board have taken the initiative to begin a number of programmes to improve good manufacturing practice in facilities processing spices. These training programmes are also targeted at spice growers, traders as well as officials of State Agriculture Department.</p>
<p>The Quality Evaluation Laboratory of the Spices Board should be in line with the general criteria for the operation of testing laboratories laid down in ISO Standard 17025 and should also participate in international inter-laboratory comparison programmes to generate reliable analysis results, in accordance with Art 3 of Council Directive 93/99/EEC.</p>	<p>The QEL of the Spices Board has:</p> <ul style="list-style-type: none"> • since obtained certification under ISO 17025 • approached FAPAS (Food Analysis Performance Assistance Scheme of the Central Science Laboratory of UK) to take part in the next available round of inter-laboratory comparison programme. 	<p>With regard to QEL substantial improvement have been made. The laboratory has been accredited to ISO 17025 by the NABL for the analysis of Sudan dyes (I, II, III and IV) chemical testing of Aflatoxins both in spice and spice products. Detailed information is described below under the laboratory visited.</p>

The Quality Evaluation Laboratory (QEL) visited

The analytical method used for the analysis of Sudan dyes has changed since the last mission and now follows the procedure described in the EC News Notification 03/99 and is based on the use of newly acquired LC-MS/MS equipment. An SOP is available for the determination of Sudan dyes present in chillies and products containing chillies. With regard to the analysis of Aflatoxins the laboratory uses HPLC instrumentation with Kobra cell.

The Laboratory has participated in international proficiency tests such as FAPAS for the determination of Sudan I – IV in chilli powder but the results were not satisfactory. However, the laboratory received a letter from FAPAS stated that they “also noticed that

the laboratories using LC-MS/MS received z-scores beyond the acceptable range of +/- 2”, followed by a statement about the fact that they could not offer further explanation but “it appears that LC-MS/MS may not be appropriate for quantifying these colours at high levels”, was shown to the mission team. In addition, the QEL participated in a limited check sample programme for the determination of Sudan I to IV with the participation of 3 laboratories (QEL and 2 German laboratories) with favourable results.

The Laboratory also participated in international proficiency tests such as FAPAS for the determination of aflatoxins with favourable results. In addition, the QEL participated in a limited check sample programme on Aflatoxins involving 4 laboratories (1 Italian, 1 UK, 1 Japan and QEL). The results were favourable.

With regard to reporting of results neither the recovery factors nor the measurement of uncertainty are included as required by Commission Directive 98/53/EC.

Response to the RASFF notifications

In response to the increasing rapid alert notifications, the Spices Board have suspended 5 companies, which has been notified several times through the RASFF system, for its activities.

6. CONCLUSIONS

6.1. Relevant national legislation

(1) The provisions relating to groundnuts which are subject to export to the EU have been laid down since February 1999. Following an increase in the number of RASFF alerts relating to aflatoxins in groundnuts these provisions have been strengthened in July 2005 which now lays down additional requirements regarding the export of groundnuts and groundnut products to the EU to control of aflatoxins.

6.2. Competent Authorities

(2) The central competent authority within the scope of the mission is the Agricultural and Processed Food Products Export Development Authority (APEDA) of the Ministry of Commerce.

(3) Customs are responsible for ensuring that, (in addition to their other responsibilities), consignments of groundnuts for export are accompanied by the relevant export certificate from APEDA.

(4) The Indian Oilseeds and Produce Exporters’ Association (IOPEA) is the liaison body with APEDA as regards registration of groundnut export contracts destined for the EU.

(5) The National Research Centre for Groundnut (NRCG) is the main research body in this area in India. The Centre provides (among other services) technical support and dissemination of information relating to the control of aflatoxins in groundnuts.

6.3. Process Controls in the groundnut production chain

(6) Groundnut cultivation is carried out mainly by small farmers. Good farm practices, such as irrigation and crop rotation are used according to the resources, which in many small farm cases are not available.

(7) In the past, groundnut processors were not subject to official control regarding aflatoxin. However the new recognition procedures will require that all processors wishing to export to the EU are approved for that purpose.

(8) Those premises visited have initiated requests for recognition for export of groundnuts for human consumption to the EU. In terms of aflatoxin control internal checks were undertaken by all of the companies regard to moisture control and damage prior to unloading the groundnuts from the suppliers. In process, groundnuts are handpicked to remove damaged and mould affected kernels.

(9) All had implemented general hygiene requirements, and one of them has been certified by a recognised private certification agency regarding the implementation of food safety systems based on HACCP principles. However, a number of deficiencies relating to food hygiene were noted in one of the premises.

6.4. Method of sampling for groundnut consignments

(10) There are two different sampling procedures depending on the intended use (human consumption or bird feed).

(11) According to APEDA export procedures, sampling of groundnuts intended for direct human consumption destined for the EU must be carried out by one of the 8 APEDA recognised laboratories in accordance with the requirements of Commission Directive 98/53/EC while for groundnuts intended for bird feed, samples will be taken from 10% of the bags selected at random.

(12) The sampling procedure observed was not adequate to produce a representative sample of the whole consignment as required by sampling Commission Directive 98/53/EC.

6.5. Procedure for exporting groundnuts to the EU

(13) Prior to the implementation of Trade Notice No APTN all consignments of groundnuts which were exported to the EU should have been accompanied both by an export certificate from APEDA, and a separate certificate of analysis for aflatoxins. Nevertheless, given the fact that there is no community requirement to indicate the intended use of groundnuts on the export certificate or for importers to submit the analytical certificate, it would have been possible for importers to misdeclare consignments which were originally intended for bird feed.

(14) The Indian authorities' commitment to amend the export procedures for groundnuts for direct human consumption to EU should, when implemented, ensure that all consignments of groundnuts are clearly labelled with intended use and are accompanied by the relevant documentation (analytical certificate and export certificate) which will also clearly state the intended use.

(15) These new export procedures are expected to be implemented early 2006. As the system is not yet fully operational it was not possible to fully assess its efficiency.

6.6. Laboratory services

(16) There are 8 designated private accredited laboratories located in different regions.

(17) The laboratory evaluated had sufficiently qualified staff, procedures and equipment with which to carry out its responsibilities. However, a number of deficiencies were noted with regard to calibration, proficiency testing, recovery factor and measurement uncertainty. The laboratory recognised the shortcomings in the physical structure of the building which they are currently located and will move to a purpose built site in 2006.

6.7. Response to the RASFF notifications

(18) Investigations carried out by APEDA have indicated that supply of birdfeed as food by importers at the point of import to the EU rather than the controls systems in place were primarily responsible for the rise in RASFF alerts concerning aflatoxins.

6.8. Follow-up to mission 7075/2004

(19) Recommendations made in the last report have been adequately addressed. However, in the laboratory visited a number of minor deficiencies were noted with regard to recovery factor and measurement uncertainty.

(20) The homogenisation of the sample for aflatoxins in spices, in particular whole chilli is not in line with the requirements set down in Annex I (5.2.1) of sampling Commission Directive 98/53/EC.

6.9. Overall Conclusion

(21) An adequate framework of controls has been proposed by the Indian authorities, which if implemented should ensure that consignments are adequately labelled with intended use, and that they comply with EU legislation. However, some deficiencies were noted concerning the sampling procedure, the laboratory visited and the food premises visited. With regard to the follow up, recommendations made in the last report have been adequately addressed. However, a number of minor deficiencies were noted in the laboratory visited and in the sampling procedure for aflatoxins in spices.

7. CLOSING MEETING

A closing meeting was held on 17 November 2005 at the premises of IOPEA in Mumbai. Representatives from APEDA, IOPEA, the Spices Board 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

- (1) 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 export 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.
- (2) Ensure that all groundnut processing units exporting to the EU implement standards at least equivalent to Article 3 of Council Directive 93/43/EEC¹⁸ on food safety procedures based on HACCP principles.
- (3) 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.
- (4) Ensure that the deficiencies noted in the designated laboratory with responsibility for sampling and analyses of groundnuts destined for the EU are corrected.
- (5) Ensure compliance both with the Annex I (5.2.1) of Commission Directive 98/53/EC concerning homogenisation of the sample for aflatoxins in spices and with regard to the analytical performance criteria set out in Annex II (4.4) of the same Directive.

A programme in response to these recommendations should be produced by the Competent Authority **within 2 months of receipt of the final report**, which should provide detailed information of the actions that will be taken and propose deadlines by which these actions will be completed.

9. ADDENDUM

The Indian competent authorities responded to the draft report making factual corrections and additional comments regarding the conclusions and recommendations.

Recommendation (1): The competent authority stated that it has started to implement the additional export procedures by inspecting the groundnut processing units which have applied to APEDA. The process of granting the recognition certificate to these units is in progress. In addition, the intended use on each bag has already been enforced and the bags are now marked with the intended use.

Recommendation (2): The competent authority stated that all the groundnut processing units for human consumption will be required to implement food safety systems based on HACCP principles.

Recommendation (3): The competent authority stated that adequate sampling equipment will be available for sampling.

¹⁸ OJ L 175 of 19 July 1993, p. 0001- 0011. Repealed by Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April on the hygiene of foodstuffs from 1 January 2006.

Recommendation (4): The competent authority stated that deficiencies were noted for correction. The laboratory visited has informed that they would participate in the next proficiency test conducted by FAPAS, which would be held in April 2006. They have also informed that recovery factor and measurement uncertainty will be reported in the analytical result. More frequent audit of the units would be carried out for quality control implementation.

Recommendation (5): The competent authority stated that the Spices Board has corrected the deficiencies pointed out by the Commission with regard to recovery factor and measurement of uncertainty. They will be incorporated in the analytical result with effect from 20.02.2006. Sampling procedures have been revised to bring them in full conformity with EC requirements and now, the sub samples drawn from the lot will be ground and mixed together to make a homogenised aggregate sample from which 3 laboratory samples will be taken.