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FINAL REPORT OF A MISSION
CARRIED OUT IN CHINA
FROM 06 NOVEMBER TO 16 NOVEMBER 2006
IN ORDER TO
ASSESS THE CONTROL SYSTEMS IN PLACE TO CONTROL AFLATOXIN
CONTAMINATION IN PEANUTS INTENDED FOR EXPORT INTO THE
EUROPEAN UNION

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



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EXECUTIVE SUMMARY

This report describes the outcome of a mission carried out by the Food and Veterinary Office in The People's Republic of China, from 06 November to 16 November 2006.

The objective was to assess the control systems in place to control aflatoxin contamination in peanuts intended for export into the European Union.

Adequate legislation was put in place, setting national standards in the area of peanut cultivation and processing, in order to take account of EU requirements for peanuts to be exported into the EU.

Responsibilities for policy making, supervision and controls were assigned to the MoA and the AQSIQ. Implementation of GAP at farmers visited was found to be at an early stage.

Companies wishing to export peanuts into the EU have to undergo a sanitary registration process, requiring compliance with GMP and HACCP principles. Only those peanut consignments tested negative by the AQSIQ for aflatoxin contamination are permitted for EU export. All companies visited fulfilled the national standards with the exception of one shelling operation belonging to a peanut exporter. Furthermore, official sampling as demonstrated was considered not fully in compliance with Commission Regulation (EC) 401/2006 and supervision from the point of sampling until shipping of consignments was limited.

There are a number of official and private laboratories testing peanuts to be exported for aflatoxin contamination, of which 3 were visited by the mission team. Two official laboratories were accredited in accordance with ISO 17025, and the private laboratory carried out analysis following ISO 17025 requirements. All laboratories were found to be in line with the criteria of Annex 2 of Regulation (EC) 401/2006.

Overall, there is an acceptable control system in place for exporting peanuts into the EU. In particular, in the area of peanut processing and laboratories, significant improvements have been noted in comparison to the last mission. However, shortcomings were identified in relation to the implementation and supervision of GAP, supervision at one sheller visited, sampling of peanuts, supervision of peanuts to be exported from the point of sampling and expression of analytical results attached to the health certificates.

The report provides a number of recommendations to the authorities of China to address the noted deficiencies.

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AQSIQ	General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China
CCA	Central Competent Authority
CCCFNA	Chinese Chamber of Commerce of Food and Native Agricultural Products
CIQ	Entry-Exit Inspection and Quarantine Bureau of the People's Republic of China
CNAL	Chinese National Accreditation Body
CNCA	Certification and Accreditation Administration of the People's Republic of China
EU	European Union
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Point
HPLC	High Performance Liquid Chromatography
IAC	Immuno-Affinity Column
ISO	International Organisation for Standardization
LC	Liquid Chromatography
LOD	Limit of Detection
LOQ	Limit of Quantification
MoA	Ministry of Agriculture
MS	Member States
RASFF	Rapid Alert System for Food and Feed

1. INTRODUCTION

The mission took place in the People's Republic of China (China) from the 06 to 16 November 2006. The mission team comprised 3 inspectors from the Food and Veterinary Office (FVO) and one national expert.

The mission team was accompanied during the whole mission by representatives from the central competent authority (CCA), the AQSIQ (General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China) and the CNCA (Certification and Accreditation Administration of the People's Republic of China).

An opening meeting was held on 06 November at the premises of the AQSIQ in Beijing. Representatives of the MoA (Ministry of Agriculture), CNCA, CCCFNA (Chinese Chamber of Commerce), of the provincial AQSIQ offices of Shandong and Hebei (CIQ offices) were also 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 assess the official control systems in place for the control of aflatoxin contamination in foodstuffs intended for export into the European Union. With regard to peanuts an assessment should be made that peanuts can be produced within specified European Union contaminant limits and complying with Commission Regulation 466/2001 as amended¹. Furthermore, actions indicated by the Chinese competent authorities in response to the recommendations of report SANCO 3223/2001 in relation to the prevention of aflatoxin contamination in peanuts shall be followed-up.

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

COMPETENT AUTHORITY VISITS			Comments
Competent authority	Central	1	AQSIQ
	Provincial Level	1	Shandong CIQ
		1	Hebei CIQ
		1	Shandong customs authorities
LABORATORY VISITS			
Official laboratories in Shandong and Hebei CIQ		2	City of Qingdao and Shijizhuang
Private laboratory		1	City of Qingdao
FARMERS			
Peanut cultivations		5	Shandong and Hebei provinces

¹ Legal acts quoted in this report refer, where applicable, to the last amended version. Full references to the acts quoted in this report are given in the Annex.

PROCESSING ESTABLISHMENTS		
	5	Processors/Exporters of peanuts in Shandong and Hebei provinces
	2	Sheller of raw peanut in Shandong and Hebei provinces
PORTS OF EXPORT		
Shandong	1	Port of Huang Dao
OTHER SITES		
Exporter	1	One peanut exporter in Shandong province

3. LEGAL BASIS AND OTHER RELEVANT LEGISLATION FOR THE MISSION

3.1. Legal basis

The mission was carried out in agreement with the AQSIQ 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.

3.2. Other relevant legislation

All other relevant legislation referenced in this report is detailed under Annex 1.

4. BACKGROUND

4.1. Overview of previous missions regarding aflatoxin contamination in foodstuffs

The European Commission has carried out missions to Iran, Egypt, Turkey, China, Brazil, India, Argentina and the United States with the objective of evaluating official control systems for the prevention of aflatoxins contamination in foodstuffs originated from these countries. A previous mission to China with a similar objective was undertaken from 9 to 21 May 2001, the results of which are described in report SANCO 3223/2001. In addition, missions to 16 Member States (MS), with the objective of assessing controls on imported products of plant origin were carried out. The reports of these missions are available on the DG Health and Consumer Protection Internet site at

http://europa.eu.int/comm/food/fvo/index_en.htm.

4.2. Background to present mission

The area of peanut cultivation in China amounts to approximately 5 million hectares, representing 22% of the total peanut growing area of the world. Average yields achieved annually are about 14.5 million tons, of which 1 - 1.5 % are exported into the EU. Peanuts are cultivated in 28 provinces in China, of which the provinces of Shandong, Hebei and Henan account for approximately 50% of the total annual production. Of the products exported to the EU, 80 to 85% originate from Shandong province.

Information regarding foodstuffs found by Member State competent authorities to have public health implications is disseminated through the Rapid Alert System for Food and

Feed (RASFF) to all MS and to the exporting country. From 2004 to the time of the mission 205 notifications relating to aflatoxins in peanuts from China have been notified through the RASFF. The break down of RASFF notifications as well as the volume of imports into the EU is shown in table 1. Main importing MS are indicated in brackets.

Table 1: Imports of peanuts originating from China into the EU

	Imports to EU (metric tonnes)		Number of alerts		
	2004	2005	2004	2005	2006 (Jan-Nov)
12021090 Groundnuts in shell	38,963 (ES, DE)	51,580 (D, IT, NL)	59	79	67
12022000 Shelled groundnuts	101,382 (F, NL)	127,076 (ES, NL, UK)			

Source: Eurostat, Comext database and EC, RASFF database

In view of the continuously high number of RASFF notifications, and the fact that some rejections were made on the basis of aflatoxin levels up to 190 ppb for aflatoxin B1, the European Commission decided to undertake a mission to China with the above-mentioned objectives.

4.3. Food product information related to public health issues

Aflatoxins are mycotoxins produced by certain species of *Aspergillus*, which develop at high temperatures and humidity levels and may be present in a large number of foods. The aflatoxin group includes a number of compounds of varying toxicity and frequency in food. Aflatoxin B1 is the most toxic compound. For safety reasons, it is advisable to limit both the total aflatoxin content (compounds B1, B2, G1 and G2) of food and the aflatoxin B1 content. Maximum limits for aflatoxins in food were fixed in EU 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 Annex I to Commission Regulation (EC) 466/2001/EC, the maximum admissible aflatoxin levels in groundnuts 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:
 - 2,0 µg/kg aflatoxin B1 content, and
 - 4,0 µg/kg total aflatoxin content
- b) Groundnuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs:
 - 8,0 µg/kg aflatoxin B1 content, and
 - 15,0 µg/kg total aflatoxin content

5. MAIN FINDINGS

5.1. Relevant national legislation

In addition to the information provided by report SANCO 3223/2001, the following legislation is in place:

- Order No 20, issued in 2002 by AQSIQ, requires food establishments to be registered with the Entry-Exit Inspection and Quarantine Bureaus of the People's Republic of China (CIQ) when exporting foodstuffs and to fulfil requirements in relation to GMP and HACCP as contained in that order.
- Based on the instruction "Control Requirements for the Safety of Peanuts for Export", since August 2006 AQSIQ is enforcing requirements related to the application of Good Agricultural Practice (GAP), Good Manufacturing Practice (GMP) and the Hazard Analysis Critical Control Points (HACCP) concept during cultivation and processing of peanuts for export purposes. Furthermore, provisions for exporters to undertake a survey concerning the aflatoxin contamination of supplying areas, to have in-house aflatoxin laboratories in place and to undertake aflatoxin analysis on incoming and outgoing peanuts are made.
- For the sampling of peanuts for EU export, AQSIQ has issued an instruction for CIQ inspectors. It reflects the requirements of Regulation (EC) 401/2006.
- For the domestic market, standard number GB2761-2005 establishes the limit for aflatoxin B1 in foodstuffs at 20ppb.
- For analytical examination of peanuts for the presence of aflatoxins, 3 national standards are currently in use: GB/T18979-2003, SN/T0637-1997 and SN/T1101-2002.

5.2. Competent Authorities

5.2.1. The Ministry of Agriculture (MoA)

The MoA is responsible for policy setting in the area of cultivation of peanuts for the domestic market, including a policy on Good Agricultural Practices (GAP). The agricultural branches of the provincial governments are responsible to develop specific programmes for policy implementation, supervision and for the promotion of GAP throughout the country. However, representatives of the AQSIQ explained that peanuts being exported are within their responsibility, including cultivation and all other steps of processing until export. Division of responsibilities based on the selection of peanut plantations for export purposes before harvest was not performed between the 2 authorities and co-operation in relation to GAP was not noticed during the mission.

5.2.2. The General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ)

The AQSIQ was established in 2001. It has ministerial status and is responsible for the supervision of food production and processing in relation to import and export of foodstuffs. There are 35 branch services in 31 provinces and about 300 sub-branch services (local bureaus or CIQ's). In addition, there are 200 offices in different ports and airports as well as distribution centre and more than 700 laboratories. The AQSIQ employs more than 30,000 staff all over the country. The mission team noted that the central office in Beijing communicates frequently with its subordinated offices, e.g. in relation to RASFF notifications and when issuing legislative instructions.

Within the scope of the mission, the Plant Food Division of Import and Export Food Safety Bureau under AQSIQ has responsibility for peanut cultivation, processing and export.

In relation to research undertaken, the AQSIQ reported to have initiated a project "Studies on the Risk Analysis and Control Technology for the Prevention of Aflatoxin Contamination in Peanuts", involving a budget of 870,000 RMB and 20 scientists. No

details have been presented and transfer of the results into the cultivation of peanuts was not explained.

Furthermore, subsequent to the mission, information was presented by the AQSIQ, explaining that there are 2 new peanut varieties, either resistant to infestation of the plants by *Aspergillus flavus link* or resisting aflatoxin production. However, cultivation of these varieties could not be verified by the mission team.

5.2.3. Other Organisations

The CNCA is responsible for developing, promulgating and implementing the state laws, regulations and rules concerning certification and accreditation, safety license, hygiene registration and conformity assessment, coordinating and guiding certification across the nation, and supervising and administrating the accreditation bodies and personnel registration bodies. It has issued a document on GAP in 2005 for 11 groups of commodities, including peanuts. Based on a State Council Order from 2006, it is required that 15 provinces and municipalities start to implement these standards. Complementary training material was published in 2006. However, this information was presented to the mission team only during the Closing Meeting and its use could not be verified by the mission team in the course of the mission.

In April 2006, CNCA trained 200 official auditors of the MoA and the AQSIQ, who will be responsible for instruction and training in order to implement GAP. A GAP certification programme aims to have 500 farmers certified for GAP implementation by the end of 2007.

The customs administration of the People's Republic of China is responsible for customs clearance of peanut consignments to be exported.

The CCCFNA is a private association of processors and exporters of agricultural products. It provides information and training to its members and reported to carry out a research project in relation to agricultural practices applied and aflatoxin contamination of peanuts. However, no detailed information on the scope and the outcome of the project was provided to the mission team.

5.3. Process Controls in the peanut production chain

According to the AQSIQ document "Control Requirements for the Safety of Peanuts for Export", processors have to, amongst others, promote GAP to their supplying farmers and have to carry out a survey on aflatoxin contamination in peanuts supplied at the beginning of each harvesting season. The data gathered are used to identify those areas of cultivation with a low aflatoxin incidence. After collection of all data, the provincial CIQs, publish the results of the surveys in order to allow all companies within their jurisdiction to direct their supply of peanuts for export accordingly. The final survey for the year 2005 was presented to the mission team, whilst the 2006 survey for Shandong province was still in the draft format at the time of the mission².

² *In their reply to the draft report the Chinese Competent authorities explained that Shandong CIQ had submitted the results of the aflatoxin survey to its branch services on 26 October 2006. The information provided to private companies from the branch CIQ only covers their specific administrative jurisdiction, and not all information contained in that document.*

5.3.1. *Nut cultivation*

In principle, small farmers with a field size of up to half a hectare dominate production. Harvesting begins 4-5 months after a period of cultivation usually in September through to November, depending on the variety and climate conditions.

Usually harvesting is carried out manually in 2 steps; firstly the plant is dug out and turned to let the peanuts dry on the fields for a period of 2-5 days before being collected by the farmers. While collecting, the pods are separated from the plants either manually or mechanically and the in-shell peanuts are then transferred usually to the farmers premises for further drying for up to 3-4 days. Finally, dried in-shell peanuts are usually cleaned and packaged into 50 kg jute bags and stored either on the farm site under ambient conditions for a period of up to 2 months or directly transferred to processors³.

While visiting 5 farmers, the mission team made the following observations:

- Promotion of GAP in relation to selection of seeds, use of fertilizer and pesticides were done by the processors; however, seeds are commonly saved from previous crops and pesticides were not applied by the farmers visited. Irrigation is applied depending on weather conditions. Peanut cultivation is rotated with wheat and/or corn annually.
- One out of 5 farmers mentioned to have received training/support by the provincial branch of the MoA, all other farmers did not recollect any visit by a provincial MoA representative. Three of the 5 farmers have received training and support from processors.
- In Shandong province, the mission team was informed about a pilot project, initiated by Shandong provincial agricultural bureau in 2005 which aims to facilitate the management of agricultural production. So far, the main achievement was the standardization of production by merging a number of smaller plots into one large field. No research has yet been carried out to measure the effect of the pilot project on aflatoxin contamination of peanuts.
- The document “Control Requirements for the Safety of Peanuts for Export” contains specific parameters in relation to GAP, amongst others for example maximum moisture levels of peanuts before storage. However, verification of compliance with these GAP requirements has not been performed yet by any competent authority.

5.3.2. *Nut processing*

The processing of peanuts begins with the delivery and shelling of peanuts at either independent shellers or shelling facilities of processors, the mission team visited one of each. The following observations were made:

- The independent sheller is shelling on average 20,000 tons of peanuts annually, receiving a fee for every batch shelled. There was no on-site storage. The sheller reported to have received information on GMP from a processor, but has never been visited by a local MoA or CIQ inspector.
- The shelling facility visited belonged to a peanut processor. There was a warehouse available for intermediate storage of approximately 500 tons. This

³ *In their response to the draft report the Chinese Competent Authorities explained that it was winter in the period the mission took place and that the on-farm site storage of peanuts under these climatic conditions is safe.*

facility was designed to shell and sort manually, and grade peanuts mechanically. Apart from manual moisture checks on incoming materials, no other quality criteria at reception of raw peanuts are performed. The facility was generally in a very poor condition with damaged windows and roof and no proper flooring. In-shell and shelled peanuts were stored in jute bags on the ground in-house or under tarpaulin outside the warehouse. Bags were not labelled and were stored in such a way that identification of their origin was no longer possible. The facility did not fulfil the AQSIQ requirements in relation to GMP and HACCP and reported to not have been visited by a CIQ inspector in the past.

In accordance with Order Nr. 20, processors exporting peanuts to the EU have to undergo an annual sanitary registration, which is based on applying GMP, having a HACCP system in place as adopted by Codex Alimentarius and an on-the-spot audit, carried out by CIQ inspection teams. Furthermore, according to the 2006 AQSIQ document, exporting companies are required to have an in-house aflatoxin laboratory in place and to perform aflatoxin checks of incoming peanuts and finished products.

In the provinces of Shandong and Hebei there are 75 companies, holding sanitary registration and exporting peanuts to the EU, 5 of which were visited by the mission team. Most of these companies exported a range of final products, from cleaned in-shell peanuts to blanched kernels or roasted and chopped kernels. The following observations were made:

- All companies had HACCP systems in place, which were certified by the organisation accredited by the Chinese National Accreditation Body (CNAL). All companies complied with the basic hygiene requirements as described in the 2006 AQSIQ document. Final products are usually stored under ambient conditions, which is not fully in line with AQSIQ requirements of keeping storage temperatures below 10°C and relative humidity under 70%. Warehouses visited were equipped with thermometer and hygrometer.
- All companies had in-house laboratories in place; all of them had successfully participated in annually organised proficiency tests for aflatoxin analysis at provincial level.
- Surveys on the aflatoxin contamination of peanuts in relation to their origin were undertaken by the companies since 2005 and the results were reported to the provincial CIQ and published. Verification of the results reported was not undertaken by the local CIQ's visited. There is no harmonized AQSIQ procedure, detailing sampling and analysis by the companies. It is left to individual CIQ's to give such instructions to the companies concerned.
- Traceability of the final products to the township/county of origin of the raw material was demonstrated in 2 companies. Traceability to the field of origin, as required by AQSIQ, is not possible, due to the average yield of below 1 ton/field and the maximum permitted raw material batch sizes of 100 tons.
- All companies visited performed the required visual, moisture and aflatoxin checks upon reception and aflatoxin checks when packaging final products as part of their quality procedure.

Research, which would demonstrate the effect of the AQSIQ requirements on aflatoxin contamination in peanuts, in particular the application of GAP, GMP and HACCP, was not presented.

5.3.3. *Non-Conforming Products*

According to national standards, non-conforming products are defined as containing more than 1 ppb aflatoxin B1. When exceeding this level, the local CIQ issues a note, which does not permit the lot to be exported to the EU. Companies then have 2 possibilities to handle the lot: in cases where the aflatoxin result is below 2 ppb for B1 and 4 ppb for total aflatoxin, the lot can be sold on the domestic market or exported to a third country where the aflatoxin levels found are in compliance with the legal limits. Where the results are exceeding 2 ppb for B1 and 4 ppb for total aflatoxin, the companies have to provide the local CIQ office with information about the final destination of the product. When visiting the processors, the mission team was informed that in most cases the non-complying lots are exported to countries where the legal limits for aflatoxin B1 and total are not exceeded. For a minority of lots the possibility of re-processing is applied in order to reduce the aflatoxin levels.

Non-conforming products, which were produced as a consequence of processing, are discarded as animal feed or as waste. Supervision on these products, carried out by CIQ inspectors, was not observed by the mission team during the mission.

5.4. Method of sampling for peanut consignments

The AQSIQ sent an instruction to the CIQs concerning the requirements of Regulation (EC) 401/2006 in March/April 2006, requiring its implementation as of 01 July 2006. A detailed sampling procedure for peanuts was to be elaborated and issued by the provincial CIQ branches.

In the course of the mission there were 2 demonstrations of sampling observed by the mission team, one of a lot of peanuts of 20 tons, packaged in 25 kg bags. The other sampling was of big bags, containing 950 kg of peanuts, also with a lot size of 20 tons. In general, both sampling demonstrations followed the structure laid down in Regulation (EC) 401/2006. Differences were noted as follows:

- In the case of 25 kg bags: in accordance with the CIQ instructions, every 7th bag was already selected and left open by the company before arrival of the inspector. Incremental samples of approximately 300g were taken from the top of the open bags with a bowl. It was explained that this is normal procedure (also for peanuts in cardboard boxes and vacuum packs) in order to avoid damaging the integrity of already packaged product. Samples are collected in opaque bags, clearly identified, closed and sealed and transferred by CIQ inspectors to the laboratories. After sampling, bags are re-filled with finished product from the same production lot to the weight indicated on the label.
- In the case of big bags: samples are taken from the top of each big bag at five different points with a bowl. The weight of the incremental samples was approximately 300g, amounting to a total sample size of 30kg. Finally, sample identification, sealing, and transfer to the laboratory was similar to that described above.
- During both demonstrations, sampling spears were not in use.

5.5. Procedure for exporting nuts to the EU

In order to export peanuts into the EU, companies have to fulfil the provisions of Order Nr. 20 and have to pass an annual sanitary registration audit, carried out by CIQ inspection teams. For every peanut lot to be exported, an application form to carry out an official sampling, the sanitary registration code, an in-house analytical report for

aflatoxin analysis, a client contract, invoice, the packaging list and information about the origin of the peanuts have to be provided to the local CIQ office. Official sampling will only be performed upon reception of all documents and verification of correctness and completeness of the information and provided the result of the in-house aflatoxin analysis was below the detection limit of the laboratory. Furthermore, the peanuts to be exported into the EU must originate from areas with a low aflatoxin incidence as proven by the aflatoxin survey.

Subsequently, a CIQ inspector carries out the sampling, requiring also checks upon the sanitary conditions of the lot, correctness of labelling and a check to verify full traceability from the finished products through to the raw materials received. The local CIQ will permit export to the EU on the condition that the result of the official aflatoxin analysis (B1 and total) is below the detection limit of the laboratory. It issues a health certificate as required by Commission Decision 2002/79/EC (now replaced by Commission Decision 2006/504/EC), a phytosanitary certificate and a CIQ export permit. After having obtained the CIQ export permit, containers are filled and sealed at the processors site, during which CIQ inspectors are occasionally, but not routinely present. Container and seal numbers are recorded on the export documentation. The average time for exporting peanuts from the point of official sampling until arrival in EU is approximately 7-8 weeks.

The mission team examined health certificates along with additional information attached to the file such as the results of aflatoxin analysis, details of sampling and method of analysis issued by the CIQ office. The results of the aflatoxin analysis in these examples were expressed just as “n.d.”(not detectable) without indication of the actual limit of detection (LOD).

As 80 – 85 % of all peanuts exported to the EU originate from Shandong province, the mission team visited the port of Huang Dao, which is the main point of export of peanuts into the EU. When arriving at the port, access to the container terminals is possible through 18 customs controlled check points, where customs verifies container and seal numbers, but does not routinely perform identity checks on the peanut consignments. The export documentation is to be presented to the port CIQ office. In the case of the consignments originating from Shandong province, the port CIQ office does not perform any checks apart from documentary checks and gives its final export approval. Where the consignment originates from other provinces, 3-5% of containers are randomly selected and identity checks on the consignments are performed by the port CIQ, before granting final export approval. The port CIQ office produced a document confirming that in December 2005, 4 out of 54 consignments of peanuts were identity checked. After containers were opened, new seal numbers are reported in the export documentation. Customs release exports usually within 3 to 5 hours.

A clear link between the peanut lot to be exported, the health certificate and the report for aflatoxin analysis was demonstrated by customs and Shandong CIQ.

5.6. Laboratory services

There are 12 CIQ laboratories designated to perform official aflatoxin analysis for peanuts and peanut products destined for export into the EU. In addition, 2 private laboratories have been approved by the Shandong CIQ laboratory for the same purpose.

The 12 CIQ laboratories have been accredited according to ISO 17025 by the CNAL, among other things, for the determination of aflatoxins in food. With regard to the two

approved private laboratories, one is accredited to the above requirements whereas the other one is not. The procedure of approval by the Shandong CIQ laboratory includes checks on the quality system of the private laboratories, on-site audits, analysis of blind samples and successful participation in international proficiency tests. Sufficient documentation was presented to the mission team in relation to the approval procedure and regular on-site inspections of the approved labs. If shortcomings were found, these had to be rectified and reported upon by the laboratory concerned.

5.6.1. Laboratories visited

The three laboratories visited used the same analytical procedure described in the National Standard GB/T 18979-2003, which was based on the method described in the AOAC Official Methods of Analysis, method 991.31 (2000).

The mission team visited a private laboratory in Qingdao (Shandong province, laboratory 1), which is authorised since 2002 by CIQ to carry out official analysis of aflatoxins in peanuts intended to be exported to the EU. The laboratory has 3 divisions and employs 10 staff. The Liquid Chromatography division is responsible for performing aflatoxin analysis and employs 6 staff, 4 of whom are technicians. Training records of these staff were shown to the mission team. Although the laboratory is not accredited to ISO 17025, it follows its requirements. Since its approval, the laboratory has been inspected on a regular basis by staff of the Shandong CIQ laboratory.

For sample preparation, the aggregate sample of 30kg is divided into three sub-samples of 10 kg each and ground. The analytical procedure was based on immunoaffinity cleanup and liquid chromatography (LC) with fluorescence detection. The laboratory participated regularly in international proficiency tests with satisfactory results. The in-house validation of the analytical procedure was carried out in November 2005 and the values for the expanded measurement uncertainty were included in analytical reports since 2006. The validation of the analytical procedure was found to cover the range from 1 to 5 µg/kg of aflatoxin B1. The expression of the analytical results fulfilled the requirements of the Regulation (EC) 401/2006. The LOD cited in the analytical reports was 1.0 µg/kg for aflatoxin B1. In 2005, 2124 lots destined for export to the EU were tested for aflatoxins, of which 25 were found not to be in compliance with the EU limits. In the first 6 months of 2006, 152 lots were tested, of which 12 exceeded the EU limits for direct human consumption.

At Qingdao, the mission team visited the Technical Centre Laboratory of Shandong CIQ, laboratory 2) which has been designated by AQSIQ as a national reference laboratory for aflatoxin analysis in peanuts. This laboratory employs 68 staff, 7 of whom are working in the mycotoxin analysis section. As a reference laboratory, it is responsible for a number of activities, such as provision of technical assistance and supervision of other CIQ laboratories and approved private laboratories. Furthermore, it coordinates a series of proficiency tests for both official and private laboratories of peanut processing establishments at provincial and national level since 2002. Some staff have received external training (UK, Switzerland) in mycotoxin analysis.

Sample preparation followed the same method as described for laboratory 1. The analytical procedure was based on immunoaffinity cleanup and LC with fluorescence detection. The laboratory had re-validated in-house its procedure for the determination of aflatoxins in peanuts in June 2006. The validation report was assessed and the performance criteria were found to be in line with Regulation (EC) 401/2006, regarding recovery and precision requirements. The tested concentrations covered the range from 2

to 4 µg/kg for aflatoxin B1 and 5.2 to 10.4 µg/kg for total aflatoxins, respectively. Evidence was presented of former validation assays covering the range between 1.0 and 8.0 µg/kg for aflatoxin B1 and 2.5 to 20.0 µg/kg for total aflatoxins. The LOD, based on the signal to noise ratio, was found to be 0.1 µg/kg for aflatoxin B1. The laboratory participated regularly since 2001 (once per year) in international proficiency tests with satisfactory results. As regards traceability, two analytical reports, issued in 2006, were checked. The reported LOD and limit of quantification (LOQ) in the case of the negative sample were 0.5 and 1.0 µg/kg respectively for aflatoxin B1. The results related to the positive sample were corrected for recovery and included information about the recovery rate and the expanded measurement uncertainty. In 2006, 2012 samples of peanuts for export to the EU were analysed for aflatoxins, 37 of which exceeded the EU limits for direct human consumption.

The mission team visited the Technical Centre Laboratory of Hebei CIQ at Shijiazhuang (laboratory 3). This laboratory was established in December 1999 and employs 39 staff, 5 of whom are performing aflatoxin analysis.

As regards sample preparation, the laboratory visited had the same equipment as the two laboratories above. The laboratory also uses the same analytical procedure based on immunoaffinity cleanup and LC with fluorescence detection. The laboratory participated occasionally (2001 and 2005) in proficiency tests organized at national level by CNCA and SCIQ. An in-house validation report issued in 2005 was assessed by the mission team. The LOD for aflatoxin B1 was cited to be 0.4 µg/kg, although this level represented the LOQ, as this was the lowest validated concentration, ranging from 0.4 to 4.3 µg/kg of aflatoxin B1. As regards traceability, two analytical reports of 2006 were checked. Both reports were in accordance with the requirements of Regulation (EC) 401/2006. The reported LOD in the case of the negative sample was 0.4 µg/kg of aflatoxin B1. The results related to the positive sample were corrected for recovery and included information about the recovery rate and the expanded uncertainty. In 2005, 480 samples of peanut for export to the EU were tested for aflatoxins, of which 24 exceeded the EU legal limits for direct human consumption. In the first 6 months of 2006, 220 peanut lots were tested, of which 10 exceeded the EU legal limits.

The laboratory performance as discussed is summarized in table 2.

Four in-house laboratories of peanut processing establishments were visited during this mission. Three of them used the same analytical method, based on immunoaffinity cleanup and fluorescence detection. The fourth laboratory used immunoaffinity cleanup and LC with photometric detector. The mission team was informed about the satisfactory results obtained by the four laboratories in a proficiency test in 2006, coordinated by the Shangdong Technical Center of CIQ. Other activities related to internal quality control in these private laboratories were very limited.

5.7. Response to RASFF notifications

When peanut consignments, originating from China, are rejected at EU borders due to aflatoxin levels, exceeding the legal limits, they are mostly re-dispatched to a third country, where the aflatoxin level found is in compliance with national legislation. Another possibility is that of a re-dispatch to the exporter. On arrival in China, the consignment is treated as common importing good, for which customs procedure applies, requiring also CIQ approval to return the consignment to the exporter.

The follow-up of RASFF notifications 2006.AHX by AQSIQ and its branches was demonstrated in one of the companies visited. The local CIQ required the company to examine possible causes of the aflatoxin incidence and set a deadline to receive a written report within 3 days. Although the company reported back in time, the reason for the contamination of the lot was not identified. Instead, the company proposed to increase controls at the reception of raw peanuts.

In general, companies who are involved in a RASFF notification are suspended from EU export until such time that corrective measures are taken and the local CIQ have verified their implementation. However, when a company is involved in 3 RASFF notifications within 3 months, EU exports will be suspended by withdrawing the sanitary registration and can only be resumed when passing another full and strict inspection.

5.8. Follow-up on recommendations made in the previous report SANCO 3223/2001

In the previous mission report, the following recommendations were made:

- (1) *Take steps towards the co-ordination of laboratories in respect of developing and validating a uniform method of analysis, including development of standard operating procedures, procedures for application of screening/confirmation methods, national and international proficiency tests and evaluation of laboratory performance and results.*
- (2) *Provide a guarantee that the certificate and customs procedure can ensure the validity of the produced certification to the exported lots.*

Both recommendations were addressed as previously described in this report.

Table 2: Summary of Laboratory performance for the 3 laboratories visited

	LABORATORY 1	LABORATORY 2	LABORATORY 3
Accreditation	Not accredited to ISO 17025	Accredited to ISO 17025 by the CNAL for determination of aflatoxins in foods (nr. L2827)	Accredited to ISO 17025 by the CNAL for determination of aflatoxins in foods (nr. L0981)
Validation	Yes. Method specific in-house validation documentation in place.	Yes. Method specific in-house validation report issued in June 2006 (last version).	Yes. Method specific in-house validation report, issued in 2005.
Premises	Overall appearance of the laboratories fulfil the requirements according to ISO 17025	Clean, tidy, clearly arranged. Overall appearance of the building and laboratories fulfil general ISO17025 requirements	Overall appearance of the building and laboratories fulfil general ISO17025 requirements
Method and Equipment	Equipment fulfil the requirements Grinding: high capacity cutter mixer (Stephan) Extraction: AOAC 991.31 Clean-up: Immunoaffinity column (manually) Determination: HPLC-FLD after post-column-derivatization (Kobra-Cell)	Equipment fulfil the requirements Grinding: high capacity cutter mixer (Stephan) Extraction: AOAC 991.31 Clean-up: Immunoaffinity column (manually) Determination: HPLC-FLD after post-column-derivatization (Kobra-Cell)	Equipment fulfil the requirements Grinding: high capacity cutter mixer Extraction: AOAC 991.31 Clean-up: Immunoaffinity column (manually) Determination: HPLC-FLD after post-column-derivatization (PBPB)

	Aflatoxins standard: Liquid, Supelco AF Mix, ref. 46304	Aflatoxins standard: Liquid, Supelco Af Mix, ref.46304	Aflatoxins standard: Liquid, Supelco Af Mix, ref.46304
Quality Assurance (References, Spikes, etc).	Proficiency tests: once per year (international). Always results with z-score < +/-2. Internal audits: yes Usage of reference material (peanut paste)	Two spiked samples within each LC sequence. Proficiency tests: once per year (international). Always results with z-score < +/-2. Internal audits: yes, usage of reference material (peanut paste)	Proficiency tests: Occasional participation in tests at national level (2001 and 2005) with satisfactory results in terms of values included in some accepted range.

6. CONCLUSIONS

6.1. Relevant national legislation

- (1) There is adequate framework legislation in place, taking account of all EU requirements for the export of peanuts into the EU.

6.2. Competent Authorities

- (2) Responsibilities within the scope of the mission are assigned, although an overlap of responsibilities between the MoA and the AQSIQ in relation to the cultivation of peanuts was noted and the extent of co-operation was not clear.
- (3) The AQSIQ has sufficient resources available to carry out the designated tasks in relation to supervision and controls of peanuts for EU export and an adequate system of communication within its organisation was noted by the mission team.
- (4) Some research into the contamination of peanuts with aflatoxins is ongoing with a limited number of specific results, such as *Aspergillus flavus link* resistant peanut varieties presented to the mission team. However, application of the results when cultivating peanuts remains to be demonstrated.

6.3. Process Controls in the nut production chain

- (5) GAP standards were developed recently, requiring their application for peanut cultivation. However, implementation is at a very early stage and the effect on aflatoxin contamination remains to be demonstrated.
- (6) Supervision of the application of GAP is the responsibility of the MoA and of the AQSIQ for peanuts to be exported. However, when visiting a number of peanut farmers, very little evidence of supervision and verification of compliance with GAP was found.
- (7) Peanut shellers visited by the mission team have not been inspected by any competent authority and sanitary conditions, storage management and traceability of one sheller was insufficient and not in line with AQSIQ requirements.
- (8) All peanuts processors visited by the mission team had successfully passed a sanitary registration process as required for peanut exporters and complied with

GMP and HACCP and other requirements as defined by an AQSIQ document. Conditions demonstrated at these processors were assessed by the mission team and were found to be in line with Regulation (EC) 852/2004.

- (9) Traceability, linking final products to the township/county of production was sufficiently demonstrated at the processors.

6.4. Method of sampling for peanut consignments

- (10) Although the sampling demonstrations were in principle in line with the requirements of Commission Regulation (EC) 401/2006, differences noted could affect the representativeness of the sample taken for the whole consignment to be exported.

6.5. Procedure for exporting nuts to the EU

- (11) The procedure for exporting peanut consignments into the EU was in principle in line with the requirements of Commission Regulation (EC) 401/2006. It was noted however that there is limited official supervision from the point of sampling until shipment of peanuts to the EU, providing opportunities for product replacement.
- (12) The health certificates issued by the CIQ offices are not fully in compliance with the requirements of Commission Decision 2006/504/EC regarding the lack of reporting of the actual LOD of the methods used.

6.6. Laboratory services

- (13) All CIQ control laboratories undertaking analysis for aflatoxins in peanuts to be exported into the EU are accredited to ISO 17025. Two of these were visited and assessed by the mission team as to be in compliance with the criteria of Annex 2 of Regulation (EC) 401/2006.
- (14) In addition, there are 2 private contract laboratories, undertaking analysis for the same purpose, after official approval. The mission team assessed the approval procedure to be in line with the applicable provisions of ISO 17025.
- (15) One of the private laboratories, not accredited to ISO 17025, was assessed by the mission team and was found to carry out aflatoxin analysis in peanuts in line with ISO 17025 requirements and in line with the criteria of Annex 2 of Regulation (EC) 401/2006.

6.7. Response to RASFF notifications

- (16) Satisfactory follow-up of RASFF notifications was noted by the mission team.

6.8. Follow-up on recommendations made in the previous report SANCO 3223/2001

- (17) Satisfactory follow-up of recommendations made in the previous report SANCO 3223/2001 was noted by the mission team.

6.9. Overall conclusion

- (18) Overall, there is an acceptable control system in place for exporting peanuts into the EU. In particular, in the area of peanut processing and laboratories, significant improvements have been noted in comparison to last mission. However, shortcomings were identified in relation to the implementation and supervision of GAP, supervision at one sheller visited, sampling of peanuts, supervision of peanuts to be exported from the point of sampling and expression of analytical results attached to the health certificates.

7. CLOSING MEETING

A closing meeting was held on 16 November 2006 at the premises of the AQSIQ. Representatives from the AQSIQ, MoA, CNCA, and provincial CIQ's were present. At this meeting, the main observations and initial conclusions were presented by the mission team. The competent authorities made significant comments and/or objected the following findings:

- The number of farmers having been trained or visited by representatives of the MoA in relation to GAP was 4 out of 5, instead of 1 out of 5, as reported by the mission team. It was furthermore stated by the same representatives that the application of GAP is not a mandatory requirement.
- The application of GAP and the standardization of cultivation practices will necessarily reduce aflatoxin contamination in peanuts. However, no information was provided to substantiate this.
- There is no lack of supervision by AQSIQ in relation to the application of GAP, as processors are under control of AQSIQ and they are required to promote GAP to their suppliers.
- If deemed necessary, supervision by AQSIQ from the point of sampling until shipment will be put in place, although duplication of supervision will not be accepted.
- Regarding sampling, AQSIQ explained that sampling spears were not in use due to the fact that these would damage vacuum packs. Furthermore, the use of spears was already positively recognised during the previous mission in 2001.
- In relation to the lack of information regarding research, AQSIQ representatives explained that research has been undertaken, but as this is intellectual property of the People's Republic of China, it was not presented to the mission team.

8. RECOMMENDATIONS

The Competent Authorities of the People's Republic of China should

- (1). Ensure that all processors exporting peanuts into the EU, in particular their shelling facilities, comply with AQSIQ requirements and implement standards at least equivalent to Article 4 of Regulation 852/2004 on general and specific hygiene requirements.
- (2). Provide guarantees that the information in the health certificates as required by Commission Decision 2006/504/EC for the export of peanuts into the EU is accurate and authentic, thus opportunities for product replacement are minimised.

- (3). Report the LOD in the health certificates as required by Commission Decision 2006/504/EC.
- (4). Take account of the “Guidance Document for Competent Authorities for the Control of Compliance with EU Legislation on Aflatoxins” in so far as samples should be taken throughout the batch and should be as representative as possible.
- (5). Take account of Codex Alimentarius “Code of Practice for the prevention and reduction of aflatoxin contamination in peanuts” and should increase efforts to implement and supervise GAP standards as developed by the CNCA in the area of peanut cultivation.
- (6). Undertake research on the incidence of *Aspergillus* and points of aflatoxin production, and the effects of processing on reducing aflatoxin levels.

9. COMPETENT AUTHORITY RESPONSE TO RECOMMENDATIONS

The competent authorities’ response to the recommendations can be found at:

http://ec.europa.eu/comm/food/fvo/ap/ap_china_8126_2006.pdf

10. ANNEX 1

European Legislation	Official Journal	Title
Regulation (EC) No 882/2004.	OJ L 165, 30.04.2004. Corrected and re-published in OJ L 191, 28.05.2004 p. 01.	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.
Regulation (EC) No 178/2002.	OJ L 31, 1.02.2002, p. 01.	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.
Council Regulation (EEC) No 315/93.	OJ L 37, 13.02.1993, p. 01.	Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food.
Commission Regulation (EC) No 466/2001.	OJ L 77, 16.03.2001, p. 01.	Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs.
Commission Regulation (EC) No 401/2006.	OJ L 70, 09.03.2006, p. 12.	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the sampling methods and the methods of analysis for the official control of the levels for mycotoxins in foodstuffs.
Regulation (EC) No 852/2004	OJ L 139, 30.04.2004. Corrected and re-published in OJ L 226, 25.06.2004 p. 03.	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
Commission Decision 2006/504/EC	OJ L 199, 21.07.2006, p 21	Commission Decision of 12 July 2006 on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins.