EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG (SANCO)/8117/2006 – MR FINAL

FINAL REPORT OF A MISSION

CARRIED OUT IN THE UNITED STATES OF AMERICA

FROM 18 SEPTEMBER TO 22 SEPTEMBER 2006

IN ORDER TO

ASSESS THE CONTROL SYSTEMS IN PLACE TO CONTROL AFLATOXIN CONTAMINATION IN PEANUTS INTENDED FOR EXPORT TO THE EUROPEAN UNION

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

TABLE OF CONTENTS

EXECUTIVE SUMMARY

This report describes the outcome of a mission carried out by the Food and Veterinary Office in The United States of America, from 18 September to 22 September 2006.

The objective was to assess the control system in place to control aflatoxin contamination in peanuts that are intended for export to the European Union, and, on the basis of an application made by the USA under Art 23 of Regulation (EC) No 882/2004, to verify that pre-export checks for products exported to the EU ensure products satisfy Community requirements.

The competent authorities are clearly defined and communication between them was good with the exception of return of rejected goods. The control system is long established and based on relevant and directly applicable research.

There is a mandatory requirement for official sampling and analysis for aflatoxins on finished products, and incoming checks that also are relevant in the control of aflatoxin synthesis. The sampling and analysis in use offers equivalent guarantees to EU methods. These controls are also aided by a mandatory positive lot identification scheme.

The laboratories operating official control analysis for aflatoxin were either USDA or USDA approved laboratories.

Awareness of aflatoxin controls in industry was high with use of many measures that went beyond mandatory control. These included use of HACCP principles (which is not mandatory), in house and mobile testing for aflatoxins and segregation of any product with elevated aflatoxin levels. Processing is effective in removing damaged kernels and the link between the processing steps and aflatoxin control is well researched.

There are no official checks at the point of export on outgoing lots or documentation, including aflatoxin certificates. This enables certificates to be dispatched without there being official samples or without interpretation of the suitability of results. The time for which containers are being held in the port prior to export is considered excessive.

There is no clear allocation of responsibility and poor communication regarding the control of lots returned from Europe and dealing with communications from the Commission regarding RASFF messages.

Overall the USA has a well-defined control system for aflatoxins in peanuts, linked to well structured research projects. The system of laboratory approval appears to result in well performing laboratories. Some issues regarding the defining of the certification process for export and the dealing with returned lots are requiring attention to provide a system of pre-export checks that verify products satisfy community requirements.

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

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AMS	The Agricultural Marketing Service of the USDA
APC	The American Peanut Council
ARS	Agricultural Research Service
CCA	Central Competent Authority
CN-Code	Combined Nomenclature Code
EU	European Union
FDA	Food and Drugs Administration
FSIS	The Federal State Inspection Service
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
LIMS	Laboratory Information Management System
LOD	Limit of Detection
LOQ	Limit of Quantification
MOAB	Marketing Order Administrative Branch
MS	Member States
NPRL	National Peanut Research Laboratory
PLI	Positive Lot Identification
RASFF	Rapid Alert System for Food and Feed
SOP	Standard Operation Procedure
TLC	Thin Layer Chromatography
USDA	The United States Department of Agriculture
VCM	Vertical Cutter Mixer

1. INTRODUCTION

The mission took place in the USA from the 18 September to 22nd September 2006. The mission team comprised 2 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 USDA (United States Department of Agriculture) and the APC (American Peanut Council).

An opening meeting was held on 11 September at the premises of the USDA in Washington. Representatives of the AMS (Agricultural Marketing Service), FDA (Food and Drugs Administration) and APC 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 control systems in place to control aflatoxin contamination in peanuts intended for export to the European Union. An assessment must be undertaken of the checks made prior to export to verify that the nuts meet community requirements, as described in Art 23 of Regulation EC (No) 882/2004.[1]

The scope of this inspection covers in-shell peanuts (CN code 120210), peanut kernels (blanched or otherwise) (CN code 120220). It does not cover peanut confectionery, peanut butter, peanut flour or peanut oil.

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

COMPETENT AUTHORITY VISITS			**Comments**
Competent authority	Central	1	USDA
	Federal Private Co.	1 1	FSIS Georgia
LABORATORY VISITS		2	
Private approved laboratory USDA Blakeley		1 1	
FARMERS			
Peanut farm		1	Georgia
PROCESSING ESTABLISHMENTS			
Buying Point and interim store		1	Buying point in Alabama
Blanching company		1	Large company in Georgia
Shellers		2	Both in Georgia
PORTS OF EXPORT			
		1	Port of Savannah, Georgia
OTHER SITES			
National Peanut Research Laboratory		1	

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

3. LEGAL BASIS AND OTHER RELEVANT LEGISLATION FOR THE MISSION

3.1. Legal basis

The mission was carried out in agreement with the CCA 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.

– Article 23 of Regulation (EC) No 882/2004.

3.2. Other relevant legislation

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

4. BACKGROUND

4.1. Overview of previous missions regarding aflatoxin contamination in foodstuffs

This is the first mission carried out by the European Commission in the context of Art 23 of Regulation EC (No) 882/2004. This describes that third countries can apply for approval, following a community audit, that pre-export checks for products exported to the EU ensure products satisfy Community requirements.

There have been a number of other third country aflatoxin missions related to certain commodities, and in addition, missions to 16 Member States (MS), with the objective of assessing controls on imported products of plant origin were also 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

Approximately 2,400,000 tonnes of raw peanuts are produced annually in the USA. The majority of production is in the southern states, with Georgia producing the greatest volume. Approximately 20% of peanuts imported to the EU come from the USA (67,000 tonnes).

Information on foodstuffs found to have public health implications within the EU are disseminated as alert notifications through the Rapid Alert System for Food and Feed (RASFF) to all EU MS and to the exporting country. 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.

The information received from RASFF and from information submitted by MS directly to the Commission indicates a very low rejection rate for peanuts from the USA, when compared to peanuts from other third countries.

Table 1

USA	Imports to EU (tonnes)		Number of RASFF		
	2004	2005	2004	2005	2006 (Jan-Sept)
120220 Shelled Groundnuts	78,518 (NL,UK)	56,371(NL,UK)	4	2	7
120210 Groundnuts in Shell	9,244	10,903	0	0	0

Source: Eurostat, Comext database and EC, RASFF database. Figures from the APC are almost identical.

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 legislation taking into account the known possible effects of sorting, mixing or of other physical treatment methods to reduce the aflatoxin content of the peanuts. In accordance with Annex I to Commission Regulation (EC) No 466/2001, the maximum admissible aflatoxin levels in groundnuts (Peanuts) 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 OBSERVATIONS

5.1. Relevant national legislation

The primary national legislation relates to the establishment and control of product Marketing Orders, which are commodity specific programmes that establish conditions for the production and sale of goods.

- Public Law 107-171 of May 13, 2002 (The Farm Security and Rural Investment Act of 2002) provides a framework for commodity programmes and how they operate, including costs. Subtitle C contains specific provisions for peanuts. Whilst most of this relates to assignment of yields and payment the Law does provide (under Sec 1308) for the inspection and grading of peanuts by USDA and Federal-State inspectors. Additionally it provides a legal basis for the establishment of the 'Peanut Standards Board '.

- The Agricultural Marketing Agreement Act of 1937 provides the legal basis for the establishment of commodity specific marketing agreements. It also states there where growers or processors do not enter into agreement then similar levels of control exist. Peanuts cannot be sold if they do not meet the quality requirements specified.

- The Agricultural Marketing Act of 1946 provides a general framework for the control and inspection of agricultural goods (including when shipped to external markets), and for the funding of research in relation to such commodities.

- The Code of Federal Regulations Title 7, Part 996 provides details of the Marketing Order for peanuts. This provides that marketed nuts should be clearly lot identified, analysed by a USDA or USDA-approved laboratory for aflatoxin and found negative (defined as 15 µg/kg or less), and meet provided quality standards regarding for example weight and moisture.

The control for export of peanuts, and the requirement for further analysis to EU levels follows a defined procedure but is not contained in US legislation.

5.2. Competent Authorities

5.2.1. The United States Department of Agriculture (USDA)

The CCA is the USDA AMS. The USDA has established a number of priority areas for the marketing of agricultural commodities, and has established agencies responsible for these priority areas.

The Agricultural Marketing Service (AMS) is one of these agencies that has responsibility for the strategic marketing of products both in the USA and on international markets. It operates within the USDA 'Under Secretary for Marketing and Regulatory Programs'.

The AMS has currently developed six commodity specific programmes; covering cotton, dairy, fruit and vegetables, livestock and seed, poultry and tobacco. The programme for fruit and vegetables includes peanuts and similar commodities. The Marketing Order Administration Branch (MOAB) of the AMS oversees these programs. It does so through five marketing field offices.

Inspectors at state level implement the mandatory controls of the marketing order. These inspectors are employed by each state (Federal-State Inspection Service (FSIS)) but working on behalf of the USDA on the basis of an established co-operation agreement between the USDA and 48 states. The USDA AMS staff oversee this work through 10 Federal program managers using the branch internal quality management system (BIQMS).

Within the USDA there is also a research department (The Agriculture Research Service (ARS)). There is an annual research programme, the findings from which are presented at a Multi-crop Aflatoxin Workshop. Summary proceedings of research documents are also published on the ARS website (http://www.ars.usda.gov).

The mission team visited an ARS facility, the National Peanut Research Laboratory in Dawson, Georgia. The centre provided details of a number of commodity specific aflatoxin control programmes. Some of these are discussed under the section on process control. The centre has 43 staff, including 12 scientists. It receives funding directly from the USDA and through applying for grants. The research outputs are disseminated to farmers and processors through the APC, USDA and through county extension workers.

The approval of laboratories which are approved by the USDA for the analysis of aflatoxins in peanuts is conducted by staff of the USDA Science and Technology Program of the AMS.

5.2.2. The American Peanut Council (APC)

The APC is a trade association with a Board of Directors and Committee representing the peanut industry, primarily on market development. It is responsible for overseeing the barcode lot identification system. It is provided with no budget or staff for aflatoxin control but employs one person to deal with regulatory export issues. Costs of other controls come from the charges to exporting companies.

The APC have run a number of training programmes within the USA. It disseminates information to its members through its newsletter, through a programme of seminars and conferences and through its website (http://www.peanutsusa.com).

5.2.3. Federal-State Inspection Service (FSIS)

FSIS is established at state level to carry out mandatory inspections on incoming and outgoing products, to administer the Positive Lot Identification (PLI) labelling scheme and to supervise the treatment of non-conforming lots.

There are 250-300 FSIS staff in Georgia, overseeing 53 buying points.

The FSIS employs a large number of inspectors and assistants on a seasonal basis and thus is required to train large numbers of individuals. The mission team were demonstrated a well structured and well presented training programme in Georgia that gave practical and theoretical training on the identification of damaged nuts and specifically on the microscopic examination of moulds to identify *Aspergillus*.

5.2.4. Food and Drugs Administration (FDA)

The FDA has a general responsibility for the supervision of lots returned to the USA following rejection in Europe. Commodities imported into the USA or returned goods which are part of the 'US goods returned programme' result in a data input through prior notification to the central FDA Centre for Food Safety computer systems.

The information is then accessed by local FDA offices who can choose to check documentation or hold lots pending sampling. Evidence was found of one

consignment being held pending sampling. The routine approach or priority of peanut consignments was not clear however, and these controls are not linked to response to RASFF notifications (see section 5.7).

5.2.5. Private Control Company

In addition there is a private organisation based in the peanut production areas. The organisation's status was established in 2002 by the new Farm Bill, and consists of staff of the former Peanut Advisory Committee. It has a written agreement with the USDA to oversee the compliance with the peanut quality and handling standards. The company consists of 3 compliance officers, one for each of the main peanut production regions. Information on all lots is received from FSIS.

Non-conforming lots are checked by this private organisation that ensures the product is reprocessed or used for non-human consumption or pressed for oil extraction. This is done by visits to the processors and to the facilities handling the non-conforming product, and by documentary checks. This might include for example the supervision of the blanching of products. All the information on the quality checks, aflatoxin analysis and destination of the lot are held on a computer database.

The mission team verified the actions carried out by this private control body. This included examination of the documentation and computer system and tracking of defined examples to show they were adequately controlled and recorded.

The company reports to the USDA, and the above database is accessible by the USDA. The USDA also audit the company from technical and procedural perspective annually. This audit also examines any possibility of conflict of interests, and none were identified in the last audit.

5.2.6. Other Relevant Bodies

There are two bodies, not visited or assessed by the mission team, that are involved in the framework of peanut controls.

The National Peanut Board is a USDA entity with members from industry appointed by the USDA that conducts research and promotion actcivities.

The Peanut Standards Board has 18 industry members and makes recommendation specifically on the legislative programmes.

5.3. Process Controls in the nut production chain

Within the framework of the peanut origin certification programme each lot of peanuts has to be labelled with a unique lot number that is assigned by FSIS. This is now a uniquely generated code that includes details on crop year, type of product (each grade has a label with a different colour to ease visual identification), information on the company and lot number. The FSIS inspector issues two labels and the details are recorded electronically. The labels are affixed to the side and top of the packaging. At present, although numbers are unique throughout the country, the computer network is ring-fenced in each state, necessitating phone calls to another FSIS office for information on lots if the lots have crossed state boundaries.

5.3.1. Nut cultivation

The peanuts are grown in privately owned farms. The majority produced in the USA are 'Runner' type, with 'Virginia' having a high percentage in the export market. In the regions visited irrigation was commonplace with overhead booms, but the extent of irrigation depends on the climatic conditions of each region. Harvesting varies depending on type and climate but predominately takes place in the months of October-November. The peanut plants are loosened by a digger, then shaken and inverted mechanically, and allowed to air dry usually in the field, or sometimes on curing trailers. Drying takes 2-3 days and is followed by threshing to separate the peanut pods. The nuts are then dried mechanically with warm air to achieve a moisture content of 8-10%, by the use of blown air through the trailer.

The processes described are laid down in detailed GAP documentation, produced by the APC in 2002 and disseminated widely through associations of growers and also freely available on the APC website. It includes detailed descriptions of land preparation, pesticide use, irrigation and harvesting. Where relevant these procedures are designed to decrease the incidence of aflatoxin synthesis.

The National Peanut Research Laboratory has also developed a competitive strain of non-aflatoxin forming *Aspergillus* that can be spread through peanut fields during the development of the nuts, and this results in a significant reduction in aflatoxin forming moulds. The use of this competitive control is now commercially available (since 2004) and usage is increasing. The estimate of crop coverage for the 2006 season is 25,000 acres.

The growers then transport their stock peanuts to the buying points or shelling plants directly on (open) trucks. The scheme of peanuts aflatoxin control does not permit for on farm storage. Storage of farmstock takes place at the buying point or processing facilities in bulk. Some buying points are owned specifically by the processors, others are separate entities.

Stores at the buying points are generally metal. Design features such as ventilated headspaces, double skinned roofing and in some cases mechanically pumped air through the nut piles are in place. This keeps moisture levels low and limits temperature extremes. The extent of these features varied dependant on the age of the facility.

The NPRL presented three strands of research that impact on aflatoxins loads in raw products. These can be summarised as follows;

- Moisture controls during the final stages of setting and maturation of the seed. As the aflatoxin production is linked to periods of drought during this time and also to higher levels of immature nuts, advice is given on weather mapping and on irrigation. There is also available a colour identification table which is used, following removal of the shell outer layer, to identify if the crop is at the right stage for harvesting.

- The development of the competitive non-toxin forming *Aspergillus*.

- The development of resistant peanut varieties.

5.3.2. Nut processors visited

Following visual inspection and grading of the incoming product by the FSIS inspectors the product is then stored. This FSIS check is formally part of the payment conditions specified under the marketing order. The incoming check is recorded on a standard computer package of FSIS. It includes a breakdown of the fraction of different classes of nuts (such as foreign material, whole/kernels, empty shells, and immature nuts) and measurement of moisture. At risk fractions are then examined for signs of mould and a microscope is used to specifically identify *Aspergillus* moulds. This enables all at risk lots to be separated and sent for specific sorting.

The warehouses visited were constructed of metal or concrete and kept the product both dry and cool. Those examined by the mission team were fitted with electronically centrally monitored humidity and temperature. Usually before longer-term storage the peanuts are shelled and cleaned. This process involves gravity beds and forced air for the separation of foreign material and residual shell. Grading of the nuts also takes place. Storage in these facilities may be up to a year.

Due to the large volume of stored nuts at buying points and in processing facilities traceability to the farm is not possible, but traceability is usually possible to regions and specific buying points. Normally a processor segregates different types and categories of nuts into different bulk stores.

The mission team visited 3 peanut processors in the states of Georgia and Alabama. Application of HACCP principles is not mandatory in the USA for this type of commodity, but all the processors visited had HACCP plans that included the parameters for the control of aflatoxins as a hazard. GMP for peanut shelling operations and for further processing is laid down by the GMP documentation of the ACP, last updated in 2002. This provides detailed prescription on the manufacturing process and includes procedures specific to the avoidance of aflatoxin incidence.

In the premises visited, hand sorting and electronic colour sorting were also in use for the removal of damaged or discoloured kernels and a range of machinery for the removal of foreign matter and damaged or out of size nuts.

In the processors visited the nuts are stored after processing in large refrigerated warehouses, maintaining a temperature of less than 10^{o}C and maintaining low humidity levels.

One of the companies described the use of a 'mobile laboratory' that is used to test farmstock and ensure that any stock with aflatoxin levels is subject to rigorous sorting in a separate line. All facilities had a private laboratory facility on site, also capable of aflatoxin analysis.

One of the 3 premises included a blanching facility. It conducts whole and split nut blanching and other further processing (such as roasting). The premises also sorts products in the raw stage. When a blanched lot is to be exported to Europe the lot loses its original lot identification as it may be made of more than one lot (the blanching and subsequent sorting results in a reduction in weight). Whilst the company have adequate traceability to show the link between the final lot and

original lot, the fact that the certificate of aflatoxins analysis relates to a different lot number than the finished lot, may cause confusion at the point of import to Europe.[2]

Due to the effects of blanching and the ease of colour sorting a blanched product, this process is also considered a prime decontamination step, and is used as such when a product is sampled and fails analysis to US levels. In such a case the lots must be processed under the supervision of FSIS and the lot is then sampled using in-line automatic sampling for further analysis, and given new positive lot identification. Documentation was examined that demonstrated this.

The company also had its own laboratory, which was used for auto control purposes and was capable of the analysis for aflatoxins using VICAM Aflatest.

The companies visited are not regularly inspected by a competent authority. It was stated that the processor can elect to be audited by a private third party auditor instead of FSIS, which is the preferred option.

All PLI data, including grading and quality certificates and aflatoxin certificates are sent to the private company, described in section 5.2.5, who monitors (using the lot identification) the destination of any non-conforming lots. This includes visiting the premises concerned, and verifying the re-processing, non-food use, or destruction of the lots. As the database held also includes aflatoxins levels found it has also provided useful information on the aflatoxin distribution in non-conforming products.

5.4. Method of sampling for nut consignments

5.4.1. Sampling procedure

The outgoing aflatoxin sampling procedures in use have been developed and validated by USDA-ARS and accepted by the European Commission as having equivalence to the sampling methods described in Regulation EC (No) 401/2006 (as stated in communication from the European Commission of the 25th May 2000, reference D06703). The sampling procedures have been laid down in the USDA document 'Milled Peanuts Inspection Instructions'.

The incoming sampling of raw peanuts prior to processing, although not formally for aflatoxins, includes checks, such as presence of visible mould and levels of damaged nuts. The sampling is usually undertaken directly from the curing wagons, which are situated beneath an overhead gantry that has inbuilt sampling probes and sampling follows a defined protocol, developed by the USDA ARS. This was visually evident in all the processing facilities and buying points.

An inspector of the FSIS undertakes outgoing sampling, including the sample for aflatoxins analysis. Prior to visiting the premises to undertake sampling the FSIS inspector generates a 'Notice of Sampling Form'. Sampling is usually undertaken during the processing of a lot, using a USDA approved automatic in line sampling device. This is used to produce an aggregate sample of 70Kg.

[2] ***In their response to the draft report the USDA added that in this regard the APC will establish a policy for PLI and official USDA sampling.***

From this 70 Kg a 4 Kg sample is removed and retained for physical and quality examinations. The remaining aggregate is then divided into three using a mechanical dividing machine. Each of three 22Kgs is then placed in a separate opaque sack and labelled. The label contains the unique number of the lot and is signed by the FSIS inspector. It is then sent with the above-mentioned 'Notice of Sampling Form' to the relevant USDA or USDA approved laboratory.

The first 22Kg is analysed for all markets (including domestic use) and must meet the requirement of 15 µg/kg . If this is clear then the second 22 Kg is divided into three 7.3 Kg sub samples, each of which are ground and analysed and must comply with EU levels. This sampling protocol has been formally recognised by the European Commission as having equivalent certainty to the EU method. Moreover, in the laboratories visited it was common practice for export lots to have two 22 Kg samples combined to provide three 14.5 Kg samples, which are analysed to EU levels and provide the same sampling and analysis as in EU legislation.

5.5. Procedure for exporting nuts to the EU

The procedure for export of peanuts to the EU is primarily carried out at the exporters' premises. Most of the companies visited export their product directly. Samples for analysis are taken by the FSIS inspector from the line and specific analysis is required at a USDA or USDA-approved laboratory if for EU export. Most export products are exported in 1 tonne woven plastic sacks, which are produced solely for peanut transportation.

The ambient container is loaded and filled at the exporters' premises and sealed under the supervision of the FSIS inspectors. Processors described the use of moisture absorbent substances within the container. The container is then transported by lorry in most cases to the port. In 70-80% of peanut exports this is the port of Savannah, Georgia, which was visited by the mission team.

At present there is no formal check on certification for aflatoxins. If the private laboratory issues a certificate of analysis it is issued to the processing company who have to make a decision on whether to export or not. USDA in the port often open the container to make a physical check related to pest incidence and issue a phyto-sanitary certificate but this is not dependant on aflatoxin certification. Export checks by Customs and Homeland Security are limited to other 'at-risk' products.

Due to restrictions on the movement of containers that have been fumigated for safety reasons the container is usually opened again once on the quayside by a private fumigation company, and stands for 48 hours before loading. The fumigation company put on the seal that will be identified on the bill of lading. This procedure can result in a delay of export of up to 5-7 days from dispatch from the processor, during which the container is stacked in a storage field adjacent to the quayside. Given this excessive time scale and the climatic conditions it is possible that the conditions may contribute to aflatoxin synthesis.

5.6. Laboratory services

For some commodities there are established lists of approved laboratories created and maintained by the USDA. All peanuts for export must be analysed for aflatoxins at a USDA laboratory or one of these approved laboratories. Accreditation to ISO

17025 is not a pre-requisite of involvement in this programme and only two of the laboratories are accredited.

USDA approval is dependent upon detailed documentary submission including relevant SOP's, validation data and other quality assurance documents. Following review of submitted documentation the laboratory receives from the AMS five spiked samples of known contamination levels. These samples must be analysed and demonstrate results within the range 80-110% of the known level. This analysis must be undertaken within five working days. If at either of these stages there are unacceptable results the AMS staff try and help rectify the problem and provide a second analysis. If this is again inadequate then the laboratory cannot reapply for six months.

If this stage is acceptable then the laboratory receives five similar samples but is not informed of the contamination level. Again within five days results are produced and must be within the 80-110% range.

If this stage shows acceptability the laboratory is subject to an on-site laboratory review by technical staff of the AMS, which includes detailed assessment of the analytical method and of quality assurance procedures. On the basis of this audit the approval is granted or otherwise. Documentation relating to this audit was examined at the visited sites.

Each laboratory maintained on the approved list is then subject to an annual review and participation in a proficiency test analysis on samples sent by AMS. One sample is sent each month for the eight months of main activity.

The visited USDA laboratory in Blakely, Georgia is accredited to ISO 17025 and plays a role in co-ordination of the approved laboratories. This includes the preparation and dissemination of proficiency test samples described above.

5.6.1. Laboratories visited

A summary of the performance of the two laboratories visited is detailed in tables 1 and 2 below.

Table 1: Mycotoxin analysis performed in 2005 as part of export analysis

Laboratory	**No of export samples**	**% non-conforming**
USDA Blakeley	1500	Data not provided; no LIMS in use.
Private laboratory	4500	5-10 %

Source: Individual Laboratory data.

Table 2: Summary of Laboratory performance for 2 laboratories visited

	Laboratory 1 (USDA Blakely)	**Laboratory 2 (Private Laboratory)**
Accreditation	Yes Laboratory is accredited according to ISO 17025 by A2LA for analysis of Aflatoxins: B1, B2, G1, G2 in peanuts and peanut-products	No Laboratory is not accredited according to ISO 17025. USDA approval for determination of aflatoxins in peanuts and peanut-products.

	Laboratory 1 (USDA Blakely)	Laboratory 2 (Private Laboratory)
Validation	Validation including estimation of measurement uncertainty was seen and generally adequate. Within the accuracy-tests the homogeneity of ground samples was checked.	Validation including estimation of measurement uncertainty was seen and generally adequate. Recovery-rates were determined once a week only but internal QC-samples ran daily. Homogeneity of ground samples is checked for every grade once in two month (2 grade a month).
SOP for Method	Detailed SOPs developed. Elaborated instructions/recommendations in all fields necessary. Separate SOPs available for general procedures.	No specific SOPs but elaborated method descriptions developed. Separate descriptions available for general procedures (e. g. grinding, validation)
Premises:	Adequate.	Adequate.
Method and Equipment	Equipment fulfils the requirements. Extraction and clean-up procedure according to AOAC 991.31, A-F, H. Aflatoxin-standard-solution (stock; ready to use). Determination using HPLC coupled with post-column derivatization (Kobra-cell) and fluorimetric detection for aflatoxins.	Equipment fulfils the requirements. Extraction and clean-up procedure according to AOAC 991.31, A-F, H. Aflatoxin-standard-solution (stock; ready to use). Determination using HPLC coupled with post-column derivatization (Kobra-cell) and fluorimetric detection for aflatoxins.
Quality Assurance (References, Spikes, etc).	Laboratory participates in USDA and AOCS proficiency tests (LPP) several times a year (34 samples annually) with good results. For internal control of accuracy and precision external (USDA) and internal reference material (QC-samples) was used. Spiking experiments were done daily and several control samples (blanc, reagent-blanc, eluent, QC-sample) injected within every series. Calibration curve was checked daily. Control charts and logs are used for assuring the quality of tests. Procedure of internal audits was stated within a SOP. Corresponding audit-protocols were available and corrective actions executed.	Laboratory participates in USDA, AOCS (LPP) and FAPAS proficiency tests several times a year (27 samples annually) with good results. For internal control of accuracy and precision external (USDA) and internal reference material (QC-samples) was used. The internal QC samples were prepared centrally and tested for homogeneity. Spiking experiments were done weekly, but the internal QC-sample checked daily. Several control samples (blank, reagent-blank, eluent, QC-sample) were injected at least daily. Calibration curve was checked daily. Control charts and logs are used for assuring the quality of tests. Internal audits are not regularly implemented yet. External audits were performed by the program-manager of the USDA; only minor quality assurance concerns. Corrective actions are well documented and carried out immediately after the audit.
Analytes	Aflatoxin B1 and total aflatoxins (B1, B2, G1, G2).	Aflatoxin B1 and total aflatoxins (B1, B2, G1, G2).
Sample Management	Generally adequate. LIMS not in use yet but planned in the near future. Paper work (e.g. internal inspection plan, accompanying documents) was comprehensible. Traceability was given.	Generally adequate. Modification of LIMS in process (regarding ISO 17025 certification). Paper work (e.g. internal inspection plan, accompanying documents) was comprehensible. Traceability was given.
Calibration Standards	Certified stock-standard solution (ready to use). Certificate available. Concentration is determined and checked via an alternative method (TLC). Different certified standard solutions are compared via HPLC.	Certified stock-standard solution (ready to use). Certificate available. Concentration is not checked. Different certified standard solutions are compared via HPLC.
Calibration Curve	3-point calibration (4, 8, 12 ppb total) ran daily. The “8 ppb-level” was injected every 8 samples as “unknown”. Calibration curve provided was linear.	3-point calibration (5, 10, 26 ppb total) ran daily. The “5 ppb-level” was injected every 9 samples as “unknown”. Calibration curve provided was linear.

Recovery (%)	Determination of recovery-rates once a day at 12 ppb level (total aflatoxins). Recovery rate for total aflatoxin content was stated only (although single toxins measured).[3]	Determination of recovery-rates once weekly at 10 ppb level (total aflatoxins). Within the certificate recovery rates were not explicit reported for total aflatoxin content, nor for every single aflatoxin. Estimated recovery rate for aflatoxin G2 is sometimes below EU-requirements
Analytical uncertainty	Analytical uncertainty determined and expanded measurement uncertainty calculated statistically using replicate analysis of "check-samples". Resulting values (< 2%) comparatively low for an inter-laboratory deviation and reported within the certificate only for aflatoxin total.	Analytical uncertainty determined and expanded measurement uncertainty calculated statistically via determination of single uncertainties of different areas (sample homogenisation, standard purity, bias in extraction, HPLC-precision). Procedure laid down in specific method-descriptions. Resulting values are reliable (22-24 %) and stated within the certificate for aflatoxin B1 and total aflatoxin respectively.
LOD and LOQ	LOD validation calculated statistically using replicate analysis. LOD below EU-limits. LOQ was not calculated but based on the LOD provided below the EU-Limit as well.	LOD adopted from literature (method was not modified in-house). In-house validation of the LOD not provided. LOQ was not calculated but based on the LOD presented below the EU-Limit as well.

Both laboratories visited are well organised, laid out and capable of analysing large numbers of peanut-samples for aflatoxins. The USDA-laboratory is accredited to ISO 17025 and besides the export analysis is also involved in the assessment of private laboratories regarding the application of required analytical procedures and basic quality requirements.

Although the private laboratory was not accredited according to ISO 17025, nearly all principles of a quality system necessary for official accreditation (e.g. method-descriptions, validation procedures, quality control charts, logbooks, training records) are in place. In both laboratories a quality manager was assigned and the latest external audits together with the corrective actions taken are available and well documented. However, a system for internal audits and the documentation of the corresponding corrective actions (as required in ISO 17025) was only available for the USDA laboratory.

Both laboratories used published AOAC-methods without further modifications. Grinding equipment (VCM-mixer) for sample preparation was suitable and demonstrated low particle size deviation (paste). Validation procedures, including recovery experiments, determination of sensitivity and analytical uncertainty are in place and the respective results well documented. Only HPLC methods are used for analysis for EU export.

Both laboratories participate annually in a range of proficiency tests with individually favourable results.

Test samples for the USDA-approval-process of private laboratories (5 known and unknown levels of aflatoxin respectively) and all samples for the annual "check-sample-program", were produced by one laboratory of a private laboratory group. All private USDA-approved laboratories for peanuts belong to this group and therefore have to analyse these test-samples as well. This situation could lead to a

[3] ***In their comments to the draft report the USDA commented that low values represented PPB. SOP's updated and uncertainty levels calculated using the Horowitz equation. Recovery rates for B1 have begun at the USDA lab in Blakely.***

conflict of interest because samples for USDA-approval of private laboratories are produced by one of the private laboratories which is approved itself within the program by the USDA.[4]

The respective measurement of uncertainty was always reported within the certificate of both laboratories but in the case of the USDA laboratory only for the total aflatoxin content, while in laboratory 2 uncertainties for aflatoxin B1 and total aflatoxin were reported.[5]

In both laboratories the recovery rates for every single toxin was determined. In the USDA laboratory the analytical result is reported uncorrected for recovery and the recovery factor is reported for the total aflatoxin-content only. In laboratory 2 the analytical result is reported corrected for recovery but the recovery factors are not reported. On the certificate it was stated only that the recovery-rates are within 80-110 %. This lack of consistency does not provide for the requirements of Regulation EC (No) 401/2006, and create difficulty in adequate interpretation of the suitability of results.

Within the certificate the USDA-lab officially states if the actual sample “meets/does not meet” EU aflatoxin regulations, while in the certificate of laboratory 2 this statement was absent. One certificate was also found that appeared to have been issued on the basis of an informal sample as it was marked on the certificate as being from an informal sample.

5.7. Response to RASFF notifications

The consignments returned from Europe and subject to RASFF messages are notified currently to the FDA via the EU delegation. The information regarding all returned lots is also data captured by the FDA centrally under the 'USA Goods return programme'.

At present there is some divergence of opinion within the CA's as to who is responsible for supervision of returned consignments of peanuts, with the USDA and FDA having some claimed responsibility. It was also suggested that this might be a role for the private company who track non-conforming lots.

The information from the RASFF is then sent to a person from the Almond Board of California, but there is no evidence of any action taken to investigate the destination of the returned lot.

There was evidence of one consignment returned with aflatoxin levels above USA limits of 20ppb being held at the port by the FDA whilst it was sampled and analysed, on the basis of data capture through the FDA's own computer system.

---

[4] ***In their comments on the draft report the USDA commented that the policy of obtaining check samples from the same private laboratory group will be changed so as not to appear as a conflict of interest.***

[5] ***In their comments on the draft report the USDA commented that the USDA laboratory now reports uncertainty for both B1 and total.***

During the mission a discussion was held between the USDA and the EU delegation to the USA to request that the information on returned lots be sent to a contact in the USDA-AMS to allow them to follow up on the consignments and respond to the Commission.

6. CONCLUSIONS

6.1. Relevant national legislation

(1) The relevant legislation relates to marketing orders and provides mandatory requirements for sampling and analysis for aflatoxins, but doesn't specifically provide a mandatory and enforceable standard for export requirements, although this procedure is well defined.

(2) The application of HACCP principles is not a legislative requirement for the processors covered within the scope of this mission.

6.2. Competent Authorities

(3) The allocation of responsibility between the CA's is clearly defined (with the exception of returned rejected lots), with the AMS being the CCA and FSIS inspectors carrying out inspections under USDA supervision.

(4) The APC is an industry body that also disseminates the marketing order and plays an important role in co-ordination and communication with industry as it relates to peanut standards.

(5) A private company contracted to the USDA conducts tracking of non-conforming lots adequately.

(6) The National Peanut Research Laboratory demonstrated relevant and applicable research on aflatoxin control that is effectively integrated into the control system.

6.3. Process Controls in the nut production chain

(7) The industry demonstrated extensive knowledge of the aflatoxin issue and steps to control it. This included steps beyond legislative requirements such as use of HACCP principles, provision of mobile and in house laboratory analysis, use of sorting equipment, more rigorous sample preparation protocols and separation of contaminated lots.

(8) The processing lines appear highly effective at removing damaged nuts and thus higher aflatoxin levels. The effect of processing steps is demonstrated by research from the ARS.

(9) Blanched lots may be allocated new lot identification, and in some situations this results in a different lot number being present on aflatoxin certification. This could potentially cause confusion when certificates are checked at point of entry to the EU.

6.4. Method of sampling for nut consignments

(10) The sampling and analysis programme covers initially peanuts for all markets, with additional testing for products for EU export which offers equivalent guarantees to EU sampling methods (Regulation EC (No) 401/2006).

6.5. Procedure for exporting nuts to the EU

(11) Peanuts for export to Europe have to be sampled and accompanied by an aflatoxin certificate issued by a USDA or USDA approved laboratory.

(12) There are no official checks during the export procedure on either the outgoing products or the aflatoxin certification, either by the USDA or Customs and Homeland security. Thus decisions on the suitability for export are made by the exporting company without official approval.

(13) Due to fumigation requirements the time at the port of between 3 and 7 days is considered by the mission team as excessive, given the climatic conditions, and may contribute to aflatoxin synthesis.

6.6. Laboratory services

(14) The laboratories for official control are either USDA or USDA approved laboratories and operated adequately. Accreditation to ISO 17025 is not a pre-requisite of such approval.

(15) Reporting of recovery and measurement uncertainty is not consistent between different labs (for every single toxin or total aflatoxin content only) and not in compliance with EU-legislation as recovery rates and measurement of uncertainty for at least aflatoxin B1 and aflatoxin total must be reported.

(16) With the exception of the above issue the laboratories were operating in a satisfactory manner, with only minor quality assurance issues that would not call in to question the validity of results.

6.7. Response to RASFF notifications and rejected consignments

(17) There are at present inadequate procedures for the supervision of lots rejected in Europe and inadequate communication pathways for handling information provided by the European Commission Delegation regarding RASFF messages. Thus there are not adequate written responses to communications regarding RASFF messages.

6.8. Overall conclusion

(18) Overall the USA has a well-defined control system for aflatoxins in peanuts, linked to well structured research projects. The system of laboratory approval appears to result in well performing laboratories. Some issues regarding the defining of the certification process for export and the dealing with returned lots are requiring attention to provide a system of pre-export checks that verify products satisfy community requirements.

7. CLOSING MEETING

A closing meeting was held on 22 September 2006 at the premises of the USDA. Representatives from USDA, APC and the European Commission Delegation in the USA were present. At this meeting, the main observations and initial conclusions

were presented by the mission team. The USDA and APC provisionally accepted the observations and initial conclusions presented during that meeting with some general comments.

8. RECOMMENDATIONS

The Competent Authorities of the USA should

(1). Ensure that the requirements for export controls and for specific limits for export to Europe are mandatory and enforceable.

(2). Develop a system of official supervision of documentation to ensure that aflatoxin certificates are always issued on the basis of official samples, with correct lot identification and with an official judgement of result acceptance.

(3). Ensure that the time at port prior to export does not contribute to aflatoxin synthesis.

(4). Ensure the system of supervision of returned lots, including the communication pathways and responsibilities are clearly defined.

(5). Consider the accreditation to ISO 17025 of official control laboratories to ensure the equivalence with Article 18 of Commission Regulation (EC) No 2076/2005. Equivalence to Art 12 (2) of Regulation (EC) No 882/2004 should be demonstrated by 1 January 2010.

9. COMPETENT AUTHORITY RESPONSE TO RECOMMENDATIONS.

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

http://ec.europa.eu/comm/food/fvo/ap/apunitedstatesofamerica8117_2006.pdf,

as soon as this report is published

10. ANNEX

European Legislation	Official Journal	Title
Regulation (EC) No 882/2004	OJ L 165, 30.04.2004 p.1 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.
Commission Regulation (EC) No 2076/2005	OJ L 338, 22.12.2005 p. 83.	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004.
Regulation (EC) No 852/2004	OJ L 139, 30.04.2004 p.1 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.
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, 9.03.2006, p.12.	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.