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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

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FINAL REPORT OF A MISSION

CARRIED OUT IN THE UNITED STATES OF AMERICA

FROM 11 SEPTEMBER TO 15 SEPTEMBER 2006

IN ORDER TO

ASSESS THE CONTROL SYSTEMS IN PLACE TO CONTROL AFLATOXIN CONTAMINATION IN ALMONDS 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.

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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 11 September to 15 September 2006.

The objective was to evaluate the facilities and measures in place to control aflatoxin contamination in almonds that are intended for export to the European Union.

The USDA is the central competent authority. Almonds are the subject of a marketing order that controls the quality of the raw ingredient. There is no mandatory outgoing control or aflatoxin monitoring. Most of the controls are undertaken voluntarily by the industry or recommended through the Almond Board of California.

There is proposed legislation to increase the percentage of inedible nuts removed from the raw ingredient, and for a voluntary aflatoxin sampling plan. It is currently too early to assess the effect these changes will have.

There is no system of official laboratory approval for aflatoxin analysis in almonds. The laboratories visited exhibited significant quality control deficiencies, and in one case poor analytical capability.

Official control is primarily related to the removal of inedible or damaged nuts, with no-mandatory aflatoxin controls. The level of research into the incidence of *Aspergillus*, the points of aflatoxin synthesis, or the effects of processing is inadequate. Thus the efficacy of current and proposed measures has yet to be demonstrated. The current control system is considered inadequate to offer guarantees over the compliance of exported products to EU standards, and as the laboratories visited were inadequate the validity of US certification is also questioned.

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
ABC	The Almond Board of California
ARS	The Agricultural Research Service of the USDA
AOCS	American Oil Chemists Society
CCA	Central Competent Authority
EU	European Union
FDA	Food and Drug 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
MS	Member States
MOAB	Marketing Order Administration Branch
RASFF	Rapid Alert System for Food and Feed
SOP	Standard Operation Procedure
TEU	Twenty foot equivalent units or small container, the shipping industry's standard unit of measure
USDA	United States Department of Agriculture
VASP	Voluntary Aflatoxin Sampling Plan

1. INTRODUCTION

The mission took place in the United States of America (USA) from the 11 September to 15 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 ABC (Almond Board of California).

An opening meeting was held on 11 September at the premises of the USDA in Washington, DC. Representatives of the ABC, FDA and USDA ARS (Agricultural Research Service) 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 verify whether the control systems are in place to control aflatoxin contamination in almonds intended for export to the European Union within specified European Union (EU) contaminant limits, complying with Commission Regulation (EC) No 466/2001[1].

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

COMPETENT AUTHORITY VISITS			**Comments**
Competent authority	Central	1	USDA
	State Level	1 1 1	FSIS inspectors California FDA San Francisco District Almond Board of California
LABORATORY VISITS			
Private laboratories		2	Private laboratories in California
FARMERS			
Almond Orchard		3	
PROCESSING ESTABLISHMENTS			
		3	Processors/Exporters, California
		1	Huller/ Sheller of raw farmstock, California
PORTS OF EXPORT			
California		1	Port of Oakland, California
OTHER SITES			
Exporter		1	One almond exporter

[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.

3. LEGAL BASIS AND OTHER RELEVANT LEGISLATION FOR THE MISSION

3.1. Legal basis

The mission was carried out in agreement with the USDA of the USA 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 of the report.

4. BACKGROUND

4.1. Overview of previous missions regarding aflatoxin contamination in foodstuffs

The European Commission has carried out missions to Iran, Egypt, Turkey, China, Brazil, India and Argentina with the objective of evaluating official control systems for the prevention of aflatoxins contamination in foodstuffs originated from these countries. In addition, missions to 16 Member States (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

Approximately 97% of Almonds imported to the EU originate from the USA. Almost all of these are produced in California, and specifically in the central counties. Almonds are the top export agricultural commodity from California by value. The crop for 2006 is envisaged to be of a record level of 476,000 tonnes, and approximately one third of these will be exported to the European Union.

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 67 notifications relating to aflatoxins in almonds from the USA have been notified through the RASFF. Specific information on rejection rates has also been received by the Commission from one of the main importing MS (Spain and Germany). 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

USA	Imports to EU (metric tonnes)		Number of alerts		
	2004	2005	2004	2005	2006 (Jan-Sept)
080211 Fresh or dried almonds in shell	2649 (ES, DE)	2696 (ES, DE)	1	0	1
080212 Fresh or dried almonds, shelled and peeled	170,557 (ES, DE)	146,921 (ES, DE)	7	28	30

Source: Eurostat, Comext database and EC, RASFF database. Note ABC export figures show a slightly higher export volume.

In view of the increasing number of notifications, and the fact that some rejections were on the basis of aflatoxin levels up to 119 ppb for aflatoxin B1 the European Commission decided to undertake a mission 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, nuts and dried fruit are as follows:

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

   2,0 µg/kg aflatoxin B1 content, and

   4,0 µg/kg total aflatoxin content

c) Nuts and dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs :

   5,0 µg/kg aflatoxin B1 content, and

   10,0 µg/kg total aflatoxin content

5. MAIN OBSERVATIONS

5.1. Relevant national legislation

- 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.

- The Agricultural Marketing Agreement Act of 1937 provides the legal basis for the establishment of commodity specific marketing agreements.

- 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 Almond Marketing Order is listed under the Code of Federal Regulations Title 7, part 981. The Almond Marketing Order standards provide for mandatory incoming quality standards for products received at processors. They do not provide any standards for aflatoxin or mandatory outgoing (finished product) standards; however there is a provision to enable such standards to be made. The order is administered locally by the Almond Board of California, with oversight by the USDA.

- The FDA has established a limit of 20 µg/kg total aflatoxin for nuts on the domestic market.

USDA is currently engaged in a rulemaking process to amend the marketing order to reduce the tolerance for inedible kernels received from growers by processors and increase the percentage of inedible kernels that must be removed by processors. Although not in place yet the proposed change would apply to the 2006 crop forward.

5.2. Competent Authorities

5.2.1. The United States Department of Agriculture (USDA)

The CCA is the USDA. 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 the '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 AMS Fruit and Vegetables Programs covers marketing of almonds as well as a range of other commodities. The Marketing Order Administration Branch (MOAB) of the AMS Fruit and Vegetable Programs oversees these programs and works with the groups responsible for each specific commodity. It does so through five marketing field offices

The market controls are implemented by inspectors at state level. These inspectors are employed by the state (Federal-State Inspection Service (FSIS)) but work 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 36 federal market inspection services.

The California Marketing Field Office oversees the Almond Marketing Order, and works with the ABC to do so. An AMS representative attends ABC meetings and is contacted by ABC to follow up on serious non-conformances relating to the marketing order. Evidence of this communication was presented to the mission team.

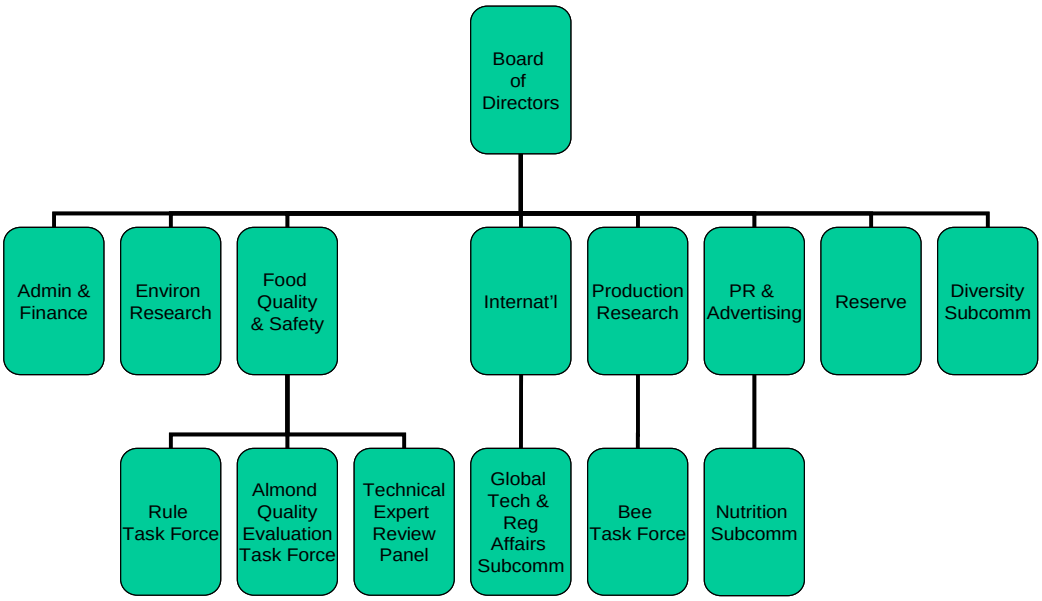
The USDA also has an Agricultural Research Service (ARS). They have undertaken numerous research projects relating to aflatoxins which are disseminated through their website.

5.2.2. The Almond Board of California (ABC)

The ABC was established in 1950 by the establishment of the marketing order for almonds that defined the ABC as a designated 'administrative agency'. It is a local committee made up of representatives of the almond growing and processing industry. It operates under a board of Directors consisting of 5 almond growers and 5 almond processors who are appointed by the USDA. It is considered as a 'quasi-governmental' entity (government instrumentality): all programs and budgets must be approved by the USDA and be authorized under the marketing order.

The board has a number of committees, again of industry representatives. These are identified in the diagram below. Of specific relevance is the Food Safety and Quality Committee that oversees food safety initiatives, including for aflatoxin control. The Committee has developed GAP and GMP guides which are readily available through the website (www.Almondboard.com), and include self audit documents for industry to carry out auto-control against the prescribed standard. It should be noted however that, given the status of the ABC, the control programs described are voluntary. Specific task forces or sub-committees can be established where required and they may call on external experts.

Organigram of the Almond Board of California



The ABC receives no direct funding from the USDA, apart from some funding specifically for marketing and product promotion. Funding to develop control programmes is raised from a levy on every pound of edible almonds produced by a grower and received by a processor.

The ABC has initiated a Voluntary Aflatoxin Sampling Programme (VASP). This was produced in 2006 and undertaken as a pilot programme from the beginning of the 2006 crop (September 2006) with 5 processors subscribing in 2006. Although only a small number of the total processors involved in export it includes one of the largest exporters and thus constitutes nearly a third of the total crop. Those subscribing to the programme will take a sample of three 5 Kg bags from a finished product with above 2% damage for aflatoxin analysis at a laboratory listed by the ABC. For 2% or less damage there is a voluntary possibility to test two 5 Kg samples. If all three 5 Kg samples are tested each must be below 2 ppb aflatoxin total to be shipped to Europe. If the product fails it may be reprocessed and re-sampled or go to the domestic market.

The scheme is voluntary and it is as yet too early to assess its efficiency. There is no formal check on lots being exported but if the ABC in a later document review identifies that a processor subscribing to the programme is not complying it can de-list the establishment from the voluntary programme.

The FDA have issued a letter stating that for the purpose of communication with Competent Authorities or importing companies in Europe regarding products rejected in Europe the ABC is able to communicate the FDA's regulatory procedures and procedures for dealing with American goods returned.

5.2.3. Federal-State Inspection Service (FSIS)

FSIS is established at a state level to carry out mandatory inspections to the grade of incoming goods and where requested by the processor to take voluntary samples of outgoing products. The FSIS staff are employed at a state level but overseen by USDA AMS staff located in each region.

There are 75 almond inspectors and this may increase during the harvest period. In the largest processors the FSIS inspectors are normally full time (but rotated to avoid conflicts) in smaller processors they are contacted when incoming goods are arriving.

5.2.4. Food and Drug Administration (FDA)

The Food and Drug Administration visited was that of San Francisco District, part of the Pacific Region. It has 155 staff (some based in satellite offices).

The FDA is responsible for the supervision of lots that are returned to the USA following rejection at the port of destination. Commodities imported to the USA, or returned goods which are deemed part of the 'US goods returned programme' result in a data input through prior notification to FDA's Division of Import Operations and Policy computer system.

This is then accessed by the FDA District Field Offices. In the case of the San Francisco office there is a specific 'Import Control' branch (18 staff). They use the information provided to decide on a course of action. In most cases this is examination of documentation, and if the product complies with US aflatoxin limits (20 ppb) on the basis of the documentation then the product is allowed access. If the limit exceeds this level then the product is detained on the basis of an "appearance of violation", and the emphasis on the company importing to prove otherwise (usually through private laboratory analysis). In some case where there is a history of violations the product may be sampled and analysed at the FDA laboratory. The level of FDA sampling for aflatoxin in this context was not made clear, despite requests.

Figures provided by the FDA indicated that of 121 returned lots of almonds in a three year period, 39% resulted in a request for documentation and release, 22% proceeded without checks, 38% were allowed access after sampling and analysis (usually by the company), although some of these were only released after reconditioning. One consignment was refused.

The FDA was not able to demonstrate the final use of each consignment.[2]

5.3. Process Controls in the nut production chain

In relation to aflatoxin contamination, the main control activities are initiated by the ABC or the industry directly as there is no specific legislative control requirement.

5.3.1. Nut cultivation

There are approximately 6,000 almond growers in California. The almond trees are grafted onto peach rootstock and remain in production for 20-25 years. Harvesting begins in August through to October, depending on the variety and climatic conditions.

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[2] ***The Competent Authority of the United States noted that if goods returned are not in violation of US law, the FDA has no need to track final use of consignments.***

Usually harvesting is carried out mechanically. The ground is cleared and then mechanical shakers are attached to the tree to shake the nuts to the ground. A sweeping machine brushes the nuts into central piles. The nuts remain on the ground for 4-5 days for sun-drying before being gathered by a harvester and taken to a huller/sheller facility. This employs a process of applying friction forces to mechanically remove the outer husk, and if required the shell, and to remove any extraneous matter, such as sticks and stones. The hulling/shelling process is usually completed by January following the harvest, and then longer term storage is of kernels.

The nuts are then usually transported directly to the processing facilities, either in bulk or in 1 ton bins.

The ABC stated that in 2006/2007 they intended commencing a research programme to look at incidence of field contamination of *Aspergillus*, and point of aflatoxin synthesis. There is currently voluntary GAP, produced originally by the ABC in 2001.

In the orchard visited the appearance of the orchards and the harvesting procedure was fairly standardised, but there were numerous irrigation methods in use (drip, spray and flood irrigation). Extensive insect damage was also evident in one orchard visited by the mission team.

5.3.2. Nut processors visited

On arrival at the processing facility the incoming nuts are inspected by FSIS officials with regard to grade and percentage of edible nuts. The kernels are then fumigated and stored in bulk until ready for processing.

Processing of kernels consists of using gravity and vibration tables to remove dirt and small foreign material, the use of electronic or laser sorting, sometimes hand sorting, and then sorting into grades before packing. Export packaging is often 25-50 lb cardboard boxes, or bulk packing of 1 tonne containers of either woven plastic or cardboard.

Further processing may take place such as blanching, slicing, roasting or manufacture of flour. These goods constitute only a small proportion of those commodities exported to the EU.

Application of HACCP principles is not mandatory in the USA for nut processing. Only one of the premises visited had developed a HACCP plan, and then it did not cover aflatoxin control.

Whilst traceability within the processors was good the nature of bulk storage and purchasing means that traceability to the farm is not possible.

In terms of aflatoxin control there is no formal programme of inspections for control carried out by ABC or USDA, although inspection for hygiene conditions are carried out once every two years by the FDA or California Department of Health Services. These inspections were related to cleanliness, personal hygiene and other hygiene standards and did not cover aflatoxin controls directly. In the premises visited most processors employed a private auditing body to conduct independent third party audits of the hygienic conditions of the premises.

There is evidence from details of rejected consignments and from the companies visited that the majority of the rejected product in the EU is of a 5% damaged kernels grade. This quality is significantly inferior to the minimum USDA Standard for grades of shelled nuts of 2% damage for whole kernels and 3% for broken kernels.[3] This was described by producers as being due to market demand. The legislation regarding the inedible proportion of nuts will decrease the volume of inedible portion available on the market, but not stop the practice of export of 5% damaged goods. The inedible portion would include rancid, rodent damaged, embedded shell, mouldy and insect damaged kernels.

Some research data was presented to substantiate the claim made by the ABC that aflatoxin incidence correlates with insect damage. Whilst this would appear a logical assertion, the examination of this data indicated that the correlation with insect damage is weak.

A further data set of aflatoxin levels in different types of product throughout the processing was also provided to the mission team. Conversely to the expected low levels in processed products the data showed that in reality the processing is not wholly effective in removing high levels of contamination.

5.3.3. Non-Conforming Products

Non-conforming products produced as a consequence of processing, or found by any sampling to be not acceptable for the domestic market or for further processing has to be disposed of. The ABC provides a list of approved users who produce either oil or animal feed from the product. This list is updated annually and checks are made by the ABC that the user is acting correctly, and check documentation to ensure the volumes of incoming product correlate to the volumes sent by processors.

5.4. Method of sampling for nut consignments

5.4.1. Sampling procedure

Sampling procedures for aflatoxins in almonds are not formally laid down in legislation and there is no legal requirement for sampling. The Food Quality and Safety unit of ABC has however developed recommendations on sampling. This has been approved by the ABC Board of Directors and will be used voluntarily in sampling of exported lots from some exporters for the 2006 crop.

The described sampling protocol differs from the EU sampling method prescribed in Regulation 401/2006. A sample size of three 5 Kg samples is taken and analysis undertaken to 2 µg/kg total aflatoxin to provide an equivalent level of control to EU standards with a smaller sample size. Scientific research undertaken by the ARS was presented that demonstrated that this sampling protocol offers a comparable level of confidence as the EU sampling method. Samples are generally taken from the end of the processing line at the same time as voluntary quality samples, often by the company themselves.

[3] ***The Competent Authority of the United States commented that these standards are voluntary.***

5.5. Procedure for exporting nuts to the EU

The procedure for export of almonds is similar to other commodities. There is no specific mandatory programme or requirement for the consignment to be analysed for aflatoxins prior to export.

Most almonds are exported. For export to Europe the product is containerised and shipped through Ports in Oakland or Long Beach, or alternatively by land bridge to Houston. The average time for arrival in Europe is four to five weeks.

The export procedure can take place directly at the processors, or via an exporting company. In either case the container is filled at the processor, and a seal put on the container by the processor which is reflected on export documentation. The container is usually transported by lorry to the port. There are no formal checks on export documentation. Any aflatoxin certificates from laboratories are voluntary and at the decision and discretion of the exporter and his/her customer.

It is rare that the container is opened from this point. Checks by Customs and Homeland Security staff are limited to situations where there is a security risk, and there are no checks on documentation.

The product is only held for maximum two days at the port, and usually less, due to the proximity of the growing area to the port, and effective logistics at the port.

The one exporter visited by the mission team had made significant unilateral steps to certify outgoing products as free from aflatoxin. This included private laboratory analysis, and from 2006 a requirement that all packers using the exporting company should follow the ABC VASP.

5.6. Laboratory services

For some commodities there are established lists of approved laboratories created and maintained by the USDA. Approval for this is dependent upon detailed documentary submission, audits and participation in proficiency tests. ISO 17025 accreditation is not necessarily a requirement for such approval.[4]

In the area of analysis for almonds there is no USDA approved laboratory programme. Analysis undertaken as part of voluntary programmes for aflatoxin uses a range of private laboratories that undergo no formal approval. The ABC undertook in 2005 a survey of private laboratories that are capable of undertaking analysis for aflatoxins in Almonds. In addition a number of larger producing companies have their own laboratory facility for auto-control purposes.

ISO 17025 certification is not a requirement for the operation of these laboratories, with only 2 of the 12 identified in the survey being accredited to ISO 17025. Some (7) of the laboratories are approved by the USDA to carry out analysis for other matrixes, usually pistachios. Nearly all the laboratories use dry sample preparation

[4] ***The Competent Authorities of the United States added that the USDA cannot require USDA approved laboratories to be accredited to ISO 17025. There is only one association in the USDA that can officially accredit to ISO 17025 and this is a private company. USDA cannot require accreditation by a private company. There are two USDA laboratories that are accredited to ISO 17025.***

and HPLC analysis although there is no standardised method. Tests on the homogeneity of samples after grinding were not performed.

Samples are received in clear plastic bags, which may result in sunlight degrading aflatoxin levels in the sampled portion. This is particularly relevant when ground samples are received or stored.

The lack of approval means there is no established national reference laboratory and no structured system of inter-laboratory quality control.

The mission team visited two laboratories in the state of California that are listed by the ABC and regularly used by the industry for aflatoxin analysis and for use in the VASP.

5.6.1. Laboratories visited

A summary of the performance of the two laboratories visited is detailed in table 1 below. Neither laboratory could offer a breakdown of the percentage of sample conformity as any of the samples could have been from unprocessed products, or even reject lines, and this isn’t disclosed to the laboratory.

Table 1: Summary of Laboratory performance for 2 laboratories visited

	LABORATORY 1	**LABORATORY 2**
Accreditation	Accredited to ISO 17025; not USDA approved	Not accredited to ISO 17025; USDA approval for determination of aflatoxins in pistachios
Validation	No method specific in-house validation-procedures or -documentation in place at all	No method specific in-house validation-procedures and -documentation in place at all
SOP for Method	SOP available but incomplete. SOP-managing system insufficient. Furthermore wrong number of the SOP in the certificate of the accreditation body	No SOP available but reliable and complete method description. Managing system (e.g. current valid method versions) not in place
Premises:	Overall appearance of the laboratories and the building itself is not sufficient to fulfil the requirements according to ISO 17025	Clean, tidy, clearly arranged. Overall appearance fulfil general ISO17025 requirements
Method and Equipment	Equipment partially not fulfil the requirements Grinding: small cutter (insufficient) Extraction: AOAC 994.08 Clean-up: Immunoaffinity column (hand) Determination: HPLC-FLD after pre-column-derivatization Aflatoxin standard: Liquid, Suppelco	Equipment fulfil the requirements Grinding: vertical cutter mixer (VCM) Extraction: AOAC 999.07 Clean-up: Immunoaffinity column (Aspec-Robot) Determination: HPLC-FLD after post-column-derivatization (Kobra-Cell) Aflatoxin standard: Liquid, Suppelco
Quality Assurance (References, Spikes, etc).	Up to two QC-samples within every HPLC-sequence. In case of deviations no corrective actions. Nor blank and spiked samples respectively neither reagent blancs at all. Proficiency tests: one sample a year (external). Result within 2s-3s. Internal audits: yes, but insufficient protocol, no corrective actions No usage of certified reference material	One spiked sample (recovery) within one day. Eluent and one standard concentration injected across the HPLC-sequence. Nor blank and spiked samples respectively neither reagent blancs within every sequence. Proficiency tests: several samples a year (external) Results within 2s-3s but always below mean value. Internal audits: yes, but last presented from September 2004, insufficient protocol No usage of certified reference material
Analytes	Aflatoxin B1, B2, G1, G2 and total	Aflatoxin B1, B2, G1, G2 and total
Sample Management	Obsolete LIMS and documentation system (e.g. internal inspection plan) in use, therefore partly comprehensible but traceability was given	Modification of LIMS in process. Paper work (e.g. internal inspection plan, accompanying documents) comprehensible. Traceability was given
Calibration Standards **Calibration Curve**	4 concentration levels injected once within every HPLC-sequence. Levels prepared from "ready to use" stock-solution Range: 1-9 ppb Afla B1,G1; 1,3 - 11,7 total Linearity beyond this range was not proofed. Afla B1 and G1 not baseline separated (in any concentration level)	3 concentration levels injected once within every HPLC-sequence. One standard concentration injected across the sequence as sample. Levels prepared from "ready to use" stock-solution. Range: 0,8-3,9 ppb Afla B_1, G_1; 2-10 ppb total Linearity beyond this range was not proofed (dilution of the respective samples and new inject). Afla B1 and G1 not baseline separated (beyond first concentration level)
Recovery (%) **Analytical uncertainty**	No determination of recovery rates No determination/calculation of analytical/expanded measurement uncertainty	Determination of the recovery rates once a day at low level (0,9 ppb B1, B_2; 0,3 ppb G1, G2) No determination/calculation of analytical/expanded measurement uncertainty
LOD and **LOQ**	0,1 ppb (each single toxin). Validation procedure (protocol) for the in-house--method not presented (adopted from literature) Not calculated	0,1 ppb (each single toxin). Validation procedure (protocol) for the in-house--method not presented (adopted from literature) Not calculated

The first laboratory is accredited by the American Association for Laboratory Accreditation (A2LA) to ISO 17025, including aflatoxin analysis for almonds within the scope. It uses an HPLC method adopted from literature. The SOP number on this method did not correspond to the SOP reference on the accreditation documents, which appeared to refer to a method for clay-minerals. Three different SOP's were presented to the mission team, including a version with a newer sequential version number than that which was found on the 'official' version log. The SOP for aflatoxin analysis was also incomplete (e.g. grinding conditions, IAC clean-up procedure). The method demonstrated to the mission team was not fully in accordance with the SOP.

Grinding equipment for sample preparation was unsuitable and demonstrated large particle size deviation. It is particularly unsuitable for the larger sample sizes specified in the VASP. Validation procedures, including recovery experiments, determination of sensitivity and analytical uncertainty, are not in place. Results for internal QC samples were presented for 2005 only. Relative deviation up to 30% for B1 and B2 were stated and G1 and G2 was detected in 6 of 17 measurements only. No corrective actions were presented. There was one proficiency test a year, with presented results satisfactory.

The second laboratory undertook much more aflatoxin analysis than the first (2500 almonds for example). The laboratory was well organised and laid out. It was not accredited to ISO 17025.

A quality system was under development but not fully implemented. Some principles such as method description, quality control charts, logbooks and training records were in place. A laboratory quality manager was not assigned and the last internal audit presented dated from September 2004.

The laboratory used a published AOAC method, and although the method was subsequently adopted (e.g. use of IAC clean up via Aspec-Robot) there was no internal validation procedures or data. Grinding equipment was adequate but particle size was not always fully homogenous. Recovery experiments were only at one low concentration. Linearity of the calibration was checked only at 10 ppb total aflatoxin.

The laboratory performs in a range of proficiency tests (AOCS, USDA) with individually favourable results. All results examined were however below the mean value, with no-corrective action resulting.

The laboratory was approved by USDA for aflatoxin analysis in pistachios.

5.7. Response to RASFF notifications

The Commission services via their delegation in Washington disseminate information on consignments rejected at EU ports that are notified via the RASFF system. The information is then forwarded to the FDA and to the ABC.

The FDA carry out some control on returned goods irrespective of the RASFF notification (see section 5.2.4.).

At present the ABC receive the notification and then carry out an investigation as to which port it arrived at and to which company it was released. They then reply to the Commission in writing with this information. The information does not include confirmation as to the final use of the returned consignment, which may be use on the domestic market, non-food use, reprocessing or re-export.

6. CONCLUSIONS

6.1. Relevant national legislation

(1) Relevant legislation pertains to the administration of marketing orders and the grading of incoming products. There is at present no legislation concerning the official control of aflatoxin levels for export. The FDA prescribes a 20ppb total aflatoxin limit for products on the marketplace.

6.2. Competent Authorities

(2) The USDA AMS is the central competent authority. Inspection of raw ingredients is undertaken by FSIS inspectors under USDA supervision. Most activities related to research or to the control of aflatoxin however are initiated and administered by the Almond Board of California (ABC) and approved by the USDA.

(3) The ABC is an industry organisation with a quasi-governmental status conferred on it by the USDA and the Marketing Order under which it was established. It has developed GAP and GMP guidelines and initiated a voluntary sampling plan for aflatoxins.

(4) The FDA plays a role in supervising the return of non-conforming products.

6.3. Process Controls in the nut production chain

(5) There is voluntary GAP and GMP in place initiated by the ABC. There is at present inadequate research to conclude on the beneficial effect of this.

(6) Controls concentrate on reducing insect damage due to an assumed correlation between insect damage and aflatoxin levels. Incidence of localised extensive pest damage was seen.

(7) There is evidence that the majority of the product rejected in the EU is of a 5% maximum damage, significantly higher than the 2% damage established in the minimum USDA standards.

(8) The processing defined in GMP is assumed by the ABC to effectively reduce aflatoxin levels. The only data provided does not substantiate that processing, including blanching, in a real situation, is fully effective in removing aflatoxin.

(9) There is no mandatory requirement for HACCP use in almond processing and it was not observed being used in aflatoxin control.

(10) There is a proposed regulation to increase the proportion of non-edible nuts removed during processing. This will reduce the number of damaged and inedible nuts available for use, but not stop the export of nuts classified as 5% damaged.

6.4. Method of sampling for nut consignments

(11) Although there is no requirement for aflatoxin sampling, there is a voluntary aflatoxin sampling plan being introduced in 5 exporters from the beginning of the 2006 crop (September 2006). This describes mandatory sampling for products over 2% damage, to a sampling plan that appears to provide equivalent sampling certainty to that described in EU legislation.

6.5. Procedure for exporting nuts to the EU

(12) The export procedure currently does not include official control on aflatoxin and official checks on outgoing documents or consignments is minimal.

6.6. Laboratory services

(13) Accreditation to ISO 17025 is not a requirement for laboratories for analysis for aflatoxins for almonds, and there is at present no USDA approval scheme for laboratories for aflatoxin analysis in almonds.

(14) The first laboratory visited exhibited inability to operate within parameters of analysis required by Regulation 401/2006. The laboratory exhibited non-conformity with nearly all aspects of ISO 17025. As this laboratory has an accreditation certificate the deficiencies observed cast doubt over the reliability of the assessment and accreditation process.

(15) The second laboratory is not currently capable of analysing within the parameters of Regulation 401/2006, due primarily to a lack of calculation of analytical uncertainty and of recovery. It exhibited numerous quality control deficiencies that demonstrate it does not comply with ISO17025 standards.

(16) At present the results of aflatoxin analysis for almonds from US laboratories cannot be relied upon.

6.7. Response to RASFF notifications

(17) The FDA and ABC are involved in tracking returned consignments and the ABC in replying to the Commission. Neither authority can currently provide adequate guarantees over the final destination of returned lots.

6.8. Overall conclusion

(18) Official control is primarily related to the removal of inedible or damaged nuts, with no-mandatory aflatoxin controls. The level of research into the incidence of *Aspergillus*, the points of aflatoxin synthesis, or the effects of processing is inadequate. Thus the efficacy of current and proposed measures has yet to be demonstrated. The current control system is considered inadequate to offer

guarantees over the compliance of exported products to EU standards, and as the laboratories visited were inadequate the validity of US certification is also questioned.

7. CLOSING MEETING

A closing meeting was held on 22 September 2006 at the premises of the USDA. Representatives from USDA, ABC, FDA and the EU Delegation in the USA were present. At this meeting, the main observations and initial conclusions were presented by the mission team. They provisionally accepted the observations and initial conclusions presented during that meeting with some general comments.

8. RECOMMENDATIONS

The Competent Authorities of the USA should

(1). Develop and implement a control system that can ensure that almonds exported or re-exported to the European Union are able to comply with EU standards regarding aflatoxins as specified in Regulation 466/2001.

(2). Undertake research on incidence of *Aspergillus* and points of aflatoxin production, and the effects of processing on reducing aflatoxin levels.

(3). Ensure that food business operators exporting to the EU implement standards at least equivalent to Article 5 of Regulation 852/2004 on food safety procedures based on HACCP.

(4). Undertake analysis in laboratories that are capable of analysis within the parameters of Regulation 401/2006.

(5). Consider the accreditation to ISO 17025 of official control laboratories to ensure the equivalence with Article 18 of Regulation 2076/2005 and to ensure these laboratories provide reliable analytical results. 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/apunitedstatesofamerica8300_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 an 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.