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Directorate F - Food and Veterinary Office

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FINAL REPORT OF A MISSION CARRIED OUT IN THE UNITED STATES FROM 11 JANUARY TO 16 JANUARY 2009 IN ORDER TO ASSESS THE CONTROL SYSTEM IN PLACE TO CONTROL AFLATOXIN CONTAMINATION IN ALMONDS INTENDED FOR EXPORT TO THE EUROPEAN UNION AND TO FOLLOW UP ON THE RECOMMENDATIONS OF MISSION 8300/2006

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected;any clarification appears in the form of an endnote.

Executive Summary

This report describes the outcome of a mission carried out by the Food and Veterinary Office in The United States of America, from 11 January to 16 January 2009.

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 and to follow up on the five recommendations made in report 8300/2006.

The USDA is the central competent authority. Almonds are the subject of a marketing order that controls the quality of the raw ingredient. Most of the controls are undertaken by the Almond Board of California (ABC).

The competent authorities have undertaken research related to aflatoxin production and control, and GAP/GMP is currently being amended in the light of this. The Voluntary Aflatoxin Sampling Programme (VASP) certification system and the electronic version in particular are operating effectively, and the ABC claim 100% VASP participation in export to the EU.

Analysis for the VASP exports are undertaken by one of 12 USDA approved laboratories. Some deficiencies were identified in laboratory performance and in the USDA approval system in particular.

Two of five of the recommendations made in 2006 are satisfactorily addressed, for one satisfactory proposed action is in place. Two, regarding laboratory performance standards, require further action.

There have been significant improvements made by the industry. The VASP system operates effectively, apart from the laboratory performance criteria. The current USDA approval system offers inadequate guarantees of laboratory performance in relation to both quality standards and to method specific standards.

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

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
ABC	The Almond Board of California
AMS	The Agricultural Marketing Service of the USDA
AOAC	AOAC international (Association of Analytical Communities)
ARS	The Agricultural Research Service of the USDA
CA	Competent Authority
CCA	Central Competent Authority
CRM	Certified Reference Material
CRM	Certified Reference Material
EU	European Union
eVASP	Electronic version of the Voluntary Aflatoxin Sampling Plan
FAPAS	Food Analysis Performance Assessment Scheme, UK
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
LAP	The Laboratory Approval Programme
LOD	Limit of Detection
LOQ	Limit of Quantification
MoU	Memorandum of Understanding
MS	Member States
NOW	Navel Orange Worm
OJ	Official Journal of the European Union
PHRED	Photochemical Reactor Enhanced Detection

Abbreviation	Explanation
RASFF	Rapid Alert System for Food and Feed
SANCO	Health and Consumers Directorate-General
SOP	Standard Operation Procedure
TSB	Technical Services Branch of the USDA
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 January to 16 January 2009. The mission team comprised 2 inspectors from the Food and Veterinary Office (FVO) and one national expert.

The mission team was accompanied during the mission by representatives from the United States Department of Agriculture (USDA) and the Almond Board of California (ABC).The mission was undertaken as part of the FVO's planned mission programme.

An opening meeting was held on 11 January at the premises of the ABC in Modesto, California. Representatives of the USDA Agricultural Marketing Service (AMS), Foreign Agricultural Service (FAS) and Agricultural Research Service (ARS) 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 objective of the mission was, in the context of the EU import controls on food and feed of non-animal origin:

- 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 or being at least equivalent to Commission Regulation (EC) No 1881/2006.

Additionally, the mission team followed up on action taken by the CAs in response to recommendations made by the FVO in the previous report (DG SANCO 8300/2006).

In pursuit of this objective, and in accordance with the itinerary agreed between the USDA and the FVO the following sites were visited :

Competent authority visits			Comments
Competent authority	Central	1	USDA
	State Level	1	Almond Board of California
Laboratory visits			
Private approved laboratories		5	Private USDA approved laboratories in California
Processing establishments			
		2	Processors/Exporters, California
		1	Almond Exporter, California

3 Legal Basis for the Mission

The mission was carried out in agreement with the CA of The United States of America 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.

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

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, Ghana, Argentina, USA with the objective of evaluating official control systems for the prevention of aflatoxin contamination in foodstuffs originated from these countries. In addition, missions to 17 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 Consumers Internet site at

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

This mission follows up on the recommendations made in a report of a mission in September 2006 (SANCO 8300/2006). In 2007 the Commission put in place special measures for the control of almonds imported into the EU from the USA in Commission Decision 2006/504/EC. These measures included a 5% testing requirement for consignments covered by the Voluntary Aflatoxin Sampling Plan (VASP) and a 100% testing requirement on import for consignments not covered by the VASP.

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 2008 is envisaged to be increased to approximately 680,000 tonnes and has been increasing since 2005. Approximately 55% of the harvest will be exported to the European Union, with Spain as the largest importer.

Information regarding foodstuffs found by MS 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. The break down of RASFF notifications as well as the volume of imports into the EU is shown in table 1.

Table 1

TC	Imports to EU (metric tonnes)		Number of alerts		
	2007	2008	2006	2007	2008
Fresh or dried almonds, shelled or peeled(CN code 0802 21 2)	627,000	680,000	36	66	33

Source: Eurostat, Comext database

From the information received from the MS in the context of reporting in Article 5 (4) of Commission Decision 2006/504/EC, there is a current rejection rate of 4.4% for the first three quarters of 2008.This is half of the 8.5% reported in 2007.

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 the Annex (Section 2) of Commission Regulation (EC) 1881/2006, the maximum admissible aflatoxin levels in groundnuts, nuts and dried fruit are as follows:

a) Groundnuts, nuts, 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.

In addition, sampling plays a crucial part in determining mycotoxin levels, which are very heterogeneously distributed in a consignment. Therefore, in Commission Regulation (EC) No 401/2006 methods of sampling, and criteria for sample preparation and for methods of analysis were established to ensure that laboratories in charge of the analysis use methods of analysis with comparable levels of performance.

5 MAIN FINDINGS

5.1 RELEVANT NATIONAL LEGISLATION

Legislation remains fundamentally unchanged from the previous mission, as described in report DG SANCO 8300/2006:

- The Almond Marketing Order is listed under the Code of Federal Regulations Title 7, part 981. This provides for details of grading and marketing. It also identifies the ABC as the control body for the marketing order.
- A final rule of the USDA (71 FR 65373-65376) was issued in November 2006 strengthening the inedible programme. This is described in report DG SANCO 8300/2006.
- The FDA has established a limit of 20 µg/kg total aflatoxin for nuts on the domestic market.

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 legal provision that would enable such standards to be established.

5.2 COMPETENT AUTHORITIES

5.2.1 The United States Department of Agriculture (USDA)

The CCA is the USDA, unchanged from the previous mission in 2006.

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. In addition to the role regarding the administration of marketing orders as described in the previous report the AMS is also responsible for the laboratory approval programme (LAP) for laboratories operating in the VASP programme, established since the last mission.

The USDA Agricultural Research Service (ARS) have undertaken numerous research projects relating to aflatoxins which are disseminated through their website. They presented a summary of the relevant research to the mission team during the opening meeting.

5.2.2 The Almond Board of California (ABC)

The structure and purpose of the ABC remains unchanged since the 2006 mission but the number of staff has increased significantly. 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. It describes itself as a 'quasi-governmental' entity, and operates a number of Committees. Information on the ABC can be found at the website www.almondboard.com .

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. It became fully operational with the 2007 crop. Handlers/processors are required to report shipping information to the ABC. From this official data the ABC reports that 100% of exporters to Europe (some 80 companies) have signed up to the VASP and are using it for all exports to Europe. As far as could be verified by the mission team from the visited companies and the ABC this is the case. The VASP procedure is described in detail under section 5.6.

In the context of the VASP programme the ABC have conducted compliance visits to the 80 handlers/exporters that ship to Europe. These visits checked the procedures of the VASP certification, the sampling procedures and related documentation, and the compliance with hygiene conditions and the use of HACCP principles. The ABC also has central access to documents processed through the eVASP computer version of the certification scheme (see section 5.6). The ABC also make regular communication with the industry through a newsletter, their website, training courses and provision of training materials.

The ABC stated that it was the industries intention to pursue making the VASP system mandatory.

5.3 RESEARCH OUTCOMES

Since the mission conducted in 2006 the ABC have undertaken or supported a number of research initiatives, with a funding budget of $700,000 over 2 years since the last

mission. The main research outcomes are summarised as follows;

- The role of the Navel Orange Worm (NOW) as a vector for *Aspergillus*, as a source of *Aspergillus flavus* colonisation of almonds, and possibly in creating ideal conditions for aflatoxin synthesis have been conducted. The levels of aflatoxin show a direct correlation with the level of NOW damage.
- Research into the distribution of strains of *Aspergillus* indicates that three strains are present but in different levels in different regions. The presence of a competitive a-toxigenic strain raises the possibility of using biocontrol.
- The USDA/ ARS have done detailed statistical analysis of all the results generated by the VASP analysis. These indicate a lower rejection rate in USDA approved laboratories (4.4%) in 2008/9 crop year than in previous years.
- Statistical analysis of this same data set indicates that the ratio between aflatoxin B1 and aflatoxin total is higher than previously thought, with a 92% frequency of the B1 value exceeding 2 ppb if the total aflatoxin level exceeds 4 ppb.
- Analysis of products at different stages of processing, and of different grade categories demonstrates the efficiency of electronic and visual sorting in the reduction of aflatoxin levels. Analysis of reject grades demonstrates that insect damaged kernels have the highest aflatoxin levels.

The ABC are currently updating GAP/ GMP and applying HACCP principles to the processing of Almonds to take into consideration these research outcomes. Further research programmes are also planned to follow on from these results.

5.4 Process Controls in the almond 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.

5.4.1 Almond cultivation

The procedure for nut cultivation remains unchanged since the previous mission. As there was no harvesting at the time of the mission no visits were made to orchards.

5.4.2 Almond processors visited

The system of almond processing remains unchanged since the description in the previous report. The mission team only visited two handlers and one exporter during this mission as the visit was made outside the main harvest period and emphasis was put on the implementation of the VASP certification system.

In both of the visited processors, the processing of kernels consists of using gravity and vibration tables to remove dirt and small foreign material, the use of electronic or laser sorting followed by 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. Since the previous mission it appears that the use of electronic, laser and/or x-ray sorting, followed by hand sorting is more systematically

applied. The use of electronic sorting on incoming raw material streams was also in use to reduce damaged products.

Application of HACCP principles is not mandatory in the USA for nut processing. Both of the premises visited had developed a HACCP plan, and both had incorporated the control of aflatoxins in the identification of CCPs.

Whilst both handlers reported a high level of success it was also reported that the past two years had produced relatively clean incoming raw products due to improved GAP and to climatic conditions.

The handlers visited, whilst large, demonstrated significant additional efforts in the control of products, including in traceability to the orchard, quality monitoring on supplying farms and reducing the damage level in outgoing products

The system of USDA quality and grade certification remains, including verification of the proportion of inedibles in the raw products and the percentage removed by the handler.

5.4.3 Almond Exporter Visited

The nut exporter visited required VASP certification on all almonds exported to Europe.

5.5 METHOD OF SAMPLING FOR ALMOND CONSIGNMENTS

5.5.1 Sampling procedure

Sampling procedures for aflatoxins in almonds are laid down in the VASP procedures. The mission team was provided with training materials that are provided to handlers to facilitate the correct sampling procedure. The evaluation of the sampling procedure also takes place during the compliance visits for the VASP made by the ABC, and a number of sampling training events have been run by the ABC.

Two sampling procedures are described- either in line (manual or automatic) after all processing or from the bags/boxes of the finished product. Both require the production of 15 kg of sample, broken into 5 kg samples.

The training materials describe in detail the use of mechanical diverters or manual sampling frequency to achieve a homogenous sample of 15 kg, or the use of sampling spears with described sampling patterns for common individual package size.

5.6 PROCEDURE FOR EXPORTING ALMONDS TO THE EU

The procedure of export with the VASP procedure can take place by use of paper certification, or more commonly now by the use of the ABC developed eVASP system.

To use the VASP system the exporter must have registered with the ABC on an annual basis (being a crop year starting with a harvest in September) by signing a Memorandum of Understanding (MoU). This MOU includes an undertaking that to export to the EU the company will carry out sampling of 3 x 5 Kg in line with the ABC sampling protocol, and that analysis to EU aflatoxin limits are carried out a USDA LAP approved

laboratory. The VASP certificate must accompany the exported consignment.

In addition the company undertakes to allow the ABC to verify compliance by documentary check and to follow Good Hygiene Practices and to transport the goods to the EU under hygienic conditions. The ABC informed the mission team that from the next VASP year the companies would have to incorporate HACCP principles in the control of aflatoxins as part of the MoU.

Once the lot details are filled in on the carbon copied form, including lot information and company details a sample is taken following the VASP sampling protocol (see 5.5.1). There are four copies of the VASP certificates which are uniquely numbered. The original accompanies the consignment, a yellow copy is kept by the handler (the company exporting), a pink copy by the laboratory and a final copy by the ABC.

Samples are usually taken by the company concerned and sent by courier to the laboratory for analysis. The details are completed by the laboratory and reported back to the company to allow export to proceed. The certificate is dated with four month validity.

More commonly the above paper procedure is replaced by the eVASP system, whereby the details are completed on a password protected website, and fixed so that they cannot be altered. Results are then entered online by the laboratory. The interpretation of the acceptability of the results is then made by the handler.

The eVASP facilitates the rapid processing of the VASP export and reduces the potential for error in documentation. A field on the eVASP labelled 'shipping information' allows the entering of information at a later stage regarding, for example, the change in lot size. The VASP documentation is accessible by the ABC.

The ABC has adopted a recommendation to phase out the use of paper certification, and to make the procedure of VASP exportation mandatory.

The certificates are valid for a period of four months. In some cases certificates had expired, following delays in European ports such as strikes.

5.7 LABORATORY SERVICES

Since the mission in 2006 and in the context of the VASP system the USDA has developed and implemented a programme for the approval of private laboratories to carry out analysis for VASP export. This approval is specific to the analysis of almonds for aflatoxin. It is administered by staff of the Technical Services Branch (TSB) of the USDA AMS in Washington, aided by the USDA laboratory in Blakely, Georgia, which is the US reference laboratory that evaluates methodology and prepares the proficiency test samples. The approval procedure is funded by an annual charge to the approved laboratories.

The approval procedure as described by the USDA to the mission team and on the USDA website is as follows;

- The applicant sends an expression of interest to the USDA. The USDA then sends out a pack detailing the procedures and required documents, and a number of forms that need filling in.
- This applicant sends in payment and detailed information on the method (in the

form of SOPs), the qualified analysts, validation data and analytical results, and a list of qualified analysts.

- If this is acceptable for the USDA then five samples of almonds containing known (to the USDA and to the applicant) amounts of aflatoxin are sent for analysis. This is done to test the applicants' analytical procedure, and must be done in five days.
- If the results are seen as acceptable then five further samples of almonds containing spiked samples of aflatoxin are sent to the applicant, but without the levels being known by the applicant.
- If either set of the results are not acceptable then a further set is sent out. If this set is not acceptable then the applicant may not reapply for admission for a further six months.
- If the unknown samples are effectively analysed then the TSB conduct an on site laboratory review. The review covers the analytical process in detail for adherence to official methodology and analytical technique. All SOPs are reviewed and there is an exit interview and review report. A full report is sent by mail when completed.
- Once admitted to the programme then annually ten samples, of unknown levels for the recipient, are sent out to assess proficiency.
- For this analysis the following criteria are applied;
    - One outlying result and the laboratory will receive a letter asking it to review its actions and make any corrections
    - Two consecutive unsatisfactory results in the analysis of a further sample being analysed and possible discussion with the TSB programme manager
    - Three consecutive results in ten will result in suspension from the programme until corrective action has been taken and the laboratory has demonstrated its ability to correctly analyze samples.
    - Three intermittent unsatisfactory results in ten will result in discussion between the laboratory and the TSB program manager to seek a resolution.
- TSB staff then undertake an annual on site laboratory review which includes all elements of the initial on site review.

The laboratory review reports are sent to the applicant, the AMS and to the ABC. The reports contain corrective actions and recommendations for actions. The laboratory will respond in writing to identify the action taken in respect of these actions and recommendations. Following the initial review report the Laboratory programme manager decides to accept the laboratory into the USDA LAP and informs the applicant and the ABC of this decision for inclusion on the VASP list.

In the supporting documentation provided to the mission team it is emphasised that the audit evaluates the adherence to official methodology and that the applicant cannot alter the method unless the AOAC method has been revised and published in the AOAC publication ' *Official Methods of Analysis of AOAC international*'. At the opening meeting the mission team was informed that to ensure adequate homogeneity it was necessary that the laboratory undertakes particle size measurements using a USDA

approved 20 mesh sieve for daily particle size testing, and undertakes homogeneity testing using analysis of a ground sample. Records should be kept of this.

All approved laboratories take part in the FAPAS round for aflatoxin in almonds and the results are reported to the participating laboratory and to the ABC.

Two of the five laboratories were accredited to EN ISO/IEC 17025 with the aflatoxin method within the scope of the accreditation. A further laboratory was ISO 17025 accredited but without the aflatoxin method in the scope.

At the date of the mission there were 12 USDA LAP approved laboratories, 11 in California.

The mission team assessed this described procedure of approval both through documentation provided by the USDA and through examination of the procedures in the laboratories visited, as described in 5.7.1 below.

Only those 5 laboratories visited by the FVO have received a full annual USDA audit, despite some being approved since April 2007. The approval system provides that official analysis in the VASP programme can take place prior to the conduct of an audit, contrary to the described USDA approval procedure.(see Endnote)

The initial audits were not conducted in any of the detail of the later annual audits and seemed to cover issues of documentation and safety rather than the compliance with either a specific method or specific standards. Thus significant non-conformances identified in the later audits had not been previously noted or rectified.

The written reporting on USDA audits took up to 5 months from the audit date, and is worded as recommendations for action, not as corrective actions required. A response to this letter was not expected by the USDA in at least one of the visited laboratories. Thus the mission team identified significant non-conformances in place some 14 months after they had been identified by the USDA, without adequate corrective action.

There is no standard method in use, contrary to the stated USDA procedure; although based on a published method, significant variations are demonstrated in the method of sample grinding, extraction, type and usage of IAC, use of automated clean up and injection equipment and of PCD. Different procedures in validation and use of internal quality assurance procedures are also noted. Whilst the alteration of the method would not necessarily affect the accuracy of results, some laboratories' methods were altered without adequate validation, and without notification to the USDA LAP manager.

Prior to the visits made by the USDA in December 2008 there is no evidence of any use of mesh for particle size measurement or of adequate homogeneity testing.

The laboratory summary in Annex Two of this report demonstrates there is no standard approach to the reporting of results regarding the consideration of analytical uncertainty or measurement of recovery, or of its inclusion in the reporting.

All the laboratories visited took part in the USDA and FAPAS proficiency test with acceptable results.

5.7.1 Laboratories visited

A summary of the performance of the five laboratories visited is detailed in a table in Annex Two of this report.

Laboratory One. In 2008 the laboratory analyzes up to 100 samples a day for Aflatoxins. The laboratory had a USDA review audit prior to the mission that identified some deficiencies regarding environmental conditions which might cause a cross contamination risk, a lack of particle size or homogeneity testing, and some quality procedure deficiencies such as lack of syringe calibration, document control deficiencies on SOP's.

The mission team found that the analyzing procedure in general (extraction, clean-up, HPLC-methodology e.g. running of check-samples, detection-procedure, including the respective documentation, results of USDA-check- and FAPAS-samples) was appropriate. Prior to November 2008 particle size and grind homogeneity tests (contrary to the specifications given by the USDA-LAP) were not checked. Homogeneity tests were documented since December 2008 but always performed with an uncontaminated sample which doesn't allow homogeneity to be measured. Internal audits were performed according to an ISO 17025 scheme. However, the system of the internal audits was not fully integrated as part of the quality manual.

The Second Laboratory had been visited for the initial USDA-audit in early 2008 and only two recommendations were stated (grinding equipment was not sufficient to grind the whole 5 kg samples and spiking experiments were performed with Aflatoxin G2 only at one high level). Written corrective actions related to these findings were not required by, and thus not provided to the USDA.

The laboratory received a more detailed audit in the USDA-review in late 2008. This identified numerous deficiencies, including the repeated failings of inadequate grinding equipment and lack of homogenization testing. The audit also identified a different extraction method being used for USDA proficiency test samples than for routine samples, inadequate spiking experiments and partially insufficient recovery-rate.

The mission team confirmed that no adequate homogeneity test had been conducted, and that the lowest calibration level was too high, the recovery rates in initial validation studies were too low (particularly for G2), problems of insufficient peak shape were solved by a deviation in approved methodology that was neither validated or reported to the LAP manager.

The Third Laboratory. Documentation of the USDA-approval process was very poor. From December2007 on, the laboratory was approved for analyzing VASP-samples pending site visit which took place in early 2008. The laboratory was not accredited to ISO 17025.

During the initial USDA-audit (early 2008) with regard to the analyzing-procedure no major or minor non-conformances were reported. The review focused mainly on equipment and laboratory safety in general. In contrast to these findings a lot of major non-conformances (14 pages) were stated during the USDA review in late 2008. These included risks of cross-contamination, no testing of particle size or records of homogeneity testing, unsatisfactory deviations from the approved procedure and the recovery determination being run at just one low total Aflatoxin value (1,7 ppb - outside the EU/VASP limits).

The mission team identified that the overall appearance of the facility was poor. One single room was used for managing incoming samples, extraction, clean-up and

HPLC-Determination. Room temperature was quite high (nearly 30oC). Until the end of 2008, following the latest USDA report, grinding was performed in a separate room. The grinding equipment was insufficient to produce appropriate particle sizes (mean particle size > 20 mesh).This finding was not described within the recent USDA-review. No homogeneity tests with naturally contaminated samples had taken place and numerous deficiencies were noted in the analytical method, which deviated from the approved methodology without adequate validation.

The Fourth Laboratory was accredited according to ISO 17025 including analyzing of Aflatoxins in several different matrices (including almonds). From summer 2007 on, the laboratory was approved analyzing VASP-samples pending a site visit which took place in early 2008.

During the initial USDA audit no or only minor non-conformances were reported regarding the analytical method. The review focused mainly on equipment and safety in general. The report from the USDA on this audit was only received some 5 months later.

In the later annual USDA review only a few non-conformance were identified, but including the lack of records for the check/documentation of homogenization of samples and grind particle size.

The FVO mission team identified that particle grind size was inadequate, although a new grind procedure was about to be implemented, no homogeneity tests with naturally contaminated samples were performed. The analyzing procedure in general (extraction, clean-up, HPLC-methodology, detection-procedure, results of USDA-check and FAPAS-samples) was appropriate, and the procedure of in line robots for direct injection had been fully validated. However, standards (3 levels) are cleaned-up via the IAC-columns and thus the real recovery rates could be lower than USDA (and EU) specifications

The Fifth laboratory solely analyses almonds. All steps of the whole USDA-approval process are well documented in several folders. From October 2007 the laboratory was approved for analyzing VASP-samples pending a site visit which took place in January 2008. The report to this audit was provided in April 2008.

During the initial USDA-audit with regard to the analyzing-procedure no or only minor non-conformances were reported (e.g. no maintenance log books in place; backup of computer-files). As in other visited laboratories the review focused mainly on laboratory equipment and safety in general. In contrast to these findings a lot of major non-conformances (19 pages) were stated during the USDA-review 11 months later, non of which were identified in the initial audit.

These included that a Quality Assurance Manager was not assigned, SOPs were absent or not specific enough, no grind size or homogenization tests, storage conditions for standard solutions and IAC were insufficient, usage of non-validated IAC that were not approved by the USDA, method changes without notification to the USDA LAP manager, unsatisfactory chromatograms and an unrealistically low LOD and LOQ.

The main findings of the mission team were that a continuous flow grinding system (hammer mill with sieve)was in place. This requires further homogenisation of the ground samples, which was not described in the corresponding SOP, homogeneity samples had been undertaken in 2008 but as they were only with 'clean' samples could

not demonstrate homogeneity. Unsatisfactory chromatograms were already provided by the laboratory to the USDA within the initial approval process in 2007, but not noted in documentation until the latest USDA audit in late 2008. During the FVO-audit this problem was still observable also in current HPLC-chromatograms. No corrective action is currently proposed. The validation process for the laboratory could not be adequately explained by laboratory personnel. Recovery rates are very high (up to 130%). The laboratory, despite a written response to the USDA, had not put in place corrective actions to significant non-conformances.

5.8 Follow Up to Recommendations in Report SANCO 8300/2006

The current status of recommendations made in 2006 is summarised in the following table:

Recommendation made in report 8300/2006	Summary of Actions described by the USDA	FVO Comment
1) Develop and implement a control system that can ensure that almonds exported to the European Union (EU) are able to comply with EU standards regarding aflatoxins as specified in Regulation 466/2001.	In May 2006, the Board endorsed a voluntary aflatoxin sampling program (VASP). Handlers participating in the VASP have agreed to be audited by the Board, and their identities are available from the Board. The Board continues to take measures to encourage more handler participation in the VASP.	VASP system is in place and operating at a 100% involvement for export to the EU, on a voluntary basis. The ABC stated that it was the industries intention to pursue making the VASP system mandatory.
2) Undertake research on incidence of *Aspergillus* and points of aflatoxin production, and the effects of processing on reducing aflatoxin levels.	The USDA ARS and ABC will undertake a programme of research. This includes research into insect damage, the effectiveness of sorting and B1 to total ratio.	A summary of the research is provided to the Commission and verified by the mission team.
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.	HACCP is being promoted to the industry and by signing the 'Memorandum of understanding' of the VASP the handlers undertake to produce in line with good hygienic practices.	This is not seen as offering a standard equivalent to Article 5 of Regulation EC (No) 852/2004. However during the mission the ABC indicated the level of HACCP in the industry is now high and that from the next crop year this would be a requirement of VASP participation.
4) Undertake analysis in laboratories that are capable of analysis within the parameters of Regulation 401/2006.	Laboratories are now part of the USDA LAP programme of approval.	Whilst a satisfactory response to the recommendation the mission findings indicate the LAP does not at present offer such guarantees.
5) Consider the accreditation to ISO	Accreditation to ISO 17025 by USDA approved	The number of IS0 17025 accredited laboratories has

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 January 2010.	laboratories will be encouraged, but cannot be required. USDA will work with the Board to explore laboratory protocol that would be acceptable to the EU. USDA approval system offers equivalent guarantees to ISO 17025	increased, all visited laboratories were at some stage of seeking accreditation. The mission team found that the USDA system does not offer equivalent guarantees to ISO 17025.

6 CONCLUSIONS

6.1 RELEVANT NATIONAL LEGISLATION

(1) Legislation in place remains unchanged since the mission in 2006, apart from the formal adoption of the amendment to the order regarding the inedible component.

6.2 COMPETENT AUTHORITIES

(1) The structure and responsibilities of CCAs remains unchanged since the last mission. In the context of the VASP the ABC has now an increased role regarding training and the carrying out of compliance visits.

(2) The USDA AMS is responsible for administering the LAP.

6.3 RESEARCH OUTCOMES

(1) There have been funded industry specific research programmes that effectively demonstrate the causes of *Aspergillus* contamination and the effect of some means of controlling aflatoxin levels.

(2) The results of these research outcomes are now being effectively implemented in GAP/GMP and in HACCP principles.

6.4 PROCESS CONTROLS IN THE ALMOND PRODUCTION CHAIN

(1) Visited handlers indicated the percentage of inedible nuts in exported commodities is decreasing, due to two years clean crop, the increased inedible proportion rule and to increased sorting capabilities.

(2) In the companies visited, there is an increased use of electronic/laser/x-ray sorters in addition to hand sorting. This appears as an industry norm since the last mission. Use of

such sorting equipment at an early process stage is being introduced.

(3) Both handler/processors visited had HACCP systems in place that included aflatoxin controls. At present the CA cannot ensure that all exporting companies have HACCP systems in place. The ABC stated that the use of HACCP would be a condition of the MoU in the context of the next round of VASP.

(4) Adequate traceability was demonstrated in the visited processors/handlers.

6.5 METHOD OF SAMPLING FOR ALMOND CONSIGNMENTS

(1) Sampling is undertaken either in line or from the finished packaged product. The training material indicates a random sampling pattern and the sampling offers equivalent guarantees to EU sampling procedures.

6.6 PROCEDURE FOR EXPORTING ALMONDS TO THE EU

(1) The system of certification based on the analysis of lots for exports is operating effectively, particularly in the framework of the eVASP system which eliminates potential for much error.

(2) The system is voluntary but according to the ABC and to all exporters visited is currently operating at 100% participation.

(3) The eVASP contains a field for the input of shipping comments which provides potential for comments regarding, for example, lot identification to enable clear links between lot numbers on the certificate and labelling on packaging.

6.7 LABORATORY SERVICES

(1) The USDA LAP is not operating as stated by the USDA. Deficiencies in quality procedures demonstrate the approval system does not currently provide adequate guarantees regarding the equivalence to ISO 17025 or the compliance with the criteria in Regulation (EC) No 401/2006.

(2) The laboratories visited operated at a sufficient level to provide dependable analytical results for proficiency test samples, but the lack of compliance with the USDA standard, for example regarding homogeneity testing, and the deficiencies identified in the laboratories visited mean the validity of real analytical results is sometimes questionable.

(3) The laboratories visited performed well in the national and international proficiency tests.

(4) There is no standardised approach to the reporting of results in relation to consideration of the recovery rate or expanded measurement of uncertainty, which could result in mis-interpretation of results (Annex II of Regulation (EC) No 401/2006).

6.8 FOLLOW-UP TO RECOMMENDATIONS IN REPORT DG SANCO 8300/2006

(1) 2 of the 5 recommendations have been adequately addressed, in one the action described offers adequate measures to address the recommendation. The other two

recommendations are being actioned in the context of the USDA LAP programme but are not currently offering adequate guarantees.

6.9 Overall conclusion

There have been significant improvements made by the industry. The VASP system operates effectively, apart from the laboratory performance criteria. The current USDA approval system offers inadequate guarantees of laboratory performance in relation to both quality standards and to method specific standards.

7 Closing Meeting

A closing meeting was held on 16 January 2009 at the premises of the USDA in Washington. Representatives from USDA, ABC 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

To the competent authorities of The United States of America.

An action plan in response to the recommendations should be forwarded to the Commission within 25 days of receipt of the report. This action plan should clearly set out the manner and deadline by which the competent authorities will address each of the following recommendations:

The competent authority of the USA should

No.	Recommendation
1	Ensure that food business operators exporting to the EU implement standards at least equivalent to Article 10 in connection with Article 5 of Regulation (EC) No 852/2004 on food safety procedures based on HACCP principles.
2	Ensure that VASP analysis is undertaken in laboratories that are capable of analysis within the parameters of Regulation (EC) No 401/2006, or equivalent, particularly relating to the using of a process that has been demonstrated to achieve complete homogenisation.
3	Ensure that there is a standard approach to the reporting of analytical results in relation to the rate of recovery and the expanded measurement of uncertainty, to ensure clear interpretation of results and to provide equivalence with the provision of EU Regulation (EC) No 401/2006, Annex II.
4	Consider the accreditation to ISO 17025 of official control laboratories to ensure the equivalence with Article 18 of Regulation (EC) No 2076/2005 and to Art 7a of Commission Decision 2006/504/EC and to ensure these laboratories provide reliable analytical results. Equivalence to Art 12 (2) of Regulation (EC) No

No.	Recommendation
	882/2004 should be demonstrated by 1 January 2010.

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

http://ec.europa.eu/food/fvo/ap/ap_the_united_states_8074_2009.pdf

9 ENDNOTES

Concerning	Detail
Section 5.7	In order to move the program along expeditiously, laboratories were initially permitted to conduct official analyses for the VASP program, prior to their final approval under the USDA approval procedure. This procedure was agreed by the EU following the origianal mission in 2006

ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Regulation (EC) No 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Regulation (EC) No 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Regulation (EC) No 2076/2005	OJ L 338, 22.12.2005, p. 83–88	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 of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Regulation (EC) No 178/2002	OJ L 31, 1.2.2002, p. 1–24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Regulation (EC) No 315/93	OJ L 37, 13.2.1993, p. 1–3	Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food
Regulation (EC) No 1881/2006	OJ L 364, 20.12.2006, p. 5–24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Regulation (EC) No 401/2006	OJ L 70, 9.3.2006, p. 12–34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs
Decision 2006/504/EC	OJ L 199, 21.7.2006, p. 21–32	2006/504/EC: Commission Decision of 12 July 2006 on special conditions governing certain foodstuffs imported from certain third countries due

Reference	OJ Ref.	Detail
		to contamination risks of these products by aflatoxins