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FINAL REPORT OF A MISSION
CARRIED OUT IN SPAIN
FROM 6 TO 10 NOVEMBER 2006
IN ORDER TO EVALUATE IMPORT CONTROLS ON FOOD AND
FEED OF NON-ANIMAL ORIGIN



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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

AESA	Agencia Española de Seguridad Alimentaria (Spanish Food Safety Agency)
BIP	Border Inspection Post
CA	Competent Authority
CCA	Central Competent Authority
CCAA	Comunidades Autónomas (Autonomous Communities)
CN	Combined Nomenclature
CNA	Centro Nacional de Alimentacion (National Food Centre)
DPI	Designated Point of Import
DUA	Documento Único Aduanero (single customs document)
ELISA	Enzyme Linked Immunosorbent Assay
EU	European Union
FAPAS	Food Analysis Performance Assessment Scheme
FVO	Food and Veterinary Office
HACCP	Hazard Analysis and Critical Control Point
HPLC	High Performance Liquid Chromatography
ISO	International Organisation for Standardization
LOD	Limit of Detection
LOQ	Limit of Quantification
MAP	Ministerio de Administraciones Publicas (Ministry of Public Administration)
MAPA	Ministerio de Agricultura, Pesca y Alimentación (Ministry of Agriculture, Fisheries and Food)
MISACO	Ministerio de Sanidad y Consumo (Ministry of Health and Consumer Affairs)
MS	Member States
OJ	Official Journal of the European Union
RASFF	Rapid Alert System for Food and Feed
SANCO	Health and Consumer Protection Directorate General
SA	Sanidad Animal (Animal Health)
SE	Sanidad Exterior (Foreign Health)
SGMPG	Subdirección General de Medios de Producción Ganaderos (Sub-directorate General for Means of Livestock Production)
SGSE	Subdirección General de Sanidad Exterior (Sub-directorate General for Foreign Health)
SOP	Standard Operation Procedure

1. EXECUTIVE SUMMARY

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in Spain, from 6 to 10 November 2006.

The objective of the mission was to evaluate, in the context of the import controls on food and feed of non-animal origin, the implementation of Regulations (EC) No 882/2004 and (EC) No 178/2002 of the European Parliament and of the Council, and the implementation of relevant Commission Decisions concerning mycotoxin contamination and Sudan dye adulteration. Additionally, the mission team followed up on action taken by the Competent Authorities (CAs) in response to the recommendations made by the FVO in report SANCO 7308/2004.

Within the scope of this mission the Ministry of Health and Consumer Affairs (MISACO), the Ministry of Agriculture, Fisheries and Food (MAPA) and the Customs Authority are the main CAs responsible for import controls on food and feed of non-animal origin.

Compliance with the relevant Commission Decisions concerning mycotoxin contamination was generally achieved in respect of frequency of sampling.

The mission team observed two official control samplings for aflatoxins in almonds that were in line with the requirements of Commission Regulation (EC) No 401/2006. A sampling of peanuts, which was not an official control, was also observed by the mission team.

The mission team visited two laboratories, which demonstrated good quality controls for aflatoxin and dyes analysis.

As regards follow-up, all recommendations within the scope of the previous mission have been addressed.

Overall, Spain has a clearly defined structure of CAs responsible for import controls, with vertical communication pathways in place. Nevertheless, a number of shortcomings have been identified as regards the requirements to be fulfilled by the designated points of import (DPIs), supervision of consignments subject to physical treatment, reporting of analytical results, accreditation scope of laboratories undertaking official control analysis for Sudan dye and delays in RASFF notifications of rejected consignments to the Commission services.

The report makes a number of recommendations to the competent authorities of Spain to address the deficiencies noted.

2. INTRODUCTION

The mission took place in Spain from 6 to 10 November 2006. The mission team comprised two inspectors from the Food and Veterinary Office (FVO) and one Member State expert.

The mission was undertaken as part of the FVO's planned mission programme.

The inspection team was accompanied during the whole mission by a representative from the Ministry of Health and Consumer Affairs (MISACO).

An opening meeting was held on 6 November 2006 with the CCAs: (MISACO), the Ministry of Agriculture, Fisheries and Food (MAPA) and the Spanish Food Safety Agency (AESA). At this meeting, the objectives of and itinerary for the mission were confirmed by the inspection team, and additional information required for the satisfactory completion of the mission was requested.

3. OBJECTIVE OF THE MISSION

The objective of the mission was to evaluate, in the context of the import controls of food and feed of non-animal origin:

- the implementation of Regulation (EC) No 882/2004¹ of the European Parliament and of the Council,
- the implementation of Regulation (EC) No 178/2002 of the European Parliament and of the Council, and
- the implementation of Commission Decisions imposing special conditions on the import of certain products concerning mycotoxin contamination and Sudan dyes adulteration in foodstuffs.

Additionally, the mission team followed up on action taken by the CAs in response to recommendations made by the FVO in the previous report (SANCO 7308/2004).

This was the third mission undertaken to Spain for this purpose. It formed part of a wider series of missions to some Member States (MS) evaluating control systems and operational standards in this sector.

In pursuit of this objective, the following sites were visited:

COMPETENT VISITS	AUTHORITY		Comments
Competent authority	Central	1	MISACO, MAPA and AESA
	Regional	2	Customs and port authorities, and peripheral units of MISACO (SE) and MAPA (SA) at Valencia and Barcelona
LABORATORY VISITS			Comments

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

Laboratory in Barcelona	1	Undertakes analysis for official control of Sudan dyes
Private laboratory in Valencia	1	Undertakes analysis for official control of mycotoxins
VISITS TO PREMISES		
Designated point of import	3	Ports of Barcelona and Valencia, and private company near Valencia
Food processor in Valencia	1	Processor of imported nuts

4. LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of Community legislation (the Treaty of the European Community, in particular Articles 10, 152, 153 and 211) and other general provisions of Community legislation, specifically:

- Regulation (EC) No 882/2004 of the European Parliament and of the Council, in particular Article 45.

5. OTHER RELEVANT LEGISLATION

Other relevant legislation is listed in Annex II.

6. BACKGROUND

6.1. Summary of previous mission results

A previous mission to Spain with a similar objective was undertaken from 21 to 25 June 2004, the results of which are described in report DG (SANCO)/7308/2004 - MR Final (hereafter: report 7308/2004).

The report of this mission is available at:

http://ec.europa.eu/food/fvo/index_en.htm

The report of the previous mission made a number of recommendations for action to the Spanish competent authorities (CA). Where appropriate the relevant recommendations set out in report 7308/2004, and the corresponding actions as planned and/or undertaken by the CCA are indicated under the appropriate section headings in Chapter 7.10 below.

6.2. Background to present mission

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

In recent years, there have been an increasing number of rapid alert messages circulated within the European Union relating to food products containing mycotoxins above the maximum limits established in the EU legislation.

In fact, there were 992 RASFF messages for mycotoxins in 2005 and 640 from January to October 2006. Implicated products included peanut and peanut products, pistachios, hazelnuts, Brazil nuts, almonds, dried fruits, spices, coffee and cereals. For Sudan dyes, there were 183 RASFF notifications in 2005 and 40 from January to October 2006.

A series of missions was carried out by the FVO between 2002 and 2005 to major importing MS, to assess controls at import on food products of plant origin. Seventeen MS were visited and three of these were the subject of additional follow-up inspections. This series of missions identified weak controls at the import stage in some MS. In particular, the following major problems were identified:

- Deficiencies concerning the application of Commission Directive 98/53/EC regarding sampling and sample preparation.
- Non-compliant consignments are in general rejected and returned to the country of origin or a third country with little supervision by the CA.
- A significant volume of products of plant origin, such as peanuts and cereals, enter the community for use in either feed material for wild birds or in compound feedingstuffs. In many MS, the control of feedingstuffs is undertaken by a different CA or the responsibilities of the CA are not clear, making it possible for feed to enter the food chain.

6.3. Public health information

Mycotoxins

Mycotoxins are naturally occurring metabolites produced by certain species of moulds (e.g. *Aspergillus spp*, *Fusarium spp*), which develop at high temperatures and humidity levels and may be present in a large number of foods.

This group of toxins includes a number of compounds of varying toxicity and frequency in food. Some mycotoxins are known to be carcinogenic: Aflatoxin B1 in particular is a potent genotoxic carcinogen and, even at extremely low levels, increases the risk of liver cancer.

In order to protect public health, it is essential, to keep contaminants at toxicologically acceptable levels. The presence of contaminants must be reduced as far as possible by means of good manufacturing or agricultural practices.

In addition, sampling plays a crucial part in determining the precise levels of mycotoxins, which may be very heterogeneously distributed within a lot.

Therefore, EU legislation establishes:

- Maximum limits and sampling procedures for mycotoxins in foodstuffs and feedstuffs;
- General criteria to ensure that the laboratories in charge of analysis use methods of analysis with comparable levels of performance.

Sudan dyes

Sudan dyes have been classified as category 3 carcinogens by the International Agency for Research on Cancer and are not authorised for food use.

Under relevant EU legislation, imported consignments of chilli, chilli products, curcuma and palm oil have to be accompanied by an analytical report confirming the absence of Sudan dyes.

7. MAIN FINDINGS

7.1. General information about the Member State

Annex II of Commission Decision 2006/504/EC lists 49 designated points of import (DPIs) for Spain. The CA, following a recommendation of report 7308/2004, decided to reduce their number and recently informed the Commission of the 15 DPIs to be included in Commission Decision 2006/504/EC. The major DPIs for nuts are Valencia and Barcelona harbours.

There are 40 points of entry for feedstuffs of non-animal origin.

7.2. Competent authorities

The structure of the relevant competent authorities has not changed since the time of the last mission in June 2004.

Ministry of Health and Consumer Affairs (MISACO)

The central authority with responsibility for the controls over foodstuffs at import point is the Sub-Directorate General for Foreign Health (SGSE). As in the previous report, it is part of the Directorate General for Public Health, under the authority of MISACO.

Sub-Directorate General for Foreign Health (SGSE)

SGSE is responsible for public health at borders and import points including goods and food for human consumption, international travellers and sanitary checks on international transport.

Control activities and enforcement actions are discharged to peripheral offices of SGSE at the nominated points of entry. The staff at the SGSE peripheral offices amounts to 111 veterinary inspectors, 94 assistants and 28 heads of Foreign Health (SE).

An information system SISAEX IV links the central competent authority with all the BIPs and DPIs, and allows data exchange on rejected consignments and interrogation by the central authority. The ports of Valencia and Barcelona do not introduce the data for all consignments on a daily basis, which negates its validity as an integrated control system. It is foreseen that in the future the operators will electronically input their data, which would improve the efficiency of the system.

In 2006, the SGSE has audited the premises of the 15 DPIs and has informed the Port Authorities of the results of the audits. In October 2006, 3 DPIs were considered fulfilling the requirements of Commission Decision 2006/504/EC, 5 DPIs had submitted proposals to correct the deficiencies identified and were pending approval from the central C.C.A. and 7 DPIs had not yet submitted proposals. SGSE has requested that missing proposals are received by February 2007. Some of these proposals will be fully implemented several months after their approval. This is the case of the new DPI in the Barcelona port that should be finalised around 15 months after its approval. These deadlines are beyond the 1st of October 2006, date of entry into force of the Commission Decision.

SGSE is preparing a 2006-2010 quality system to be implemented in all nominated points of entry. The plan includes objectives, standard operating procedures (SOP) and evaluation mechanisms. SGSE is also preparing SOP for evaluating premises and procedures for import controls. The SOPs will cover BIPs, DPIs, customs

premises, free zones, free warehouses, customs warehouses, temporary warehouses and detention warehouses.

In 2005 and 2006 the SGSE has run training courses for both veterinary inspectors and assistants. These courses lasted 24 and 16 hours respectively and covered a range of issues. Included in the provided course programme for veterinarians were training on detention, rejection and re-dispatching of consignments, illegal imports, and tracing of commodities in a harbour and an airport. The course for assistants was broader but included the new food hygiene package and implications of food labelling for border controls. In addition, a 16 hour course on inspection and certification systems for food imports and exports was organised.

At present, the SGSE has no operational contingency plans setting out measures to be implemented without delay when food is found to pose a serious risk to human health.

In Barcelona port there are 12 veterinary inspectors, 2 assistants and 3 administration staff under the head of SE. 5 of these inspectors are concerned with consignments of food of plant origin. The mission team was informed that there are 5 vacancies that are expected to be filled by the end of 2007 and that 4 auxiliary staff are provided by the port authority. Sampling is undertaken in a warehouse adjacent to the BIP, owned by the port authority. The sampling is physically carried out by a private company on behalf of the port authority, with supervision of the competent authority.

In Valencia port there are 11 inspectors and 5 assistants concerned with inspections of food of plant origin. The mission team was informed that there are 6 vacancies for inspectors. There has been a decrease in the volume of products of plant origin entering the port, and in particular Iranian pistachios, since the intensification of the official controls. The new DPI includes facilities to perform the unloading and the sampling in a sheltered space and a storage room for samples.

The DPI located at a private company near Valencia is used only by this company that owns the premises. The SE staff allocated to the Valencia port is also assigned to this DPI. It includes facilities to perform the unloading and the sampling in a sheltered space and a storage room for samples.

Ministry of Agriculture, Fisheries and Food (MAPA)

The central authority with responsibility for the controls over feedstuffs at import point is the Sub-directorate General for Means of Livestock Production (SGMPG). It is part of the Livestock Directorate General of the MAPA. The SGMPG contains the Feedstuffs Area that is responsible for feed safety, including contaminants, and planning official controls.

Control activities and enforcement actions are discharged to SGMPG peripheral offices of Animal Health (SA) at the BIPs. These are staffed with 56 veterinary inspectors under both the MAPA and the Ministry of Public Administration (MAP).

The SGMPG has an operational contingency plan setting out measures to be implemented without delay when feed is found to pose a serious risk to humans or animals. This plan specifies the CAs to be engaged, their powers and responsibilities, the role of stakeholders and the channels and procedures for sharing information between the relevant parties. The plan also describes the import control procedures at the entry points for feedstuffs. The last revision of the plan was on May 2006.

Customs Authorities

The customs authority is dependent on the Taxation Agency, which is part of the Ministry of Finance. The customs are responsible for the application of customs legislation. The Customs clearance system requires that all foodstuffs (plant and animal origin) imported from third countries is notified to and approved by the relevant peripheral office of SE.

Port Authorities

The Public Port Body of the state was established in 1992 and depends on the Ministry of Infrastructure. The management structure of the port authorities was amended in 1997, to include both representatives of the central authorities and representatives of the Autonomous Communities (CCAA). In Barcelona and Valencia, the involvement of the port authority in the scope of this mission includes the provision of the buildings used for the taking of samples and the contract to companies that actually undertake unloading and sampling under supervision of the SE staff.

Agencia Español de Seguridad Alimentaria (AESAs)

AESA has been in operation since early 2003 as a consultative body with no legal powers of enforcement. AESA is responsible for food safety and consumer protection and functions as a reference body to deal with food issues and crises. AESA has a co-operation role with the CCAA. AESA is concerned with risk analysis in particular risk assessment and risk communication. AESA is the contact point for RASFF (Rapid Alert System for Food and Feed) in Spain. AESA also runs the National Food Centre (CNA) that amongst other tasks plays a role in technical advice to official control laboratories.

Co-ordination and communication among the CAs

At a central level there are meetings between the customs authorities, the port authorities, the MAP, the SGSE and SGMPG every few months to clarify any problems which arise. Customs and SE work together on a daily basis but there is no link between the computer systems of the two authorities. The different CAs involved in import controls have launched the software development project ATRAE that would enable the interaction between their systems in the future.

In Valencia and Barcelona ports, there are meetings between the customs authorities, the port authorities, SE and SA. Some of these meetings are ad hoc and others have a regular frequency.

7.3. Trade information

7.3.1. Food of non-animal origin

In 2005 and from January to July in 2006, the imports to which the Commission Decisions apply were primarily peanuts from China, pistachios from Iran and hazelnuts from Turkey (see Annex I, Table 1). With regard to other products not included in the Commission Decisions, the main import were almonds from the USA (see Annex I, Table 2). The volume of imported nuts for subsequent sorting was of 271,925 kg in 2005 and of 39,916 kg from January to July in 2006.

7.3.2. Feed of non-animal origin

About 8 million tonnes of feed materials of non-animal origin were imported into Spain in 2005. The main products imported were cereal crops, oil seeds, legume seeds, tubers and roots.

7.4. Legislation

Legislation, within the context of this mission, for food is drafted by MISACO and for feed by MAPA. The EU regulations and decisions are directly applicable in Spain.

The diffusion of information among all stakeholders is ensured in case of adoption of new legislation through its publication in the Spanish Official Journal. In addition, the stakeholders are consulted before the adoption of national legislation and AESA produces a report. MAPA disseminates the feed legislation through the searchable database SILUM. The MISACO website includes some of the food legislation.

7.5. Import controls

7.5.1. Food of non-animal origin

Import procedures

Goods imported must be declared to customs in the form of a single customs document (Documento Único Aduanero, DUA) at the point of entry. Declaration may take place in advance of the arrival of the goods. A customs forwarding agent presents the DUA, on behalf of the importer, to the customs authority and to the 15 peripheral offices of SE for all foodstuffs, in parallel. The DUA gives details of the identity of the goods, mode of transport, port or airport of origin, description, number and type of sacks and total weight of the consignment.

The customs procedure uses a filter system to prioritise goods. The green filter indicates that the goods can be cleared by customs. The orange filter indicates that the goods should be inspected by either the peripheral office of SE or of SA. The red filter indicates dangerous substances and guns. All foodstuffs of plant origin (held in a list of products in Annex I of the Order of 20 January 1994) are allocated the orange category; the product is held until checked and cleared by the SE, and only released on production of an Annex 1 document (from the Annex of the Order SCO/3566/2004 of 7 October 2004), duly completed, stamped and signed by an authorised official. All foodstuffs of plant origin undergo documentary controls but identity and physical checks are performed only when it is required.

Frequency of controls

Instruction 1/IM/2006 provides that all consignments of food of non animal origin should be submitted to documentary checks. Instruction 2/IM/2006 establishes that identity checks should be carried out for all food consignments of non animal origin under safeguard clauses, RASFF or an official control programme. At least 50% of the food consignments of non animal origin not included in the former categories shall undergo identity checks.

Instruction 83/IM/2006 of MISACO details the documentary, identity and physical checks when performing official controls of mycotoxins in certain foodstuffs at the DPIs. The main aim of the Instruction is to facilitate the implementation of EU legislation on this topic and in particular Commission Decision 2006/504/EC.

Regarding the frequency of controls, the Instruction refers to this Commission Decision. Products from a company that have been the object of a RASFF will be sampled in all cases until there is proof of compliance with the legislation.

Regarding sampling and analysis, the frequency of controls laid down in the relevant Commission Decisions was mostly achieved in 2005 and 2006 (see Annex I, Table 1). To date the only commodity that is below the frequency provided by the Decisions are peanuts from China. With regard to other products not included in the Commission Decisions that have been subject to official controls as a result of monitoring of suspicious consignments and random checks, the biggest number of samples is of almonds from the USA (see Annex I, Table 2).

There are no checks on food of non-animal origin for consignments in free zones and free warehouses. There are no special agreements with third countries that could allow a lower frequency of controls.

Infringements

The most common infringement found in food of non animal origin submitted to laboratory tests is a level of mycotoxins above the legal limit. In case of infringement, the goods are rejected but penalties are not imposed.

Control at visited premises

The nut processor visited by the mission team has been implementing a quality system based on HACCP since 2000. The inspector from the Autonomous Community visited the premises in September 2006 to undertake the first official evaluation of the HACCP system in place. It was found to be generally satisfactory. Regarding aflatoxins, the inspector included in the report that the preventive measures in place did not take into account storage's hazards such as temperature, humidity and time. The inspector had previously visited the premises to assess traceability in April 2006. No non conformances were found.

7.5.2. Feed of non-animal origin

Import procedures

Import procedures for feed of non-animal origin are similar to the procedures for import of food of non-animal origin. The only difference is that the goods are checked by the peripheral offices of SA that complete, stamp and sign the form included in Commission Directive 98/68/EC. The Royal Decree 1144/2006 of 6 October 2006 on the implementation of Community legislation on feed hygiene provides that feedstuffs imports will be authorised according to the Royal Decree 608/1999 until the lists foreseen in Article 23.1(a) and (b) of Regulation (EC) No 1831/2003 of the European Parliament and the Council are finalised.

The 2006 national control plan of feedstuffs includes documentary controls for all feedstuffs at the point of entry and identity controls, depending on the type of product, for 50-90% of the consignments. Sampling is foreseen for 30% of raw materials of plant origin. No mention is made of sampling for mycotoxins.

7.6. Rapid Alert System for Food and Feed

The results of official controls at the DPIs are entered in the SISAEX IV information system. The central services of MISACO decide if a rejection should be notified to RASFF in case of non conformity of a consignment. In this case, MISACO will inform all DPIs –through SISAEX and fax-, the embassy of the country of origin of the consignment and AESA, Spanish contact point for RASFF.

AESA has sent more than 90 RASFF notifications for aflatoxins to the Commission to date in 2006. The last seven notifications were sent to the Commission between 2 to 7 months after the date of the initial sample, which is considered too long in the case of a rapid alert system.

7.7. Procedures for non-compliant lots

When a consignment of food of non-animal origin imported from a third country does not comply with food law (Article 19 of Regulation (EC) No 882/2004), a number of measures such as destruction, special treatment, re-dispatch outside the Community, and other appropriate measures (use as feed or food for purposes other than those for which it was originally intended) are to be taken by the CAs, after having heard the food business operators responsible for the consignment.

Instruction 83/IM/2006 provides for secondary treatment of groundnuts, nuts and dried fruit not complying with the maximum levels of aflatoxins for human consumption. This could either be consignments labelled, in the country of origin, as product to be subjected to physical treatment to reduce aflatoxin contamination before human consumption or consignments rejected for not complying with the maximum levels. The physical treatment should be inspected by the CCAA.

The inspection team received copies of two files of consignments of almonds that had been submitted to physical treatment in the Autonomous Community of Valencia. In both files, the supervision of the CA to ensure that the necessary authorised treatments were applied to the product is not mentioned. Moreover, the enforcement sample is transmitted by the operator to the laboratory and the analytical report is only for total aflatoxin content, including neither the recovery nor the uncertainty.

Instruction 83/IM/2006 does not provide for the import as feed of a consignment of groundnuts, nuts and dried fruit, which was found to exceed the limit for mycotoxins in foodstuffs. The CAs in Valencia and Barcelona ports informed the mission team that they could not recall any event of this kind.

The re-dispatch is only authorised after the food business operator responsible for the consignment has informed SE in writing of the destination and has notified the CA of the third country of the reasons of the rejection. When the third country of destination is not the third country of origin, the CA of the third country of destination should notify SE of its preparedness to accept the consignment.

The re-dispatch shall take place, under Customs supervision, no more than 60 days after the day on which SE informed the business operator of the rejection of the consignment, unless legal action has been undertaken. If, after the expiry of the 60-day period, re-dispatch does not take place, the consignment shall be destroyed, unless SE considers the delay justified.

The consignment is destroyed when the re-dispatching is not acceptable, after the expiry of the 60-day period or after agreement in writing of the business operator. This takes place under Customs supervision in the appropriate premises closest to the DPI that has rejected the consignment.

7.8. Sampling procedures

MISACO Instruction 83/IM/2006 details the sampling procedures for mycotoxins, which are in line with the "European Commission guidance document for competent authorities for the control of compliance with the EU legislation on Aflatoxins".

Samples for enforcement, defence and reference are taken in parallel from the consignment in presence of the operator.

The mission team observed official control samplings for aflatoxins in almonds from USA in Valencia and Barcelona ports. Both samplings were of a consignment consisting of 20 big bins of 1 ton each. The consignment was sampled in Valencia following a RASFF and in Barcelona as a result of previous documentary and physical checks. The procedures followed differed substantially.

In Valencia port, 10 big bins were sampled. Each one was sampled from 4 points selected at random and the spear of approximately 30 cm long was introduced three times in each sampling point through the outer packaging. Three baskets were filled with 30 kg each, for enforcement, defence and reference analysis. The nuts from each sampling point were divided between the 3 baskets.

In Barcelona, the 20 big bins were sampled. Each one was sampled from six points selected at random at the top of the big bin, which was fully opened to facilitate the insertion of a spear of about 1.5 m. The spear was introduced three times in each sampling point. A container was filled with 90 kg, to be divided into 3 sub samples for enforcement, defence and reference analysis.

The observed samplings were in line with the requirements of Commission Regulation (EC) No 401/2006. In both cases, the whole consignment was unloaded and the staff of a private handling company performed the sampling operations under the instruction and supervision of the inspectors. These produced minutes of the official control, sent the enforcement sample to the laboratory and placed the goods under detention.

The mission team observed also a sampling for aflatoxins in peanuts from USA in the DPI located at a private company near Valencia. The whole consignment of 20 big bags of 1 ton each was unloaded and the staff of a private company performed the sampling operations under the instruction and supervision of the inspector. The mission team was informed that not being an official control the consignment will not be sampled according to official procedures and will not be placed under detention.

7.9. Laboratory services

General Organisation

The National Reference Laboratory for mycotoxin analysis in foodstuffs is the Centro Nacional de Alimentacion (CNA). This was notified to the Commission in June 2006. The National Reference Laboratory for analysis of feedstuffs is the Laboratorio Arbitral Agroalimentario, however aflatoxin analysis is not included in the scope of the accreditation.

The official control analysis for Sudan dyes have been performed by 3 laboratories but only 1 of them includes the method in the scope of its accreditation.

Laboratories carrying out the official control analysis of food and feed can be either public or private and are accredited to ISO 17025.

Laboratory visits

The mission team visited a private laboratory in Valencia that undertakes official control analysis for mycotoxins and a private laboratory in Barcelona that performs official control analysis for Sudan dyes.

The laboratory visited in Valencia has a total of 165 staff employed, of which 28 work in the chemical analysis section. The laboratory was accredited to ISO 17025 by the Spanish national accreditation body ENAC in 2002. The HPLC and the ELISA methods for aflatoxin analysis are included in the scope of accreditation. The laboratory participates in FAPAS (Food Analysis Performance Assessment Scheme, UK) proficiency tests with satisfactory results. Approximately, 3642 analysis for official control for aflatoxin were performed in 2005 of which 2448 used the ELISA technique and 1194 the HPLC method.

A general evaluation of the laboratory system was made for sample reception, processing and reporting. Samples are brought in to the sample reception area and the details are registered in the database and assigned a code number. The analysts in the laboratory are not aware of the origins of any of the samples received. All laboratory samples arrive sealed in opaque plastic bags. To comply with Spanish sampling legislation the initial sample consists of 3 sub samples of 30kg each.

SOP are in place for all steps of the analysis including the milling step. Two new mills have been purchased for the grinding of samples such as pistachio nuts, since the last mission in 2004. These mills are suitable for dry grinding, after calculation of the edible part for nuts in shell, of all samples for aflatoxin analysis, except for Brazil nuts and figs. For the latter matrices a small bench top mill is used. ELISA screening techniques are used with a Limit of Detection (LOD) of 2 ppb. The use of ultrasound has improved the recovery of aflatoxins since the time of the last mission. HPLC fluorescence detection method is used. Results, corrected for recovery and measurement uncertainty, are specified in the results sheet. Standard reference materials are used in each run and are stored appropriately with regular checks of on their stability.

The laboratory visited in Barcelona has been accredited to ISO 17025 since 2001. There are 90 staff employed in the laboratory of which 30 work in the physiochemical department and within this 6 people are directly involved in contaminant analysis. The analysis of Sudan dyes is included in the scope of accreditation since 2004. The laboratory has received an official letter from SE requesting the analysis of samples for official control. The laboratory participates in FAPAS proficiency tests for Sudan dyes with satisfactory results. A total of 750 food samples were analysed in 2005 for Sudan dyes of which 100 were specifically for SE.

All samples are received in the sample reception area which is in a separate building to the physiochemical department. The samples details are recorded in the Laboratory Information Management System (LIMS) and the 11 digit reference code is the only information the analysts have about the samples for analysis. Samples are prepared for analysis in a specific preparation room and are transferred in a dedicated laboratory vehicle to the physiochemical department. Standard reference materials are used in each analytical run of samples. Sudan dyes are extracted from the sample using acetonitrile solvent and purification is undertaken by filtration. The detection is carried out using HPLC with UV Diode Array Detection. Another method using HPLC/MS has recently been submitted for inclusion in the scope of accreditation. SOPs are in place for all steps of the procedure. The limit of quantification (LOQ) with the former method is 0.5mg/kg and LOD of 0.1mg/kg. With the latter method there is LOQ of 50 µg/kg and LOD of 10 µg/kg. Results are provided within 2 days of receipt of samples.

This laboratory also undertakes aflatoxin analysis which is included in the scope of the accreditation. A total of 1200 food samples were analysed for aflatoxins in 2005 of which 100 were for SE.

7.10. Follow-up to mission SANCO 7308/2004

There were two recommendations made in the above mission to be followed up in this mission. The following table indicates these with corresponding action indicated by the authorities and verified during this mission.

Recommendation	Action indicated	Follow up
Ensure that all nominated points of entry in the context of the Annex to relevant Commission Decisions are able to fulfil the requirements in Commission Directive 98/53/EC and in the relevant Commission Decision.	The Spanish authorities decided to review their 49 authorised border inspection posts based on the requirements identified in the FVO report and the Commission 'Draft Guidance Document on compliance with EU legislation on mycotoxins'.	The designated points of import have been reduced from 49 to 15.
Carry out official control activities, to include sampling, for products being exposed to ionising irradiation.	Negotiations are ongoing with a research laboratory of the Ministry of Education and Science which has adequate sample equipment. A presentation to inspectors as part of their ongoing training is also envisaged.	MISACO signed agreements with a research laboratory to analyse foodstuffs exposed to ionising radiations

8. CONCLUSIONS

8.1. Competent authorities performance

- (1) Since the last mission there have been no changes as regards CCAs structure and responsibilities.
- (2) The designated points of import for food have been reduced from 49 to 15, in order to improve the efficiency of the system.
- (3) Vertical communication pathways within the relevant CAs are in place. There are regular meetings between the different CAs at the DPIs visited.
- (4) Staff are well trained to carry out their responsibilities.
- (5) An internal audit system as required by Article 4(6) of Regulation (EC) No 882/2004 was launched in 2006.

8.2. Legislation

- (6) The EU legislation within the scope of this mission has been fully and timely developed into relevant national instructions.

8.3. Import controls

- (7) Import controls on products of non-animal origin focus predominantly on foodstuffs subject to specific Commission Decisions and RASFFs.

- (8) In 2005 and 2006, several commodities other than products subject to specific Commission Decisions have been subject to official controls as a result of monitoring of suspicious consignments or random checks.
- (9) The frequency of controls laid down in the relevant Commission Decisions was achieved.
- (10) The documentary, identity and physical checks observed during the mission, including sampling, are performed as required by Article 16(1) of Regulation (EC) No 882/2004 and Annex I of Regulation (EC) No 401/2006.
- (11) Some of the DPIs have not yet submitted proposals to improve their premises to fulfil the requirements of Article 4 of Commission Decision No 2006/504/EC.
- (12) The nut processor premises visited by the mission team have been implementing a quality system based on HACCP principles. The inspector of the Autonomous Community had assessed the premises for the HACCP system in place and for traceability.
- (13) Import procedures for feed are well defined and comprehensive.

8.4. Rapid Alert System for Food and Feed

- (14) During 2006 and to date, the AESA has notified more than 90 RASFFs for aflatoxins to the Commission but excessive delays were noted in the last seven notifications.

8.5. Procedures for non-compliant lots

- (15) Procedures for non-compliant lots are in place, with the exception of the use of feed or food for purposes other than those for which they were originally intended.
- (16) The 2 files of consignments submitted to physical treatment, received by the mission team, neither mention the supervision of the CA to ensure that the necessary authorised treatments were applied to the product nor report the results of the enforcement analysis in line with Commission Regulations (EC) No 882/2004, (EC) No 401/2006 and (EC) No 466/2001.

8.6. Sampling procedures

- (17) The mission team observed official control samplings for almonds in two of the DPIs visited. The procedures followed differed substantially but were in line with Commission Regulation (EC) No 401/2006.

8.7. Laboratory services

- (18) The two laboratories visited were accredited according to ISO 17025. They are adequately staffed and equipped with regard to the official control analysis assessed and performed satisfactorily in proficiency tests.
- (19) Only one of three laboratories undertaking official control analysis includes Sudan dyes in the scope of its accreditation.

8.8. Follow-up of previous recommendations

- (20) The recommendations of the last import control mission have been addressed satisfactorily.

8.9. Overall conclusion

Spain has a clearly defined structure of CAs responsible for import controls, with vertical communication pathways in place. All recommendations from the last import control mission have been addressed. Nevertheless, a number of shortcomings have been identified as regards the requirements to be fulfilled by the DPIs, supervision of consignments subject to physical treatment, reporting of analytical results, accreditation scope of laboratories undertaking official control analysis for Sudan and delays in notifying rejections through RASFF to the Commission.

9. CLOSING MEETING

A closing meeting was held with the central competent authorities, MISACO, MAPA and AESA on 10 November 2006. At this meeting, the main findings and conclusions of the mission were presented by the inspection team.

The representatives of the competent authorities present accepted the initial conclusions and requested some clarifications. The mission team requested additional information, which was supplied during the weeks following the mission.

10. RECOMMENDATIONS TO THE COMPETENT AUTHORITIES OF SPAIN

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:

- (1) Ensure that the premises of all DPIs fulfil the requirements of Article 4 of Commission Decision No 2006/504/EC.
- (2) Ensure that the special treatment of consignments is performed under the control of the CA, as required by Article 20 of Regulation (EC) No 882/2004.
- (3) Ensure that the reporting of analytical results includes values for aflatoxin B1 and total aflatoxin content, the level of recovery and the measurement of uncertainty, as required by Article 1 of Commission Regulation (EC) No 466/2001 and 4.4 of Annex II of Commission Regulation (EC) No 401/2006.
- (4) Consider that all laboratories undertaking official control analysis for Sudan dyes include this in the scope of its accreditation, in line with Article 12 of Regulation (EC) No 882/2004 and Article 18 of Regulation 2076/2005.
- (5) Ensure that the rejection notifications are immediately communicated to the Commission, as required by Article 50 of Regulation (EC) No 178/2002.

11. 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/ap_spain_8128_2006.pdf

as soon as this report is published.

ANNEX I: TRADE INFORMATION AND LEVELS OF ANALYSIS

Table 1: Import and sampling data for 2005 and 2006 (January-July) - Food Products under Commission Decisions

Product	CN - code	Country of origin	Number of consignments imported		Volume imported in tonnes		Official Samples analysed for aflatoxins		Cases of non-compliance (percentage)	
			2005	2006	2005	2006	2005	2006	2005	2006
Peanuts and peanut products	1202 10 90, 1202 20 00, 2008 11 92, 2008 11 96	EGYPT	0	0	--	0	1	0	0	0
Peanuts and peanut products	1202 10 90, 1202 20 00, 2008 11 92, 2008 11 96, 2008 11 94, 2008 11 98	CHINA	1484	1097	29.956	23.474	199	91	6	7
Pistachios	0802 50 00, 2008 19 13, 2008 19 93	IRAN	386	76	5.444	2.530	386	76	189	47
Dried figs	0804 20 90	TURKEY	62	9	765	87	18	0	2	0
Hazelnuts	0802 21 00, 0802 22 00	TURKEY	260	191	4.070	2.036	38	12	0	0
Pistachios	0802 50 00	TURKEY	8	4	65	15	2	0	0	0
Figs, hazelnuts, and pistachios and derived products	0813 50, 2007 99 98, 2008 19, 1106 30 90	TURKEY	39	20	235	125	4	2	0	0
Brazil nuts	0801 21 00	BRAZIL	6	0	115		6	0	0	0

Sudan dyes:

Chilli and chilli products, curcuma	0904 20 90, 0910 50, 0910 30		119	75	3.780	2.706	82	19	1	0
Palm oil	1511 10 90		3	1	100	179	0	0	0	0

(source: MISACO)

Table 2: Import and sampling data for 2005 and 2006 (January-July)- Other food products

Product	CN - code	Country of origin/ contaminant	Number of consignments imported		Volume imported in tonnes		Official Samples analysed		Cases of non-compliance (percentage)	
			2005	2006	2005	2006	2005	2006	2005	2006
Peanuts and peanuts products	1202 10 90, 1202 20 00, 2008 11 92, 2008 11 96	INDIA/ aflatoxins	1	0	2	0	0	0	0	0
Peanuts and peanuts products		BRAZIL/ aflatoxins	53	23	1.150	443	12	13	0	0
Peanuts and peanuts products		GHANA/ aflatoxins	0	0	0	0	0	0	0	0
Hazelnuts	0802 21 00, 0802 22 00	AZERBAI- JAN/ aflatoxins	0	0	0	0	0	0	0	0
Peanuts and peanuts products		ARGENTI- NA/ aflatoxins	65	94	1.705	2.652	21	2	0	0
Almonds and derived products	0802 11 00, 0802 12 00	U.S.A./ aflatoxins	923.	1113	22.249	24.332	189	76	17	4
Maize		Fusarium toxins	60	32	1.026	597	0	0	0	0
Dried grapes Coffee	0806 20 0901	TURKEY/ Ochratoxin A	24	9	387	238	31	2	1	0
		Patulin	202	137	8.505	4.875	0	0	0	0

(source: MISACO)

ANNEX II: References to community acts quoted in the report

European Legislation	Official Journal	Title
Regulation (EC) No 882/2004.	OJ L 165, 30.04.2004. Corrected and re-published in OJ L 191, 28.05.2004 p. 01.	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
Commission Regulation (EC) No 2076/2005.	OJ L 338, 22.12.2005 p. 83.	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004.
Regulation (EC) No 852/2004.	OJ L 139, 30.04.2004. Corrected and re-published in OJ L 226, 25.06.2004 p. 03.	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
Regulation (EC) No 178/2002.	OJ L 31, 1.02.2002, p. 01.	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
Council Regulation (EEC) No 315/93.	OJ L 37, 13.02.1993, p. 01.	Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food.
Commission Regulation (EC) No 466/2001.	OJ L 77, 16.03.2001, p. 01.	Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs.
Commission Regulation (EC) No 401/2006.	OJ L 70, 9.03.2006, p.12.	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.
Commission Decision 2006/504/EC	OJ L 199, 21.07.2006, p 21	Commission Decision of 12 July 2006 on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins.
Commission Decision 2005/402/EC.	OJ L 135, 28.05.2005, p. 34.	Commission Decision 2005/402/EC of 23 May 2005 on emergency measures regarding

			chilli, chilli products, curcuma and palm oil.
Commission Decision 2005/317/EC	OJ L 101, 21.04.2005, p. 14		Commission Decision 2005/317/EC of 18 April 2005 on emergency measures regarding the non-authorised genetically modified organism Bt10 in maize products.
Commission Decision 2006/601/EC	OJ L 244, 07.09.2006, p. 27		COMMISSION DECISION 2006/601/EC of 5 September 2006 on emergency measures regarding the non-authorised genetically modified organism 'LL RICE 601' in rice products.
Directive 2002/32/EC	OJ L 140, 30.05.2002, p. 10		Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed
First Commission Directive 76/371/EEC	OJ L 102, 15.04.1976, p. 01		First Commission Directive 76/371/EEC of 1 March 1976 establishing Community methods of sampling for the official control of feedingstuffs
Commission Directive 98/68 (EC).	OJ L 261, 24. 09.1998, p. 32		Commission Directive 98/68 (EC) of 10 September 1998 laying down the standard document referred to in Article 9(1) of Council Directive 95/53/EC and certain rules for checks at the introduction into the Community of feedingstuffs from third countries.
Council Directive 96/25/EC	OJ L 125, 23.05.1996, p. 35		Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC.