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FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

GREECE

FROM 05 TO 13 MAY 2009

IN ORDER TO ASSESS THE OFFICIAL CONTROL SYSTEMS IN PLACE FOR FOOD
HYGIENE, EVALUATE IMPORT CONTROLS ON FOOD AND FEED OF NON-ANIMAL
ORIGIN AND FOLLOW UP ON THE RECOMMENDATIONS OF MISSIONS 2007-7201 AND
2006-8114

IN THE CONTEXT OF A GENERAL AUDIT

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 Greece, from 5 to 13 May 2009.

The objective of the mission was to evaluate, in the context of 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 the relevant Commission Decisions concerning mycotoxin contamination and Sudan dye adulteration. A further objective was to evaluate the implementation of Community legislation in the area of food hygiene and follow-up on the recommendations of missions DG(SANCO) 7201/2007 and DG(SANCO) 2006/8114.

There is an adequate import control procedure in the context of this mission. National legislation on import controls lays down additional requirements for import controls on dried figs, raisins and currants, and cereals. The import controls and the frequency of such controls are in line with those specified in Commission Decisions 2006/504/EC and 2005/402/EC. Controls on foodstuffs imported from certain third countries not subject to special conditions are not in line with Article 3(1) of Regulation (EC) No 882/2004 because they are not risk based.

At the point of import, an appropriate documentary check is carried out.

Although the sampling carried out for the analysis of aflatoxins was in accordance with Regulation (EC) No 401/2006. However, the mission team noted that the area available for unloading and sampling of consignments was not adequately covered, as is required by Article 4(2)(c) of Commission Decision 2006/504/EC.

The assessment of procedures based on HACCP principles in some establishments was not fully implemented. This is not in line with Article 10(2)(d) and (h) of Regulation (EC) No 882/2004. There are fifteen guides to good hygiene practice in Greece. The guide available for restaurants does not fully address the relevant requirements of Regulation (EC) No 852/2004. Not all rejected consignments are notified to the RASFF system which is not in line with Article 19(3) of Regulation (EC) No 882/2004.

Not all laboratories designated to perform official controls are approved and accredited to EN ISO/IEC 17025. The laboratory visited is not accredited and did not have quality control schemes in place, which is not in line with Article 18 of Commission Regulation (EC) No 2076/2005. Expired consumables (culture media and reagents) were seen at this laboratory.

Overall, official controls at import and on food hygiene of foodstuffs of non-animal origin are not fully in compliance with relevant Community legislation. A number of deficiencies have been identified, mainly related to risk-based criteria for controls, laboratories, RASFF, assessment of procedures based on HACCP and rejection of imported consignments.

The report makes a number of recommendations to the Competent Authorities in Greece to address the shortcomings identified.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
CA	Competent Authority
CCA	Central Competent Authority
CN	Combined Nomenclature
DGPH	Directorate-General for Public Health
DG SANCO	Directorate-General for Health and Consumers
DPI	Designated Point of Import
DPSQCPVO	Directorate for Processing, Standardisation and Quality Control of Products of Vegetable Origin
DVPH	Directorate for Veterinary Public Health
EC	European Commission
EFET	Hellenic Food Authority
EU	European Union
FBO	Food Business Operator
FNAO	Food of Non-Animal Origin
FVO	Food and Veterinary Office
GCSL	General Chemical State Laboratory
GHP	Good Hygiene Practice
GMO	Genetically modified organism
HACCP	Hazard Analysis Critical Control Points

ISO	International Organisation for Standardisation
MANCP	Multi-Annual National Control Plan
MH	Ministry of Health and Social Solidarity
MRDF	Ministry of Rural Development and Food
MS	Member States
NRL	National Reference Laboratory
OJ	Official Journal of the European Union
OTA	Ochratoxin A
PHD	Health Directorate of the Prefecture
PRDD	Rural Development Directorate of the Prefecture
PTD	Trade Directorate of the Prefecture
PVD	Veterinary Directorate of the Prefecture
RASFF	Rapid Alert System for Food and Feedstuffs
RCPQC	Regional Centre for Plant Protection and Quality Control
SANCO	Directorate-General for Health and Consumers

1 INTRODUCTION

This mission to Greece took place from 5 to 13 May. The mission team comprised two inspectors from the Food and Veterinary Office (FVO) and one Member State expert.

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

The inspection team was accompanied, during the mission, by representatives from the Central Competent Authority (CCA), The Hellenic Food Safety Authority.

An opening meeting was held on the 5 May with the representatives from the CCA and Customs. At this meeting, the inspection team confirmed the objectives of and itinerary for the mission and additional information required for the satisfactory completion of the mission was requested.

2 OBJECTIVES OF THE MISSION

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

- To evaluate the implementation of Commission Decisions imposing special conditions on the import of certain products concerning mycotoxin contamination and Sudan dyes adulteration in foodstuffs.
- To evaluate the implementation of Regulation (EC) No 852/2004 on the hygiene of foodstuffs and Regulation (EC) No 882/2004 on official controls.
- To evaluate the implementation of Community legislation regarding the general principles and requirements of food law, in particular the implementation of Article 18 of Regulation (EC) No 178/2002 regarding traceability.
- To evaluate the transposition and implementation of Directive 80/777/EEC and Directive 98/83/EC, in particular the recognition procedure of natural mineral water sources and official inspections and controls carried out in relation to bottled water for human consumption.

Additionally, the mission team followed up on action taken by the Competent Authorities (CAs) in response to recommendations made by the FVO in the previous reports (SANCO 8114/2006 and 7201/2007).

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

Competent Authority visits		Comments
Competent authority	Central	The Hellenic Food Authority (EFET), Ministry of Rural Development and Food (MRDF), General Chemical State Laboratory (GCSL), Ministry of Health (MH) and Customs.
	Regional	Import control authorities in Thessaloniki (Rural Development Directorate of the Prefecture (PRDDs), Regional centre for Plant protection and Quality Control (RCPPQCs), GCSL and Customs) and the EFET Regional Directorate of Thessaloniki. Prefecture of Cyclades.

Laboratory visits		Comments
Microbiology Public Laboratory	1	Institute of Food Hygiene, at the Centre of Veterinary Institutes of Thessaloniki, under the MRDF
Visits to premises		
Nut processors	2	Athens and Thessaloniki
Restaurant	2	Syros
Supermarket		Syros

3 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) a n d other general provisions of Community legislation, specifically:

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

All legal references relevant for this mission are listed in Annex 1. Legal acts quoted refer, where applicable, to the last amended version.

4 BACKGROUND

4.1 BACKGROUND TO THE MISSION

4.1.1 *Mycotoxins*

Article 50 of Regulation (EC) No 178/2002 requires information on foodstuffs and feedingstuffs found to have public health implications to be disseminated to all Member States (MS) and to the exporting country in the form of notifications through the Rapid Alert System for Food and Feed (RASFF).

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

In fact, there were 992 RASFF messages for mycotoxins in 2005, 874 in 2006, 754 in 2007 and 370 in 2008 (up to 15 May). The products involved were 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, 50 in 2006, 30 in 2007 and 8 in 2008 (up to 15 May).

Between 2002 and 2005 a series of missions were carried out by the FVO to major importing MS, in order to assess controls on food products of plant origin at import.

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 were found concerning the application of Commission Directive 98/53/EC (now repealed by Regulation (EC) No 401/2006) with regard to sampling and sample preparation.
- Non-compliant consignments are generally 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, either 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.

There are no imports into Greece of groundnuts, nuts, dried fruit and maize not complying with the maximum levels of aflatoxins and subject to further sorting as laid down in Article 4 of Regulation (EC) No 1881/2006.

This mission follows up on the action taken in response to the recommendations made after the last FVO mission concerning import controls of food of non-animal origin (FNAO) (Ref DG SANCO 8114/2006), which was carried out in Greece from 5 to 9 June. This report can be found at:

http://ec.europa.eu/food/fvo/ir_search_en.cfm

4.1.2 *Food Hygiene*

This mission follows up on the action taken in response to the recommendations made after the last FVO mission concerning food hygiene (Ref DG SANCO 7201/2007), which was carried out in Greece from 3 to 7 September 2007 concerning the evaluation of the implementation of Community legislation on official controls for food hygiene, traceability, labelling and bottled water. This report can be found at: http://ec.europa.eu/food/fvo/ir_search_en.cfm

4.2 PUBLIC HEALTH INFORMATION

4.2.1 *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, it 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 distributed in a non-uniform way 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.

4.2.2 *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 the 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.

5 FINDINGS AND CONCLUSIONS

5.1 LEGISLATION

Findings

Legislation and instructions with regard to import controls have been disseminated by the MRDF. Relevant legislation on food hygiene is sent to the relevant CAs and is available on the EFET website.

In addition to the EU provisions, supplementary national legislation on import controls of foodstuffs is in place (see report 8114/2006 section 7.5). Since the last mission, Ministerial Decision No 2144/2006 which amends Ministerial Decision No 552/25.08.2004 on “Complementary special measures in respect of importation of cereals for human consumption” has been approved (Government Gazette Issue 114/B/23.08.2006). The main points are as follows:

- Controls relate to imported and exported cereals.
- The compulsory analysis regarding the percentage of *Fusarium*-damaged grains is abolished and is replaced by analyses for the determination of toxins produced by *Fusarium* fungi.
- The sampling rate for GMOs is set at 50% instead of 100%.

Ministerial Decision No 304825/14-10-04, Ministerial Decision No 40943/22-3-05 and Ministerial Decision No 329348/5-12-05 are repealed.

Ministerial Decision No 552 of 2004 on checks on imported cereals, as last amended in September 2008, prescribes sampling for 100% GMO-testing on maize feed from Bulgaria and Romania.

Since the previous mission there have been no changes in the applicable legislation on official controls for food hygiene.

Conclusions

Legislation is properly disseminated and publicly available.

National legislation on import controls lays down additional requirements for the import controls on dried figs, raisins and currants, and cereals. This legislation has been amended since the last mission.

5.2 REQUIREMENTS ALONG THE FOOD CHAIN FOR IMPORT CONTROLS AND FOOD HYGIENE

5.2.1 *Organisation of import controls for food of non-animal origin*

Legal requirements

Article 15 of Regulation (EC) No 882/2004 establishes that CA shall carry out regular official controls on food and feed of non-animal origin imported into the EU.

Article 24 of Regulation (EC) No 882/2004 requires that, for the organisation of official controls,

the CAs and the customs services shall cooperate closely.

Article 11 of Regulation (EC) No 178/2002 requires that food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto.

Findings

The import procedure for food of non-animal origin has not changed since the last mission and is the same for all products, regardless of whether they are subject to special import conditions (Commission Decisions and specific national legislation).

- Any importer who is about to import a consignment of food of non-animal origin into Greece has to submit an application to the RCPPQC or to the relevant PRDD 24 hours prior to arrival or at the latest by 10.00 hours on the day of arrival;
- Customs and PRDD staff jointly carry out inspection and take samples if necessary. All consignments are held by customs until the relevant approval is granted by the RCPPQC or the PRDD;
- If the consignment complies with the requirements, the RCPPQC or PRDD fills out a specific certificate that is given to the customs officer, and the consignment is released for free circulation.
- If the consignment is not in compliance, it is rejected. The importer makes a decision about the final destination of the consignment and has the legal right to request a second analysis (see also section 5.2.5).

All inspections at the port of Thessaloniki are conducted by the inspectors of the PRDD, except in the case of cereals for which the RCPPQC carries out the inspections.

The import procedure for control of Sudan dyes is as described above, except that the sampling is carried out by customs and Chemical Services of the GCSL is responsible for inspecting documentation and for physical controls.

Conclusions

This mission found that there was an adequate import control procedure.

5.2.2 Frequency of controls

5.2.2.1 Foodstuffs imported from certain third countries subject to special conditions.

Legal requirements

Article 5 of Commission Decision 2006/504/EC establishes that in each MS a sample for analysis of aflatoxins should be taken from consignments of foodstuffs with a specific origin and frequency as described in this Article.

Commission Decision 2005/402/EC requires that CAs in MS check that each consignment of chilli, chilli products, curcuma and palm oil presented for importation is accompanied by an analytical report demonstrating that the product does not contain Sudan dyes I, II, III or IV.

Findings

In response to the pre-mission questionnaire, the mission team obtained data on import controls on foodstuffs of non-animal origin for 2007 and 2008 from the MRDF and the GCSL. This included products subject to Commission Decisions 2006/504/EC and 2005/402/EC. The data are presented in Annex II (Table 1).

According to these data, the main commodities imported into Greece in 2008 were groundnuts from China and almonds from the USA.

The mission team observed that the frequency of controls on foodstuffs affected by the above Decision is in compliance with the required frequency.

With regard to Commission Decision 2005/402/EC, the official control by GCSL Chemical Services includes a check on the analytical report, as required by the EU legislation; in the absence of such reports, consignments are detained and reports are requested. Samples are also taken randomly at import.

Conclusions

The import controls and the frequency of such controls are in line with those specified in Commission Decision 2006/504/EC.

Import controls regarding consignments of chilli, chilli products, curcuma, and palm oil presented for importation are carried out in line with Commission Decision 2005/402/EC.

5.2.2.2 Foodstuffs not affected by Commission Decisions

Legal requirements

Article 3(1) of Regulation (EC) No 882/2004 requires the competent authority to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency.

Article 15(1) of Regulation (EC) No 882/2004 provides that the CA shall organize import controls on the basis of the multi-annual national control plan and in the light of potential risks.

Findings

In response to the pre-mission questionnaire, the mission team obtained data on import controls on foodstuffs of non-animal origin for 2007 and 2008 from the MRDF. This included products not subject to the relevant Commission Decisions. The data are presented in Annex II (Table 2). The main commodities imported into Greece in 2008 were groundnuts from Argentina, spices from India, Basmati rice from India and Pakistan and raw coffee beans from Brazil.

In addition to the EU provisions on import controls, national legislation introduces additional requirements on import controls for the MRDF (see also section 5.1).

- dried figs (under Ministerial Decision 285279/3-9-2004): 100% of consignments, except those from Turkey, have to be controlled for aflatoxins;
- raisins and currants (under Ministerial Decision 300945/1-10-2004): at least 20% of the consignments have to be controlled for ochratoxin A;

- cereals (under Ministerial Decision 552/25-8-2004, as amended by Ministerial Decision 2144/2006): at least 5% of the consignments imported per year have to be controlled for each country of origin, to determine the level of contamination with *Fusarium* toxins, aflatoxins, ochratoxin A, heavy metals and pesticide residues. In addition, 50% of consignments of cereals have to be analysed for GMO and 100% of consignments imported by ship and 10% of consignments imported by other means have to be controlled for radioactivity. Furthermore, 100% GMO-testing on maize feed from Bulgaria and Romania.

For the other commodities there is no official food control plan in relation to import controls on food of non-animal origin that will take into account potential risks, RASFF notifications, results of samples taken at all point of import, etc. Each designated Point of import (DPI) decides according to its own criteria and experience.

Conclusions

Controls on foodstuffs imported from certain third countries not subject to special conditions are not in line with Article 3(1) and Article 15(1) of Regulation (EC) No 882/2004 because it is not risk based.

5.2.3 Types of checks on food of non-animal origin

Legal Requirements

Pursuant to Article 16(1) and (2) of Regulation (EC) No 882/2004 import controls shall include at least a systematic documentary check, a random identity check and, as appropriate, a physical check.

Article 3(3) of Commission Decision 2006/504/EC requires the CAs in the MS of introduction to ensure that imported consignments of foodstuffs are subject to documentary checks to ensure that the results of sampling and analysis and the required health certificate comply with Article 3(1) and (5).

Article 5 of Commission Decision 2006/504/EC requires that any consignment which is to be subjected to sampling and analysis may be held for a maximum period of 15 working days before release for free circulation from the Designated point of Import into the Community.

Article 16(3) of Regulation (EC) No 882/2004 stipulates that physical checks shall be carried out under appropriate conditions and at a place with access to appropriate control facilities.

Article 4(2)(c) of Commission Decision 2006/504/EC stipulates that the unloading and sampling must be performed in a sheltered place at the designated point of import (DPI).

Article 1 of Commission Regulation (EC) No 401/2006 provides that sampling for the official control of the levels of mycotoxins in foodstuffs shall be carried out in accordance with the methods set out in Annex I to the same Regulation.

Findings

There are 19 DPIs through which foodstuffs covered by Commission Decision 2006/504/EC may be imported into Greece. The mission team was informed that the main DPI for nuts and dried fruits subject to the above Decision is Piraeus, followed by Thessaloniki. The mission team visited the DPI in Thessaloniki, as Piraeus had been visited during the previous mission.

During the visit to the DPI the mission team assessed several files of imported consignments from third countries, including health certificates and accompanying documents. The documents evaluated were in compliance with Article 3 of Commission Decision 2006/504/EC. However, Annex III of the same Decision was not filled in.

The mission team evaluated two sampling demonstrations carried out by the staff of the PRDD of Thessaloniki. One sample was taken from a consignment of almonds from the USA and the other from a consignment of peanuts from China. The containers had been unloaded into a partially covered area with adequate space for full unloading, but not sufficiently covered. Sampling spears were used to take 100 incremental samples of 300 g each from a random distribution of sampling points, giving a 30 kg sample. An identity check was also carried out by the samplers before sampling.

The mission team noted that the health certificate accompanying the consignment of almonds from the USA had expired. The inspectors decided to sample and analyse the consignment nevertheless. When questioned, the inspectors informed the mission team that if the analysis results proved to be negative, this consignment would be released onto the EU market.

Conclusions

At the point of import, an appropriate documentary check is carried out for import controls on consignments subject to Commission Decisions 2006/504/EC and 2005/402/EC. However, the required Common Document for checks performed on foodstuffs covered by Commission Decision 2006/504/EC is not used (Annex III).

In one case, consignments of USA almonds subject to Commission Decision 2006/504/EC were accompanied by an expired health certificate; these consignments were sampled and analysed.

The sampling for the analysis of aflatoxins carried out was in accordance with Regulation (EC) No 401/2006. However, the mission team noted that the area available for unloading and sampling of consignments was not adequately covered, as is required by Article 4(2)(c) of Commission Decision 2006/504/EC and Article 16(3) of Regulation (EC) No 882/2004.

5.2.4 Procedures for non-compliant lots

Legal requirements

Article 19 of Regulation (EC) No 882/2004 establishes that CAs shall place under official detention consignments that do not comply with the food or feed law, and that a number of measures shall be taken in respect of such feed or food. These measures include destruction, special treatment, re-dispatch or use for other purposes. Some of these measures are described in Articles 20 and 21 of the above mentioned Regulation.

Findings

When a food consignment does not comply with EU food law, RCPPQC or PRDD offers the importer the choice of either re-dispatching the consignment or using it as feed. The MRDF stated that consignments may also be destroyed, but this has happened only in rare cases.

Non-compliant consignments are usually rejected at the point of import and sent back to the country of origin or to another third country. They can be re-dispatched once the RCPPQC or PRDD inspector has stamped and signed the relevant part of the customs declaration.

In the case of non-compliant consignments for import that are to be re-dispatched to the country of origin, the CAs do not abide by Article 21(1)(a) and (b) of Regulation (EC) No 882/2004 because they do not have a procedure in place to ensure that consignments are only re-dispatched if the destination has been agreed with the FBO and if the FBO has first informed the CA of the Third Country of origin of the reasons and circumstances preventing the placing on the market of the food concerned within the Community.

Conclusions

Procedures for non-compliant lots are in line with Article 19 of Regulation (EC) No 882/2004.

In the case of non-compliant consignments for import that are to be re-dispatched, the CAs do not comply with Article 21(1)(a) and (b) of Regulation (EC) No 882/2004.

5.2.5 Right of appeal against decisions on consignments

Legal requirements

Article 11(5) and (6) of Regulation (EC) No 882/2004 requires CAs to have adequate procedures in place in order to guarantee the right of operators to apply for an additional expert opinion.

Findings

The mission team was informed that, in the case of non-compliant consignments, the FBOs have the right to apply for a second opinion. This right is described in Joint Ministerial Decree No 15523/2006.

Evidence of this was seen during the sampling demonstration. The FBO was informed of its rights, and the sampling report containing this information was signed by both parties.

Conclusions

Food operators have a guaranteed right of appeal against rejections pursuant to Article 11(5) and (6) of Regulation (EC) No 882/2004 and Article 14(6) of Regulation (EC) No 178/2002.

5.2.6 *General Hygiene Requirements*

Legal requirements

Article 4(2) of Regulation (EC) No 852/2004 requires that food business operators carrying out any stage of production, processing and distribution of food subsequent to primary production and associated operations must comply with the general hygiene requirements laid down in Annex II to that Regulation.

Article 10(2)(c) of Regulation (EC) No 882/2004 requires that official controls on food include, inter alia, checks on hygiene conditions in food businesses.

Findings

In reply to the pre-mission questionnaire, the mission team obtained data on controls for 2007 from the CAs. This included the number of establishments, the number of establishments inspected and the total number of inspections. The data are presented in Annex II (Table 3). It was noted that, in the case of manufacturers and packers, the level of establishments inspected represents 20% of the total number of this type of establishments. Moreover, the total number of establishments inspected represents 37 % of the total of the existing establishments within the scope of this mission.

The mission team observed one inspection of a restaurant and one of a supermarket, which were carried out by inspectors from the prefecture visited; regional EFET inspectors inspected two processors of dried nuts and fruit.

Two other inspections at processing establishments using nuts were observed. The EFET inspectors carried out a comprehensive inspection, interviewing the FBOs, checking the records of incoming consignments, the full import documentation accompanying the consignments including the availability and validity of the certificates, the results of laboratory analysis and the implementation of the code system used by the company for the identification of products by randomly selecting codes and tracing back to the imported consignment.

At prefecture level, inspectors focused mainly on general hygiene prerequisites, which included controls on the general food hygiene conditions at the facility, storage of foodstuffs, control of labelling, cleaning and disinfection of facilities, pest management maintenance of the cold chain and compliance with temperature control requirements for foodstuffs.

The instances of non compliance were communicated to the FBOs in the form of a report. In some of those facilities visited, follow up had been undertaken to check whether previous findings had been rectified.

With regard to recommendations 5 and 6 of the previous report (DG (SANCO) 7201/2007) concerning the approval status of FBO currently approved under Regulation (EC) No 853/2004 and the bottled water labelling, the mission team was informed that no follow up has yet been carried out.

Conclusions

Official controls on food include, inter alia, checks on hygiene conditions in food businesses in line with Article 10(2)(c) of Regulation (EC) No 882/2004.

5.2.7 *Hazard Analysis and Critical Control Points*

Legal requirements

Article 5(1) of Regulation (EC) No 852/2004 requires that food business operators put in place, implement and maintain a permanent procedure or procedures based on HACCP principles.

Article 5(2)(g) of Regulation (EC) No 852/2004 requires that HACCP principles consist, among other things, in establishing documentation and records commensurate with the nature and the size of the food business.

Article 5(5) of Regulation (EC) No 852/2004 allows the adoption of arrangements to facilitate the implementation of the HACCP requirement by certain food business operators. These include the use of guides for the application of HACCP principles.

Article 10(2)(d) of Regulation (EC) No 853/2004 requires that official controls on food shall include the assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP) and HACCP, taking into account the use of guides drawn up in accordance with Community legislation.

Findings

The two processors visited that use nuts and dried fruit had been implementing a food safety management system based on HACCP principles, which required in-house aflatoxin testing. This HACCP plan had previously been assessed by the inspectors.

The inspectors from EFET conducted their controls on the implementation of procedures food safety systems based on HACCP principles.

At prefecture level, inspectors focused mainly on general hygiene prerequisites. Procedures based on HACCP principles were not fully assessed, as the inspector did not ask about the critical limits established that separate acceptability from unacceptability and the corrective actions taken when FBO's monitoring indicated deviations.

Conclusions

The assessment of procedures on HACCP principles in some establishments was not fully carried out according to Article 10(2)(d) of Regulation (EC) No 853/2004.

5.2.8 *Guides to good hygiene practice*

Legal requirements

Article 7 of Regulation (EC) No 852/2004 requires that Member States encourage the development of national guides to good practice for hygiene and for the application of HACCP principles in accordance with Article 8, which requires Member States to assess national guides and forward to the Commission national guides complying with the requirements of that Article.

Article 10(2)(d) of Regulation (EC) No 853/2004 requires that official controls on food shall include the assessment of procedures on GMP, GHP and HACCP, taking into account the use of guides drafted in accordance with Community legislation.

Findings

There have been no changes in the number of guides since the last report. Fifteen Guides to GHP are published (see report DG SANCO 7201/2007, section 5.3.8).

The mission team observed that the FBO of these establishments had GHP guides in place and they were following them to some extent. Those guides were also used by the inspectors during the inspection. The mission team noted that these GHP guides did not contain critical limits or corrective measures, and therefore were not in line with Article 5 of Regulation (EC) No 852/2004.

Conclusions

There are 15 Guides to GHP in Greece. The guide used at the restaurant visited does not fully address the relevant requirements of Article 5 of Regulation (EC) No 852/2004.¹

5.3 LABORATORIES

Legal requirements

Article 4(2)(c) of Regulation (EC) No 882/2004 requires CAs to ensure that they have access to an adequate laboratory capacity.

Article 11 of Regulation (EC) No 882/2004 requires that sampling and analysis methods used in the context of official controls comply with relevant Community rules.

Article 12 of Regulation (EC) No 882/2004 requires CAs to designate laboratories that may carry out the analysis of samples taken during official controls.

Article 33 of Regulation (EC) No 882/2004 requires MS to designate National reference laboratories (NRL) for each Community reference laboratory (CRL) referred to in Article 32. The NRL shall collaborate with the CRL, coordinate activities, organise comparative tests, ensure dissemination of information, and provide scientific and technical assistance.

Findings

General organisation

Currently, there are six designated laboratories (divisions of GCSL laboratories) relevant for import controls within the scope of this mission. Three of the five food laboratories are responsible for mycotoxin analysis, the others are responsible for analysis of Sudan dyes.

Private laboratories are also used for the official analysis of aflatoxins. This is the case, in particular, during periods when the number of samples increases and the official laboratories do not have sufficient capacity to satisfy the needs for analysis.

With regard to microbiological analysis, some of the laboratories used are not accredited according

¹ *In their response to the draft report the Competent Authority noted that the GHP guide has been drafted to describe specific hygiene requirements laid down by law and the measures to be implemented so as to comply with these requirements. To simplify it the guidelines did not include details on the nature of the risks and the official definition of CCPs and critical limits. Nevertheless there is a clear reference to specific points which should be controlled during the production process, the preventive measures to be taken at these points and the monitoring methods. The EFET, mindful of the existing need to ensure that the mass catering establishments carry out own checks, has added to the existing guide a table with specific corrective actions to be taken in cases of derogations.*

to EN ISO/IEC 17025. The exact number is not known and EFET is collecting information to ascertain the current situation.

The NRL for mycotoxins is the GCSL, Environment- Laboratory Division, located in Athens. This laboratory is accredited to EN ISO/IEC 17025 for the relevant methods.

There are also NRL for E Coli, Campylobacter spp., *Listeria monocytogenes*, and Staphylococcus.

It was not possible to check compliance with Article 33 of Regulation (EC) No 882/2004 as the mission team did not visit these laboratories. Nevertheless, the mission team was informed that these laboratories are accredited to EN ISO/IEC 17025 as required by Article 33.3 of Regulation (EC) No 882/2004, and several comparative tests have been organised.

Laboratory visited

The mission team visited the Institute of Food Hygiene, at the Centre of Veterinary Institutes of Thessaloniki, under the MRDF. This laboratory is not accredited to EN ISO/IEC 17025 on general requirements for the competence of testing and calibration laboratories and no application has been submitted to the accreditation body due to the lack of funding.

The microbiology laboratory visited conducts analyses of food and water samples for microbiological criteria. It had no quality manual and there were no written Standard Operational Procedures. Nevertheless, the mission team was shown diagrams describing the different steps for the methods used. These diagrams were based on relevant ISO Standards which were adopted by the laboratory.

The microbiological methods used by the laboratory for the examination of the ready-to-eat foods and water samples were ISO methods for detection and enumeration of *Listeria monocytogenes*, detection of *Salmonella spp*, enumeration of beta-glucuronidase-positive *Escherichia coli*. MPN technique and colony counting, detection and enumeration of *Enterobacteriaceae*, enumeration of coagulase positive (*Staphylococcus aureus*), detection of staphylococcal enterotoxins, among others.

The laboratory had been rebuilt in 2008. The layout and available equipment were adequate. The laboratory is adequately staffed.

The laboratory did not possess any Certified Reference Materials or Reference Materials. As a result, such materials were not used for the internal quality control system of the laboratory, for the production of standard curves or for the verification of the methods used. Instead, a daily negative control was used and was run in parallel to each microbiological test conducted.

Expired culture media were stored in storage cupboards and also in refrigerators. The mission team was informed that this was due to the fact that the distribution of consumables is centralised and thus consumables expire before they can be used.

The mission team was informed that, in some cases, expired culture media were used for the microbiological analysis of foodstuffs. Nevertheless, according to the laboratory staff, all the samples which were submitted by EFET were examined with non expired media due to the fact that EFET pays for the culture media and other materials that are used for the tests.

The traceability in the laboratory was limited. There were no satisfactory records of the media used, or of who did the test and who read the results.

The laboratory participated in three Proficiency Tests in 2008; two were unsuccessful and one was successful. The mission team was informed by the staff of the laboratory that expired culture media had been used in several Proficiency Tests, which had led to unsatisfactory results.

After the visit to the laboratory, the mission team was informed by EFET about their decision to terminate their contractual relationships with the abovementioned laboratory. Moreover, the MRDF informed the mission team that they were unaware of this situation and that appropriate instigations will be carried out immediately.

Conclusions

Not all laboratories designated to perform official controls are approved and accredited to EN ISO/IEC 17025.

The layout of the laboratory is adequate; it is well staffed and equipped.

The visited laboratory is not accredited and had never applied for accreditation. There is no quality system in place and no quality procedures are implemented, which is not in line with Article 18 of Commission Regulation (EC) No 2076/2005.

Expired consumables (culture media and reagents) were found and, according to the staff, these were also used for analysis.

5.4 RAPID ALERT SYSTEM FOR FOOD AND FEED

Legal requirements

Article 50 of Regulation (EC) No 178/2002. Where a MS has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information must be immediately notified to the Commission under the rapid alert system.

Article 19(3) of Regulation (EC) No 882/2004. Where it/this article does not permit the introduction of feed or food, the CA shall notify the Commission and other MS of its findings and of the identification of the products concerned in accordance with the procedure provided for in Article 50(3) of Regulation (EC) No 178/2002 and shall notify its decision to the customs services, together with information as regards the final destination of the consignment.

Findings

There have been no changes since the last mission (see report DG SANCO 8114/2006, section 7.6). The National Contact for the RASFF system is EFET.

EFET has issued guidelines (6975/13-4-07, 9884/26-6-08 and 10473/4-7-08), which are constantly being updated and have been forwarded to all inspection authorities; these guidelines can be found on the EFET website. They contain information as to when and how each inspection authority should notify EFET, which is the contact point for RASFF in Greece, and provide any information to determine what represents a serious direct or indirect risk.

The mission team assessed several RASFF files. One file contained a consignment intended for import into Greece from China with an expired certificate. Although the consignment was rejected and was notified by the prefecture to the RCPPQC, the latter never notified this to EFET. The other file contained documentation of a consignment of pistachios from the USA that was rejected, but this was never notified to the RCPPQC by the prefecture.

No instructions or procedures as regards to RASFF were available at the designated point of import visited.

There is specific supervision by EFET in the area of RASFF. In 2008, problems were identified in the sense that some rejections of imported consignments at the border were notified to the EU and this was due to a change of staff . Consequently, in 2009 it was decided to extend the supervision in this field so that it was carried out on a monthly basis instead of on an annual basis.

Conclusions

An adequate communication network has been established to transfer information to and from the RASFF contact point in EFET.

Not all rejected consignments are notified to the RASFF system which is not in compliance with Article 19(3) of Regulation (EC) No 882/2004.

Several instructions have been circulated from EFET to all the relevant CAs. However, these instructions were not available at the DPI visited.

6 OVERALL CONCLUSIONS

Overall, official controls at import and on food hygiene of foodstuffs of non-animal origin are not fully in compliance with the relevant Community legislation. A number of deficiencies have been identified, mainly related to risk-based criteria for controls, assessment of procedures based on HACCP, laboratories and RASFF.

7 CLOSING MEETING

A closing meeting was held on 13 May with the central competent authorities, EFET, MRDF, GCSL and Customs. At this meeting, the inspection team presented the initial findings and conclusions of the mission.

The representatives of the CAs provisionally accepted these findings and offered some clarifications and comments.

8 RECOMMENDATIONS

It is recommended that the Competent Authority of Greece:

N°.	Recommendation
1.	Ensure that CAs carry out official controls regularly, on a risk basis and with appropriate frequency in line with Article 3(1) and Article 15(1) of Regulation (EC) No 882/2004.
2.	Ensure that the required Common Document for checks performed on foodstuffs covered by Commission Decision 2006/504/EC is used (Annex III) in line with its Article 1(7).

N°.	Recommendation
3.	Ensure that the area available for unloading and sampling of consignments is adequately covered in line with Article 4(2)(c) of Commission Decision 2006/504/EC and Article 16(3) of Regulation (EC) No 882/2004.
4.	Ensure that, in the case of non-compliant consignments for import that are to be re-dispatched, the CAs follow Article 21(1)(a) and (b) of Regulation (EC) No 882/2004.
5.	Ensure that official controls include the assessment of HACCP principles (Article 5 of Regulation (EC) No 852/2004) as set out in Article 10(2)(d) of Regulation (EC) No 882/2004.
6.	Ensure that all designated laboratories comply with Article 12 of Regulation (EC) No 882/2004, or are availing of the derogation provided for in Article 18 of Commission Regulation (EC) No 2076/2005.
7.	Ensure that rejections of imported consignments are always immediately notified to the Commission under the RASFF system, in accordance with Article 50(3)(c) of Regulation (EC) No 178/2002.

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

http://ec.europa.eu/food/fvo/ap/ap_gr_2009-8142.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 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
Reg. 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
Reg. 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
Reg. 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
Reg. 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
Reg. 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
Dec. 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 to contamination risks of these products by aflatoxins

Legal Reference	Official Journal	Title
Dir. 2002/32/EC	OJ L 140, 30.5.2002, p. 10-22	Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement
Dir. 98/68/EC	OJ L 261, 24.9.1998, p. 32-38	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
Reg. 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
Dec. 2005/402/EC	OJ L 135, 28.5.2005, p. 34-36	2005/402/EC: Commission Decision of 23 May 2005 on emergency measures regarding chilli, chilli products, curcuma and palm oil
Dir. 80/777/EEC	OJ L 229, 30.8.1980, p. 1-10	Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters
Dir. 2000/13/EC	OJ L 109, 6.5.2000, p. 29-42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs