FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

ITALY

FROM 07 TO 14 SEPTEMBER 2010

IN ORDER TO EVALUATE IMPORT CONTROLS ON FOOD OF PLANT ORIGIN

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 a footnote.
Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) specific audit in Italy that took place between 7 and 14 September 2010, as part of the general audit of Italy carried out under the provisions of Regulation (EC) No 882/2004 on official food and feed controls.

The objectives of the specific audit were to check that official controls are carried out in accordance with the principles of the above Regulation and in line with the multi-annual national control plan (MANCP) as specified in Article 41 of the Regulation. Accordingly, the specific audit evaluated the implementation of EU legislation in the areas of import controls on food of non-animal origin (FNAO).

The competent authorities (CAs) have been designated. The CAs have legal powers to carry out official controls using appropriate methods and techniques in accordance with documented procedures. Communication between, and within the CAs is adequate. The CA has a sufficient number of qualified and trained staff available.

There is a general crisis plan which could be used in the event of an emergency. Provisions have been put in place to ensure transparency and confidentiality. Measures in the event of non-compliance and sanctions are available to the inspectors. Procedures for verifying official controls are in place; however, there were difficulties in generating statistical data.

Designated points of entry (DPEs) and designated points of import (DPIs) have been appropriately designated by the CA. DPEs/DPIs visited comply with the requirements laid down in Article 4 of Regulation (EC) No 669/2009 and Article 6 of Regulation (EC) No 1152/2009. Import control procedures generally comply with the EU legislation.

In the first two quarters of 2010 the reported frequency of sampling of three commodity products subject to Regulation (EC) No 669/2009 was lower than required by the Regulation.

There are prior notification procedures in place for FNAO subject to Regulations (EC) Nos 669/2009 and 1152/2009, 1151/2009 and 258/2010. However, the importers do not always follow them. RASFF procedures are in place in the framework of import controls and comply with the legal requirements. The observed sampling demonstrations for aflatoxins were adequate.

Laboratories within the scope of this mission are clearly designated but are not in all cases accredited to EN ISO 17025. In the laboratory visited the quality of analytical results is not sufficiently supported by data on homogeneity of sample preparation, regular recovery checks and participation in relevant proficiency tests.

Overall, Italy has an effective and clearly defined, centralised system in place for import controls on food of plant origin. Some minor shortcomings were identified concerning the reported frequency of sampling, prior notification procedures and quality control in the laboratory visited.

The report makes a number of recommendations to the Italian competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.
Table of Contents

1 INTRODUCTION ........................................................................................................... 1
2 OBJECTIVES OF THE MISSION ................................................................................ 1
3 LEGAL BASIS FOR THE MISSION ............................................................................. 2
4 BACKGROUND ........................................................................................................... 2
  4.1 CONTRIBUTION TO THE GENERAL AUDIT ....................................................... 2
  4.2 BACKGROUND TO THE SERIES OF MISSIONS ON IMPORT CONTROLS FOR FNAO ................................................................................................................. 3
5 FINDINGS AND CONCLUSIONS .............................................................................. 4
  5.1 COMPETENT AUTHORITIES ............................................................................. 4
    5.1.1 DESIGNATION OF COMPETENT AUTHORITIES ............................................ 4
    5.1.2 CO-OPERATION BETWEEN COMPETENT AUTHORITIES ....................... 5
    5.1.3 CO-OPERATION WITHIN COMPETENT AUTHORITIES ......................... 6
    5.1.4 DELEGATION OF SPECIFIC TASKS RELATED TO OFFICIAL CONTROLS .......... 6
    5.1.5 CONTINGENCY PLANNING ......................................................................... 6
  5.2 RESOURCES FOR PERFORMANCE OF CONTROLS ............................................ 7
    5.2.1 LEGAL BASIS FOR CONTROLS ................................................................ 7
    5.2.2 STAFFING PROVISION AND FACILITIES .................................................. 8
    5.2.3 STAFF QUALIFICATIONS AND TRAINING .................................................. 8
  5.3 ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS .......... 9
    5.3.1 REGISTRATION / APPROVAL OF FOOD BUSINESS OPERATORS .................... 9
    5.3.2 PRIORITISATION OF OFFICIAL CONTROLS .............................................. 9
    5.3.3 CONTROL ACTIVITIES, METHODS AND TECHNIQUES .............................. 10
    5.3.4 SAMPLING AND LABORATORY ANALYSIS .............................................. 10
    5.3.5 PROCEDURES FOR PERFORMANCE AND REPORTING OF CONTROL ACTIVITIES .................................................................................................................. 11
    5.3.6 TRANSPARENCY AND CONFIDENTIALITY ................................................ 12
  5.4 ENFORCEMENT MEASURES .............................................................................. 13
    5.4.1 MEASURES IN THE EVENT OF NON-COMPLIANCE ................................... 13
    5.4.2 SANCTIONS ............................................................................................... 13
  5.5 VERIFICATION AND REVIEW OF OFFICIAL CONTROLS AND PROCEDURES ... 13
    5.5.1 VERIFICATION PROCEDURES ................................................................... 13
    5.5.2 AUDIT ....................................................................................................... 14
  5.6 MULTI-ANNUAL NATIONAL CONTROL PLAN .................................................... 14
6 SECTOR-SPECIFIC FINDINGS AND CONCLUSIONS ............................................ 15
  6.1 LEGISLATION ..................................................................................................... 15
  6.2 REQUIREMENTS ALONG THE FOOD CHAIN FOR IMPORT CONTROLS OF FOOD OF NON-ANIMAL ORIGIN ................................................................. 16
    6.2.1 DESIGNATED PLACES OF IMPORT ........................................................... 16
    6.2.2 PRIOR NOTIFICATION OF CONSIGNMENTS ............................................ 17
    6.2.3 PROCEDURES FOR IMPORT CONTROLS .................................................. 18
    6.2.4 SPLITTING OF CONSIGNMENTS ............................................................... 21
    6.2.5 FEES AND COSTS ..................................................................................... 21
    6.2.6 PROCEDURES FOR NON-COMPLIANT LOTS .......................................... 23
    6.2.7 RAPID ALERT SYSTEM FOR FOOD AND FEED ...................................... 24
    6.2.8 LABORATORIES CARRYING OUT OFFICIAL CONTROL ANALYSIS ........... 24
7 OVERALL CONCLUSIONS ....................................................................................... 27
8 CLOSING MEETING .................................................................................................. 27
9 RECOMMENDATIONS .............................................................................................. 27
ANNEX 1 - LEGAL REFERENCES .................................................................................. 28
### Abbreviations and Definitions Used in This Report

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPAs</td>
<td><em>Aziende Provinciali per la Protezione Ambientale</em> (Provincial Environmental Protection Agencies)</td>
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<tr>
<td>ARPAs</td>
<td><em>Aziende Regionali per la Protezione Ambientale</em> (Regional Environmental Protection Agencies)</td>
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<tr>
<td>ASLs</td>
<td><em>Aziende Sanitarie Locali</em> (Local Health Agencies)</td>
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<tr>
<td>BIP</td>
<td>Border Inspection Post</td>
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<td>CA</td>
<td>Competent Authority</td>
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<td>CCA</td>
<td>Central Competent Authority</td>
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<td>CED</td>
<td>Common Entry Document</td>
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<td>CT</td>
<td><em>Carabinieri per la Tutela della Salute</em> (Carabinieri for Healthcare)</td>
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<tr>
<td>DGSA</td>
<td><em>Direzione Generale Sanità Animale e Farmaco Veterinario</em> (Directorate General for Animal Health and Veterinary Drugs)</td>
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<tr>
<td>DG(SANCO)</td>
<td>Health and Consumers Directorate-General</td>
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<tr>
<td>DGSAN</td>
<td><em>Direzione generale della sanità pubblica veterinaria, degli alimenti e della nutrizione</em> (Directorate General for Veterinary Public Health, Food and Nutrition)</td>
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<tr>
<td>DGPREV</td>
<td><em>Direzione generale della Prevenzione</em> (Directorate General for Prevention)</td>
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<td>DL</td>
<td>Decree-Law</td>
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<td>DPE</td>
<td>Designated Point of Entry</td>
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<td>DPI</td>
<td>Designated Point of Import</td>
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<td>EU</td>
<td>European Union</td>
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<td>FAPAS</td>
<td>Food Analysis Performance Assessment Scheme, UK</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>FBO</td>
<td>Food Business Operator</td>
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<tr>
<td>FNAO</td>
<td>Food of Non-Animal Origin</td>
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<td>FVO</td>
<td>Food and Veterinary Office</td>
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<tr>
<td>HPLC</td>
<td>High Performance Liquid Chromatography</td>
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<tr>
<td>IAC</td>
<td>Immuno Affinity Column</td>
</tr>
<tr>
<td>IOL</td>
<td><em>Istruzioni Operative Locali</em> (Local Operating Instructions)</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organisation for Standardization</td>
</tr>
<tr>
<td>ISS</td>
<td><em>Istituto Superiore di Sanità</em> (National Institute of Health)</td>
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<tr>
<td>IZS</td>
<td><em>Istituto Zooprofilattica sperimentali</em> (Animal Disease Prevention Institute)</td>
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<tr>
<td>MANCP</td>
<td>Single Integrated Multi-Annual National Control Plan</td>
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<td>MoH</td>
<td>Ministry of Health</td>
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<td>MSs</td>
<td>Member States</td>
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<tr>
<td>NRL</td>
<td>National Reference Laboratory</td>
</tr>
<tr>
<td>NSIS-USMAF</td>
<td>Web-based software for data input and data management</td>
</tr>
<tr>
<td>PCP</td>
<td>Pentachlorophenol</td>
</tr>
<tr>
<td>POS 11</td>
<td><em>Procedura Operativa Standard Unificata</em>, an SOP of USMAF/DGSAN</td>
</tr>
<tr>
<td>RASFF</td>
<td>Rapid Alert System for Food and Feedstuffs</td>
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<tr>
<td>SOP</td>
<td>Standard Operation Procedure</td>
</tr>
<tr>
<td>TCs</td>
<td>Third Countries</td>
</tr>
<tr>
<td>USMAFs</td>
<td><em>Uffici di Sanità Marittima, Aerea e di Frontiera</em> (Port, Airport and Border Health Offices)</td>
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1 INTRODUCTION

The specific audit formed part of the Food and Veterinary Office (FVO) planned mission programme. It took place in Italy from 7 to 14 September 2010.

The audit team comprised two inspectors from the FVO and one national expert. Representatives from the competent authorities (CAs) accompanied the audit team for the duration of the audit.

An opening meeting was held on 7 September 2010 with the CAs. At this meeting, the objectives of, and itinerary for, the specific audit were confirmed by the audit team and the control systems were described by the CAs.

2 OBJECTIVES OF THE MISSION

The objectives of the specific audit were:

- to verify that official controls are organised and carried out in accordance with the relevant provisions of Regulation (EC) No 882/2004, and the single integrated multi-annual national control plan (MANCP) prepared by Italy;

- to evaluate the implementation of EU legislation in relation to import controls on food of non-animal origin (FNAO), in particular:
  - Regulation (EC) No 1152/2009 imposing special conditions governing the import of certain foodstuffs from certain third countries (TC) due to contamination risk by aflatoxins and repealing Decision 2006/504/EC;

In terms of scope, the audit concentrated primarily on:

- as regards Regulation (EC) No 882/2004, the organisation of official controls (Articles 3-7), control and verification procedures and methods (Articles 8-10), registration of food establishments (Article 31), enforcement (Articles 54-55), and the MANCP (Articles 41-42);

- the implementation of European Union (EU) legislation regarding FNAO import controls.

The table below lists sites visited and meetings held in order to achieve that objective:

<table>
<thead>
<tr>
<th>MEETINGS/VISITS</th>
<th>No</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMPETENT AUTHORITIES</td>
<td>Central</td>
<td>2 Opening and closing meetings with the Ministry of Health (MoH), Directorate General for Veterinary Public Health,</td>
</tr>
<tr>
<td>MEETINGS/VISITS</td>
<td>No</td>
<td>COMMENTS</td>
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</tr>
<tr>
<td>Regional</td>
<td>2</td>
<td>Food and Nutrition (DGSAN), in the presence of the Ministry of Finance, Customs Agency</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Port, Airport and Border Health Offices (USMAFs) in Livorno and Naples</td>
</tr>
<tr>
<td>LABORATORIES</td>
<td>1</td>
<td>Regional Environmental Protection Agencies (ARPAs) in Livorno</td>
</tr>
<tr>
<td>DESIGNATED POINTS OF ENTRY/DESIGNATED POINTS OF IMPORT/CONTROL POINTS</td>
<td>2</td>
<td>Customs office and USMAF, including observation of sampling by border health inspectors at the port of Naples</td>
</tr>
<tr>
<td>FOOD IMPORTERS</td>
<td>1</td>
<td>Importer of spices in Livorno, including observation of sampling</td>
</tr>
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3 Legal Basis for the Mission

The mission was carried out under the general provisions of EU legislation, and in particular:


A full list of the legal instruments referred to in this report is provided in Annex I and refers, where applicable, to the last amended version.

4 Background

4.1 Contribution to the General Audit

Article 45 of Regulation (EC) No 882/2004 requires the Commission to carry out general and specific audits in Member States (MSs). The main purpose of such audits is to verify that, overall, official controls take place in MSs in accordance with the MANCP referred to in Article 41 and in compliance with EU law.

This specific audit was carried out as part of a general audit of Italy. Section 5 below contains findings and conclusions relating to the implementation of Regulation (EC) No 882/2004; section 6 below contains findings and conclusions relating to sector-specific issues.
4.2 BACKGROUND TO THE SERIES OF MISSIONS ON IMPORT CONTROLS FOR FNAO

A series of missions on import controls for FNAO was carried out by the FVO between 2002 and 2004 in major importing MSs, to assess controls at import on food products of non-animal origin. The second series of missions was undertaken between 2006 and 2008 and covered MSs not included in the first series and follow-up of the previous missions. The scope of this series of missions covered emergency measures for foodstuffs imported from TCs adopted on the basis of Article 53(1)(b)(ii) of Regulation (EC) No 178/2002.

The overview report on the last series of missions is available on the Health and Consumers Directorate-General (DG SANCO) website at:


The report (DG (SANCO)/8119-2006) on the last mission on import controls for FNAO, carried out by the FVO in Italy from 11 to 15 December 2006, can be found at:

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

Increased level of official controls

The relevance of imports of products of non-animal origin from a food safety perspective is witnessed by trade figures and the number of notifications of non-compliant products made to the European Commission via the Rapid Alert System for Food and Feed (RASFF). In 2008 products of non-animal origin represented more than 90% of total EU food imports. In the same year nearly 67% of RASFF notifications were triggered by import controls on feed and FNAO.

Based on Article 15(5) of Regulation (EC) No 882/2004, Regulation (EC) No 669/2009 requires MSs to carry out an increased level of official controls on imports of certain feed and FNAO from specific TCs.

Following its publication in July 2009, the Regulation has been applicable since 25 January 2010. It introduces a set of uniform rules for performing official checks on food and feed imports of non-animal origin of known or emerging risk.

Emergency measures

Over the past few years risks have been identified concerning some imported products including:

– Mycotoxins in different foodstuffs such as nuts, almonds, dried fruits and derived products from different TCs. Mycotoxins are naturally occurring metabolites produced by certain species of moulds (e.g. Aspergillus spp, Fusarium spp). 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.

– Sunflower oil from Ukraine contaminated by mineral oil. Sunflower oil originating from Ukraine was found to be contaminated with high levels of mineral oil in the year 2008. Based on exposure estimates, the European Food Safety Authority, EFSA, concluded that exposure to sunflower oil contaminated with high viscosity mineral oil, although undesirable for human consumption, would not be of public health concern in this case.
– Guar gum and its food and feed compounds containing at least 10% originating in or consigned from India, contaminated by pentachlorophenol (PCP) and dioxins. The RASFF received in 2007 a notification from an MS concerning a finding of serious contamination by dioxins and PCP in guar gum originating from India.

In all the cases specific Commission Decisions on emergency measures were adopted on the basis of Article 53(1)(b)(ii) of Regulation (EC) No 178/2002. They specify conditions of import, pre-notification of consignment arrival and official controls to be carried out by MSs such as documentary, identity and physical checks, including sampling with a specific frequency. In most cases the Decisions were revised and repealed by Regulations.

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

5.1.1 Designation of competent authorities

Legal requirements

Article 4(1) of Regulation (EC) No 882/2004 requires MSs to designate the CAs responsible for official controls.

Findings

The structure, organisation and designation of competences of the CAs are described in detail in Italy’s MANCP, accessible on the CA’s website:

http://www.ministerosalute.it/sicurezzaAlimentare/piani

and in FVO report DG (SANCO)/8105/2009 Country Profile for Italy:

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

DGSAN is the competent central authority for official controls on food of non-animal origin and food hygiene. Within DGSAN, Office II is responsible for all issues to do with the safety of products of plant origin and for policy guidance on import controls in that sector.

Controls on imported food of non-animal origin are carried out by 12 USMAF offices. They have 37 local units at the main points of entry to and exit from Italy (roads, ports and airports), mainly staffed by health technicians supervised by a medical doctor. Their responsibilities include a wide range of activities to control health risks and prevent diseases imported from abroad. Checks on products of plant origin accounted for about 48.3% of USMAFs’ work in 2009.

USMAFs report to the Directorate General for Prevention (DGPREV) within the Ministry of Health for coordination and administrative matters.

Import controls on feed of non-animal origin (including guar gum under Regulation 258/2010 intended for animal consumption) are the responsibility of the Directorate General for Animal Health and Veterinary Drugs (DGSA). Its mandate includes policy setting and preparation of legislation, administrative supervision, planning and supervision of inspection and controls.
Subordinated to the 2 offices are 36 border inspection posts (BIPs), implementing legislation and producing activity reports on a quarterly basis.

Since mission SANCO 9131/2003 the role of the Customs Agency has remained unchanged. Apart from releasing imported goods into free circulation, Customs officials perform documentary checks on manifests provided by the importer. Within the scope of the mission, Customs are also required to ensure that all imports concerned are accompanied by USMAF health certificates/Common Entry Documents (CEDs).

Local health agencies (ASLs) are not directly involved in import controls unless the food or feed concerned is sent to its destination, on the national territory, under a health restriction order, issued by the USMAF offices. In such cases, official inspections are carried out by the ASLs under the jurisdiction of the regions.

In exceptional circumstances, the regional offices of the Carabinieri per la Tutela della Salute (CT, the Carabinieri for Healthcare) could be asked by the MoH to perform inspections and samplings on food and feed. This has happened recently in the case of imports of rice falling under Commission Decision 2006/601/EC.

5.1.2 Co-operation between competent authorities

Legal requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities.

Article 24 of Regulation (EC) No 882/2004 requires that, for the organisation of official controls, the CAs and the Customs services must cooperate closely.

Findings

Evidence was provided of good cooperation between the CAs involved in import controls. The MoH and Customs Agency have signed a memorandum of understanding that specifies the fields of cooperation, and both institutions follow this approach also at regional level. At present they are working together on a software project to provide faster access to relevant information in the field of import controls.

DGSAN Office II regularly informs Customs of any decision adopted which involves restrictions on imports of specific commodities and has submitted a list of products considered to be of higher risk for inclusion in the Customs inspection system.

For example, the information on the 2009 Regulations on import controls was communicated via official letters and e-mails to the USMAFs and to the Customs offices at the same time.

The mission team observed in Livorno and Naples that USMAFs and Customs cooperate on a regular basis. Customs were informed about new amendments and legislation by the USMAFs. Customs (in their local offices) were using specific software called AIDA. The software is regularly updated and it indicates that consignments with specific TARIC (Integrated Tariff of the European Communities) codes and from specific countries cannot be released before USMAF checks are performed.

The mission team observed good cooperation between USMAFs and ASLs. Cooperation between
the USMAF and the ARPA showed deficiencies in Naples in terms of documented definition of tasks.

5.1.3 Co-operation within Competent Authorities

Legal requirements

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a CA, more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation must be ensured between the different units.

Findings

Communication within the CA for food of non-animal origin was demonstrated in relation to new legislation, RASFF notifications and USMAF reports on import controls carried out. In principle, the information is submitted by means of official letters, published on the official website of the Ministry of Health and/or provided by e-mail. Furthermore, meetings are held at central and regional/local level in order to improve communication, identify emerging problems and propose solutions.

5.1.4 Delegation of specific tasks related to official controls

Legal requirements

Article 5 of Regulation (EC) No 882/2004 sets out the scope of possible delegation to control bodies, the criteria for delegation, and the minimum criteria that must be met by control bodies. Where such delegation takes place, the delegating CA must organise audits or inspections of the control bodies as necessary. The Commission must be notified of any intended delegation.

Findings

No official tasks have been delegated to any control bodies in the area covered by this FVO audit.

5.1.5 Contingency planning

Legal requirements

Article 4 of Regulation (EC) No 882/2004 also requires that competent authorities have contingency plans in place, and are prepared to operate such plans in the event of an emergency. Article 13 of Regulation (EC) No 882/2004 requires MSs to draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to present a serious risk.
Findings

Drafting of the National Contingency Plan is the responsibility of Office VIII of DGSAN. The Conferenza Stato/Regioni (CSR, Standing Conference between Central Government and Regions) adopted Act 6/CSR of 24 January 2008 to implement the contingency plan for food and feed; on 15 May 2009 a Crisis Unit was set up, physically located at central competent authority (CCA) headquarters (room AK 48) and supplied with an e-mail address. The CCA stated that similar Crisis Units had also been set up at regional and local levels. A database with the contact points at regional and local levels is currently under construction at CCA level.

A working group was created on 29 April 2010 to draft specific emergency programmes based on updating the existing ones.

A three-day training event on ‘Food safety emergencies: procedures and management’ for 100 participants was held in May, including a simulation exercise.

Training that includes import aspects is taking place in September and a meeting is scheduled for October.

Conclusions on competent authorities

The CAs in the context of this mission have been designated. Horizontal communication between the CAs, including Customs authorities, is in general ensured. Cooperation within the CAs is adequate. There is no delegation of tasks related to the official controls in the context of this mission. There is a general contingency plan that could be used in the event of an emergency as required by Articles 4 and 13 of Regulation (EC) No 882/2004.

5.2 Resources for performance of controls

5.2.1 Legal basis for controls

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires that the necessary legal powers to carry out controls are in place and that there is an obligation on food business operators (FBOs) to undergo inspection by the CAs.

Article 8 of the above Regulation requires that CAs have the necessary powers of access to food business premises and documentation.

Findings

Public officials have powers of entry and inspection by virtue of Law 689/1981 (Article 13). Staff performing official controls at all levels have the status of civil servant and judicial police under Article 357 of the Criminal Code and also under Articles 17 and 22 of Law 441/1963. Furthermore, inspectors may request assistance from the CT (Article 3 of Law 283/1962).

In addition to the powers of control and verification conferred on the regional competent
authorities, the MoH, as CCA, has inspection powers to verify conformity with European and national legislation as laid down in Decree-Law (DL) No 112/1998 (regarding the delegation of functions and tasks from the Central Government to the Regions — Law 283/1962, DPR 327/1980).

The activity of the USMAFs is governed by the Decree of 2 May 1985 (Agreement Central Government — Regions, 2000), and includes the controls on FNAO products imported from third countries for human consumption.

5.2.2 Staffing provision and facilities

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires the CAs to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free from any conflict of interest.

Findings

The total number of staff employed by the USMAFs decreased from 544 in 2006 to 481 in 2010, of whom 80 are medical doctors and 401 are technical and administrative staff. The CCA informed the mission team that the reduction of staff reflected the decline in needs after the end of the SARS epidemic. A sufficient number of suitably qualified and experienced staff to perform the prescribed checks on consignments was met by the mission team during the visits.

The Decree of 28 November 2000 establishes a code of conduct for civil servants and lays down the obligations of public officials as regards independence and involvement in other activities. In addition, there are a number of provisions in the Criminal Code: Articles 314, 317, 318 and 319, 323, and 326.

The two DPEs and the laboratory visited have adequate facilities and sufficient equipment in place.

5.2.3 Staff qualifications and training

Legal requirements

Article 6 of Regulation (EC) No 882/2004 requires CAs to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

Findings

DGSAN and DGPREV provide USMAF directors with regular training and training materials on import controls. USMAF directors afterwards act in the USMAF offices as trainers on the issues concerned.
A training course on ‘New EU Regulations, in particular Regulation 669/2009’ was conducted this year from 29 to 30 March and was attended by 45 USMAF/Territorial Unit directors and technicians. The USMAF directors participating in the above training were given the slides and asked to train the staff in their offices.

Annual training activities are provided by the 'Istituto Superiore di Sanità' (ISS, the National Institute of Health) and/or organised by the regional/local organisations on an ongoing basis. Since 2004, the ISS has organised 5 courses on the occurrence of mycotoxins in the food and feed chain and on sampling for mycotoxin analysis. The USMAF inspectors met during the mission did attend locally organised training sessions, generally provided by their superiors.

The ISS provided in 2007 a specific training session on sampling for USMAF and Customs officials. They also provide training on demand.

Since January 2008 a management standard operating procedure (SOP) has been in force, ‘G 106, Education and Training of USMAF personnel’. It describes how to deal with periodic training for USMAF staff.

**Conclusions on resources for performance of controls**

The CAs have adequate legal powers to carry out official controls and legal procedures are in place to give them access to the premises of and documentation kept by the FBOs as required by Articles 4 and 8 of Regulation (EC) No 882/2004.

The CA has a sufficient number of qualified and trained staff available. A training plan was implemented and training regarding new legislation had already been provided.

### 5.3 Organisation and implementation of official controls

#### 5.3.1 Registration / approval of food business operators

**Legal requirements**

Article 31 of Regulation (EC) No 882/2004 requires MSs to establish procedures for the registration/approval of food and feed business operators, for reviewing compliance with conditions of registration and for the withdrawal of approvals.

**Findings**

All FBOs active in Italy must be registered at regional level. They are inspected and approved by the regional authorities. Specific registration for FBOs involved in importing FNAO is not required in Italy.

#### 5.3.2 Prioritisation of official controls

**Legal requirements**

9
Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. Controls must be carried out at any of the stages in the production and processing chain and, in general, are to be carried out without prior warning. Controls are to be applied with the same care to exports from the EU, imports into the EU and products placed on the EU market.

Article 16 of Regulation (EC) No 882/2004 requires that physical checks on imports of FNAO are carried out at a frequency depending on the risk associated with different types of feed and food.

Findings

For all imports of foodstuffs from third countries that are not covered by specific EU legislation, the Presidential Decree of 14 July 1995 sets a minimum sampling frequency of 5%. In 2009 permission was requested to import about 82000 consignments into Italy, of which 5.6% were sampled and 0.29% were rejected.

In general, it is left to the USMAF offices to decide on the sampling frequency for specific commodities. The decisions on sampling, other than those required by EU Regulations, are based on RASFF alerts, previous experience with the same importer/FBO and previous infringements. There are no special agreements between Italy and third countries regarding lower frequency of import controls.

5.3.3 Control activities, methods and techniques

Legal requirements

Article 10 of Regulation (EC) No 882/2004 specifies the control activities, methods and techniques that should be deployed.

Findings

Documentary, identity and physical checks including sampling are used as control methods during the everyday duties of the USMAF inspectors responsible for import controls on FNAO.

5.3.4 Sampling and laboratory analysis

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires CAs to have, or have access to, adequate laboratory capacity. Article 11 of the Regulation establishes requirements for sampling and analysis and Article 12 requires the CA to designate laboratories that may carry out analysis of samples taken during official controls. It also lays down accreditation criteria for laboratories so designated.

Findings

The SOPs regarding sampling during import control activities are described in ‘Procedura Operativa
Standard Unificata’ POS 11 USMAF/DGSAN, issued in January 2008 and most recently revised in June 2010, while more specific rules — according to local needs — are set out in local operating instructions, the Istruzioni Operative Locali (IOL) adopted by each USMAF.


Accredited laboratories are designated for carrying out the analysis of commodities listed in Annex I as per Article 4(c) of Regulation (EC) No 669/2009. The USMAF offices send the samples to public, accredited laboratories for analysis. However, a consignment of pistachios from the US sent for sorting was resampled by an ASL and this sample was analysed by the ARPA laboratory in Naples, which is not accredited yet.

These laboratories include two major networks:

1. The IZS network, which covers the whole national territory and is composed of 10 Head Offices located in the cities of Brescia, Foggia, Padua, Palermo, Perugia, Portici (Naples), Rome, Sassari, Teramo and Turin and over 90 Diagnostic Sections present in almost all Italian provinces.

2. The network of regional laboratories coordinated by the Regions and by ‘Istituto Superiore per la Protezione e la Ricerca Ambientale’, the National Institute for Environmental Protection and Research. It belongs to a network system known as the Environmental Agency System. In Italy, there are currently 21 ARPAs and Provincial Agencies (APPAs) established under specific Regional Laws.

The average turnaround time for delivery of laboratory analyses depends on the test to be carried out and varies between a minimum of 3 days and a maximum of 15 days. The CA stated that they are not aware of any procedure established by the laboratories for the prioritisation of the analyses required by Regulation (EC) No 669/2009, with the exception of ARPAL Liguria and ARPAM Marche.

The ISS was designated as national reference laboratory for mycotoxins. The ISS provides a central laboratory for the development of analytical methods and for the training of regional laboratory staff. In certain cases it carries out counter-analyses. It does not organise proficiency tests regarding mycotoxins in all relevant matrices listed in specific EU import control legislation (Regulations (EC) Nos 669/2009 and 1152/2009) and toxins, namely aflatoxin in nuts and peanuts, as required by Article 33 of Regulation (EC) 882/2004.

5.3.5 Procedures for performance and reporting of control activities

Legal requirements

Article 8 of Regulation (EC) No 882/2004 requires CAs to carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Article 9 of the above Regulation requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Findings
The CAs generally have written instructions and check-lists covering the areas to be controlled. Since 2008 DGSAN has agreed with the USMAFs a unified SOP, POS 11, which describes the activity and gives instructions to the medical doctors and technicians working in the USMAFs regarding import controls.

The health technicians of the USMAFs draw up a report on the inspection (including all data on the goods) countersigned by the other persons present at the time of sampling.

The USMAF offices issue the health authorisation if, on the basis of the accompanying documents, a decision against carrying out an inspection and/or analysis is taken. When samples are taken, the USMAF offices order the health certificate/CED to be issued once the results of the analysis carried out on the goods have arrived from the laboratory and it has been verified that the goods comply with the applicable legislation.

Goods are released by Customs on the basis of the necessary documentation duly filled in and provided the health certificate/CED has been presented.

5.3.6 Transparency and confidentiality

Legal requirements

Article 7 of Regulation (EC) No 882/2004 requires CAs to carry out their activities with a high degree of transparency, in particular by giving relevant information to the public as soon as possible. However, information covered by professional secrecy and personal data protection is not to be disclosed.

Findings

General audit reports, annual reports on control activities in the framework of the MANCP and rapid alert notifications are published on the website of the CCA.

The USMAFs and the FBOs use an IT application, web-based software for data input and data management (NSIS-USMAF), with different access for USMAF personnel and FBOs, for the purpose of issuing the CED. When EU Regulation (EC) No 669/2009 entered into force (January 2010), a message appeared to both the USMAF personnel and the FBOs. The message was available on the first page of the application until 28 February 2010.

Disclosure of confidential information is an offence under Article 326 of the Criminal Code.

Conclusions on the organisation and implementation of official controls

FBOs, including importers, are subject to registration requirements. Within the scope of this mission official controls are organised in accordance with the requirements and criteria of Article 3 of Regulation (EC) No 882/2004. Tasks related to official controls are carried out using appropriate methods and techniques. The USMAFs carry out their official controls in accordance with documented procedures supported by web-based software for data input and data management. Laboratories for import controls on FNAO are clearly designated but not accredited in all cases. The

Provisions have been put in place to ensure adequate transparency and confidentiality.

5.4 **ENFORCEMENT MEASURES**

5.4.1 *Measures in the event of non-compliance*

**Legal requirements**

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation.

**Findings**

Where illegal activities are suspected, or when there is an immediate risk for human or animal health, the action taken can include assistance from the CT or other police bodies, and must be reported to the public prosecutor.

5.4.2 *Sanctions*

**Legal requirements**

Article 55 of Regulation (EC) No 882/2004 requires MSs to lay down the rules on sanctions applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare and to take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

**Findings**

Not applicable in Italy for import controls because goods are not released to the territory of Italy before the checks are performed.

**Conclusions on enforcement measures**

The legal provisions are in place and provide for a range of measures in the event of non-compliance (see also section 6.2.6).

5.5 **VERIFICATION AND REVIEW OF OFFICIAL CONTROLS AND PROCEDURES**

5.5.1 *Verification procedures*

**Legal requirements**
Article 4 of Regulation (EC) No 882/2004 requires the CAs to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls. Article 8 states that they must have procedures in place to verify the effectiveness of official controls, ensure the effectiveness of corrective action and update documentation where needed.

Findings

The CCA frequently monitors the performance of the USMAF regional units, for example in terms of the sampling frequency, the quality of data delivery to the head offices and the duration of controls. These checks could be performed by analysing the data provided via the NSIS-USMAF software system. However, the mission team observed that the DGSAN and USMAF offices faced difficulties in generating data regarding the sampling frequency during the mission. The mission team was informed that statistical routines were being developed for incorporation into the software. Additional checks on import controls are performed on the spot during audits (see below).

5.5.2 Audit

Legal requirements

Under Article 4 of Regulation (EC) No 882/2004 CAs are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Findings

The USMAF offices are audited by DGSAN Office II in cooperation with DGSA Office VIII. Between October and November 2007 the first training course was conducted for 23 auditors (13 from the Rome office and 10 from the local offices). In November 2008 a second course for a new group of 23 auditors took place. From November 2007 to March 2008 a first set of test/training audits on 8 USMAF offices was carried out (2 audits for each auditor). Between June and December 2008 the first 6 actual audits (half of the USMAFs) were carried out. In 2009 only 3 audits were performed. However, in 2010, at the time of the mission, 4 audits had been carried out and the mission team was informed that another 2 audits were scheduled before the end of the year.

Conclusions on verification procedures

Verification procedures are in place and effective. However, there were difficulties in generating statistical data. In DGSAN an audit system for USMAFs is in place in line with Article 4(6) of Regulation (EC) No 882/2004.

5.6 Multi-annual national control plan

Legal requirements
Article 41 of Regulation (EC) No 882/2004 requires each MS to prepare a single integrated MANCP. Pursuant to Article 42 it should be implemented for the first time no later than 1 January 2007 and should be regularly updated in the light of developments. Details are provided on the type of general information to be given on the structure and organisation of the systems of feed and food control and of animal health and welfare control in the MS concerned.

Findings

The current 2007-2010 MANCP includes three sections identifying all control authorities responsible for food and feed safety, animal health, animal welfare and plant health controls, but is not up to date; the CCA considers the structure of the MANCP not to be fully fit for purpose, and too static, and some amendments are necessary. The plan is essentially descriptive and does not provide any significant operational information. However, the MANCP was approved by Act No 133/CSR of 14 June 2007, and the same lengthy procedure is required for amending it.

The national contact point for the Italian MANCP is the Head of the CCA.

The MANCP 2011-2014 is being drafted by Office VIII of DGSAN and is currently at an advanced stage of preparation; it will be made available on the intranet of the CCA. It includes 21 sections (one for each region and autonomous province) that can easily be modified without amending the MANCP itself.

Annual reports on the implementation of the MANCP are published on the internet, with the latest available one covering the year 2008. Regions are requested to supply the CCA with the relevant data concerning the implementation of the control programmes.

Conclusions on the multi-annual national control plan

The MANCP for 2007-2010 is in place but not up to date and the 2011-2014 MANCP is currently being drafted and updated as required by Articles 41 and 42 of Regulation (EC) No 882/2004.

6 Sector-specific findings and conclusions

6.1 Legislation

Findings

For all imports of foodstuffs from third countries not covered by EU legislation, the Presidential Decree of 23 November 1995 sets a minimum sampling frequency of 5% calculated over all products.

Conclusions

There is national legislation on import controls in place laying down additional requirements regarding sampling frequency for FNAO products from TCs.
6.2 Requirements along the food chain for import controls of food of non-animal origin

6.2.1 Designated places of import

Legal requirements

Article 15(2) of Regulation (EC) No 882/2004 requires official controls to be performed at an appropriate place, including the point of entry of goods, the point of release for free circulation, warehouses, the premises of the importing FBOs, or other points of the food chain.

Article 17 of Regulation (EC) No 882/2004 and Articles 3(b) and 5 of Regulation (EC) No 669/2009 establish definitions and specific requirements for the designation of designated points of entry (DPEs) by MSs. Article 4 of Regulation (EC) No 669/2009 lays down minimum requirements for DPEs.

For a period of five years transitional measures are established by Article 19 of Regulation (EC) No 669/2009. On that basis, when a DPE is not equipped with all the necessary facilities, another control point or other control points can be authorised by the MS.

Under Article 9 of Regulation (EC) No 669/2009, on a request by the MS, the Commission may authorise the CA of a certain DPE operating under specific geographical constraints to carry out physical checks at the premises of FBOs.

Articles 2(a) and 6 of Regulation (EC) No 1152/2009 establish definitions and specific requirements for designated points of import (DPIs) for products subject to this Regulation.

Pursuant to Article 5(4) and (5) of Regulation (EC) No 258/2010 the checks on products subject to this Regulation are to be carried out at control points specifically designated by the Member States for that purpose and the list of control points must be made available to the public and communicated to the Commission.

Article 4 of Commission Decision 2008/47/EC requires the documentary check, as referred to in Article 16(1) of Regulation (EC) No 882/2004, to be performed at the point of first arrival in the EU and evidence of this check to accompany the consignment.

Findings

The lists of designated points of entry (DPEs) and designated points of import (DPIs) are published on the official website of the MoH. The list of DPEs consists of 17 USMAF territorial units. All 37 USMAF units are published as DPIs. However, at the time of the mission, no airports had been designated as DPEs in Italy. The CA stated that if a consignment subject to increased import controls under Regulation (EC) No 669/2009 were to arrive, it would be rejected.

The DPEs visited by the mission team comply with Article 4 of Regulation (EC) No 669/2009 in terms of general hygiene conditions in the storage area and the sampling area.

The official controls on sunflower oil originating in, or consigned from, Ukraine are performed by the USMAF at the port where the consignment is presented for import, in a free trade area, and prior to presentation to customs for release for free circulation.

Control points are not needed in Italy; feed including feed that contains guar gum is inspected and sampled by BIPs that are published as DPEs for feed on the website of the MoH.
USMAF/DPEs and BIPs in Italy have always had separate tasks and separate locations. Therefore, their facilities are never shared.

**Conclusions**

DPEs and DPIs have been designated as required by EU legislation. The DPEs/DPIs visited comply with the requirements of Article 6 of Regulation (EC) No 1152/2009 and Article 4 of Regulation (EC) No 669/2009.

6.2.2 *Prior notification of consignments*

**Legal requirements**

Under Article 17(1) of Regulation (EC) No 882/2004, for the organisation of official controls subject to Article 15(5), MSs must require the FBO responsible for consignments to give prior notification of their arrival and nature.

Article 5 of Regulation (EC) No 1152/2009, Article 6 of Regulation (EC) No 669/2009 and Article 3 of Regulation (EC) No 1151/1009 establish detailed rules on prior notification requirements for products subject to these Regulations.

Article 4 of Regulation (EU) No 258/2010 requires the FBO responsible for consignments of products subject to this Regulation to provide prior notification to the CA of the MS before their physical arrival.

**Findings**

The Italian MoH has introduced an electronic format for the CED in line with the requirements of the new EU Regulations. The NSIS-USMAF is an IT system for the activities involved in official controls on food and food contact material. The package, developed, supplied and managed by the MoH, is currently used for almost all the institutional tasks of the USMAFs. It was put in place in 2006, and has been fully operational in Directorate General for Animal Health and Veterinary Drugs, in all USMAFs since 2007. It is used by about 2220 registered users (378 on the USMAF side and 1842 in the public area). There are about 850000 companies and sole traders recorded in the USMAF Register of Activities.

After logging in, the FBOs can fill in the data with information both on the import company and on the goods to be imported, thus giving adequate prior notification of the estimated date and time of physical arrival at the DPE, as well as the nature of the consignment, as per Article 6 of Regulation (EC) No 669/2009.

After entering the data, the FBO prints out Part I of the CED and submits the paper version to the DPE (Article 6 of Regulation (EC) No 669/2009) for the relevant official controls. In this initial phase, the system assigns a code to the document; this is a unique code that the DPE uses to identify the file and carry out the relevant official controls, as per Article 8 of Regulation (EC) No 669/2009. At the end of the controls the CA of the DPE completes the section concerning the controls that have been carried out and releases the CED.

The NSIS-USMAF software allows the USMAF staff, for each consignment notified to the DPE, to see a panel with detailed information on the consignment presented for import, in order to decide in
advance on the type of control to be carried out. In particular, on the basis of the data given by the FBO, the system displays an alert message to warn the USMAF/DPE personnel if the consignment is subject to Regulation (EC) No 669/2009.

The evaluation of files on imported produce in the USMAF offices visited showed that in several of the cases no pre-notification of the consignments was submitted by importers, and inspection of consignments was requested after arrival. The USMAF staff stated that it should be in the interest of the importers to pre-notify consignments. The USMAFs had not carried out specific information campaigns to make importers aware of the pre-notification requirement. The importer of spices, where one of the sampling procedures was observed, stated that he informed the USMAF offices after he had the results of his own analyses within the auto-control system available. Where mycotoxin levels were detected above maximum levels he sent the consignment back to the country of origin, before an official inspection for import was requested via NSIS-USMAF.

**Conclusions**

There are prior notification procedures in place for FNAO subject to Regulations (EC) Nos 669/2009 and 1152/2009, 1151/2009 and 258/2010. However, the prior notification procedures are not always followed.

**6.2.3 Procedures for import controls**

**Legal requirements**

Article 15(1) of Regulation (EC) No 882/2004 requires CAs to carry out regular official controls on food and feed of non-animal origin imported into the EU.

Article 8 of Regulation (EC) No 669/2009, Article 7 of Regulation (EC) No 1152/2009 and Article 4 of Regulation (EC) 1151/2009 specify official controls to be carried out by the CA on products subject to these Regulations before they are released for free circulation.

Pursuant to Article 10 of Regulation (EC) No 669/2009, release for free circulation of consignments must be subject to presentation by the FBOs or their representatives to the Customs authorities of a CED duly completed by the CA once all controls required in accordance with Article 8(1) have been carried out and favourable results of physical checks, where such checks are required, are known.

Article 5 of Regulation (EU) No 258/2010 specifies the checks to be carried out by the CA on products covered by this Regulation presented for first placing on the market.

**Findings**

**Import procedure**

The importer or his legal representative applies to the USMAF to obtain a health certificate/CED (necessary to allow the consignment to clear Customs; see section 6.2.2). With the application all relevant product information is provided (exact type, provenance, quantity, means of transport, declaration of use, etc.), together with information on the importing company (name, address, etc.). All other documents accompanying the goods are also included (invoices, waybills, health certificates, certificates of origin and the confirmation of payment).

USMAF staff carries out the health and hygiene inspection, comprising one or all of the following
elements:
- a systematic document check;
- a sample identity check based on the type of goods, especially in the case of packaged or perishable products;
- a physical check, including sampling and analysis.

The commercial documents accompanying the goods are both submitted as information in the relevant section of the NSIS-USMAF software and attached to the printout of Part I of the CED, and dispatched to the USMAF. These documents usually refer to the invoice, Customs bill, certificate of origin of the goods, phytosanitary certificate, if available, copies of the labels (if the product is for direct use), copy of the receipt of payment of the relevant tax, any other document (e.g. results of lab tests carried out in the country of origin). The NSIS-USMAF software allows all the documents to be uploaded for each consignment in e-format, in addition to the traditional paper format, so that the USMAF personnel are able to check all the documents online at any time.

The analytical check is, as a rule, carried out on 5% of consignments where there is no reason for suspicion. In general, the risks that may be posed by the type of food for which the import application is being made are taken into consideration by the USMAF inspector. Precedents relating to the same product or a product of the same provenance, in particular where they are subject to ‘more intensive checks’ on the basis of information in the alert system and specific provisions in EU or national decisions, are also taken into account. When samples are taken and subsequently sent to the laboratory for physical, chemical and/or microbiological analyses, the technical personnel of the USMAF go to the designated area where the goods are stored on arrival and, in the presence of Customs officials and the agent responsible for import, verify that the seals are intact. After opening the containers or the storage unit the conditions of the food are first examined, then a representative sample is taken.

The USMAF offices issue the health authorisation if, on the basis of the accompanying documents, a decision against carrying out an inspection and/or analysis is taken. When samples are taken, the USMAF offices order the health certificate/CED to be issued once the results of the analysis carried out on the goods have arrived from the laboratory and it has been verified that the goods comply with the relevant legislation.

Customs (in their local offices) are using specific software called AIDA that guarantees that consignments cannot be released before USMAF checks are performed. Goods are only released by Customs provided the health certificate/CED has been presented.

Onward transportation within the MS

Where onward transportation is authorised, pending the results of the physical checks, in accordance with POS 11, the container is sealed by the personnel of the USMAF using the official seals of the MoH, keeping a record of these seals. The same personnel of the USMAF/DPE notify the local ASL at the point of destination of the arrival of the sealed container, which cannot be released until favourable laboratory results are available.

Nuts subjected to sorting are forwarded to one of the two authorised facilities under supervision.
Onward transportation with final destination in another MS

For goods in T1 transit to another MS, the responsible USMAF office performs documentary and identity checks. The mission team was informed about one consignment that was transferred to the Netherlands after receiving a requested approval from the authorities of the Netherlands.

No cases have been reported by the CA regarding onward transportation from other MSs with a final destination in Italy.

Sampling frequency

All consignments of food of non-animal origin are subject to a documentary check by an USMAF (100% official control). As described in POS 11, sampling is generally carried out by the Directorate General for Animal Health and Veterinary Drugs on 5% of consignments. For the assessment of pesticide residues the official controls are carried out on 3% of consignments (Ministerial Decree of 30 July 1993).

The data reported by the Italian CA to the European Commission in the framework of the quarterly reports under Regulation 669/2009 showed that in the first two quarters of 2010, for spices from India, chilli and chilli products from third countries and vegetables from Turkey, the required sampling frequency was not met. However, the Italian CA stated that according to their interpretation the frequency had to be fulfilled over the whole year.

DGSAN provided the mission team during the mission with data on the USMAFs in Livorno and Naples, indicating that the sampling frequencies regarding FNAO subject to European legislation were met.

Furthermore, DGSAN and the DGSA are preparing a procedure for USMAFs and BIPs setting out how official controls are to be carried out on composite products (Article 6 of Decision 2007/275/EC).

The NSIS-USMAF software shows, for consignments entered into the system and subject to Regulations concerning the increased level of official controls, the samples that have already been taken for the commodity in question and allows the CA at the DPE to decide in advance on the type of control to be carried out.

On-site visits to FBOs

The FBO visited imports spices from third countries; several of its products are subject to Regulation (EC) No 669/2009. The importer explained that he is usually informed about new legislation by different associations of which he is a member and also by the CA via NSIS-USMAF.

He stated that based on his internal quality control system he requested the USMAF offices to carry out inspections after he had the results of his own analyses available. However, he had had several cases of mycotoxins detected above the maximum limits where he had sent the consignment back to the country of origin, before an official inspection for import was requested via NSIS-USMAF.

Conclusions
Control procedures for imported FNAO generally follow the EU legislation. Documentary checks are always performed adequately as required by Article 7(2) of Regulation (EC) No 1152/2009. The mission team observed good cooperation between the CA and the FBO. In the first two quarters of 2010 the reported frequency of sampling of some products subject to Regulation (EC) No 669/2009 was lower than required by the Regulation.

6.2.4 Splitting of consignments

Legal requirements

Pursuant to Article 12 of Regulation (EC) No 669/2009 and Article 8 of Regulation (EC) No 1152/2009, consignments may not be split until the official controls and the CED have been completed by the CA. Where they are subsequently split an authenticated copy of the CED must accompany each part of the consignment until released for free circulation.

Article 5 of Regulation (EC) No 1151/2009 provides that consignments may not be split until the official controls by the CA have been completed. Where they are subsequently split a copy of the official documents provided for in Article 3(2), authenticated by the CA of the MS on whose territory the splitting has taken place, must accompany each part of the consignment until released for free circulation.

Article 6 of Regulation (EU) No 258/2010 requires that if consignments of products subject to this Regulation are split, a certified copy of the health certificate provided for in Article 2(1)(a) must accompany each part of the split consignment until its release for free circulation.

Findings
The mission team was informed that no consignments are split in Italy.

Conclusions
In Italy no subsequent splitting of consignments is undertaken by the FBOs.

6.2.5 Fees and costs

Legal requirements

Article 14 of Regulation (EC) No 669/2009 requires MSs to ensure the collection of fees occasioned by the increased level of official controls provided for in this Regulation in accordance with Article 27(4) and the criteria laid down in Annex VI of Regulation (EC) No 882/2004.

Article 7 of Regulation (EU) No 258/2010 establishes that all costs resulting from the official controls referred to in Article 5(1), including sampling, analysis, storage and any measures taken following non-compliance, must be borne by the feed and food business operator.

In accordance with Article 7 of Regulation (EC) No 1151/2009 and Article 10 of Regulation (EC) No 1152/2009 all costs resulting from the official controls, including sampling, analysis, storage and any measures taken following non-compliance, must be borne by the FBO.

Findings
Decree-Law (DL) No 194 of 19 November 2008 defines the criteria for establishing and updating the fees due for official controls. At present, the fees for the import of FNAO products are as follows:

- € 63.30 per consignment for food contact materials
- € 55.00 per consignment, up to 60 tonnes
- € 0.9 for each additional tonne, up to 460 tonnes, and a maximum of € 420 beyond 460 tonnes
- Article 4 of DL 194/2008 defines the cost per hour of the service in the case of supplemental, additional and on request controls, as defined in Articles 28, 14(1) and 15(5) of Regulation (EC) No 882/2004. The cost per hour in the case of supplemental, additional and increased controls is set at € 50.00.

As per the above-mentioned DL 194/2008, the fees for the official control of goods in transit through the EU, including the release of the CED, are set at a minimum of € 30.00, increased by € 20.00 for every 15 minutes of work by each employee. The same fee applies for the time spent on sampling.

Since Italy has a federal system with a regional organisation, the costs for laboratory analysis are decided locally and the MoH has no authority over the fees applied by the laboratories. For example the fees for analysis of pesticide residues vary between 141.- Euro and 372.43 Euro and the fees for analysis of mycotoxins vary between 91.74 Euro and 257.- Euro

Additional costs arising for FBOs from the implementation of Regulation (EC) No 669/2009: hourly rate due for sampling, and costs related to the transport and emptying of the container (estimates in the different ports differ between € 350/400 and € 2000). However, these costs are not specifically due for the implementation of Regulation (EC) No 669/2009, since they can be applied to any official control which includes sampling.

Conclusions

A common approach is taken towards costs and fees for import controls on FNAO that is in line with EU requirements.

6.2.6 Procedures for non-compliant lots

Legal requirements

Article 19 of Regulation (EC) No 882/2004 provides that CAs must place under official detention consignments that do not comply with food or feed law, and that a number of measures must 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 feed or food consignment from TCs does not comply with food or feed law, a number of measures such as destruction, special treatment, re-dispatch outside the EU, and other appropriate
measures (use of feed or food for purposes other than those for which it was originally intended) are taken by the CAs after having heard the feed or food business operators responsible for the consignment. In line with Article 11 of Regulation (EC) No 882/2004, owners of products found to be non-compliant with EU legislation have the right of appeal.

Decisions on whether to allow non-compliant products to be subjected to a secondary treatment (as provided for by Article 4(c) of Regulation (EC) No 1881/2006) or on the handling of non-compliant products which are not to be subjected to a secondary treatment (Article 19 of Regulation (EC) No 882/2004) are taken by the USMAF offices. Representatives of the USMAF Livorno explained that in such cases, an official note is produced informing the importer. The importer decides on the re-dispatch and the destination of the consignment. In cases were the destination differs from the country of origin, the importer informs the country of destination about the consignment, requesting a certificate of acceptance that is send to the USMAF.

If any irregularities are discovered during official inspections, subsequent consignments are subject to more intensive checks. The USMAFs exchange information by e-mail on any irregularities ascertained. The information from the RASFF system is sent to the USMAFs, and instructions are given by DGSAN in the form of memos for information and/or operational guidance on alerts or problems that arise.

In general, the possibility exists of diverting non-compliant foodstuffs for feed use. In such cases, the owner of a non-compliant product approaches the responsible BIP. The BIP permits the conversion, provided the consignment does not exceed legal limits, such as the level set in Annex I, point 7 of Directive 2002/32/EC for aflatoxin B1 in feed materials.

**Conclusions**


6.2.7 **Rapid Alert System for Food and Feed**

**Legal requirements**

Article 50 of Regulation (EC) No 178/2002: where an 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 does not permit the introduction of feed or food, the CA must notify the Commission and other MSs 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 must notify its decision to the Customs services, together with information as regards the final destination of the consignment.

**Findings**

The operation of the RASFF network was demonstrated to the mission team by means of documentation in relation to previous RASFF notifications. No shortcomings were identified.

**Conclusions**
The RASFF procedures are in place in the framework of import controls and comply with the legal requirements.

6.2.8 Laboratories carrying out official control analysis

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

Article 11(1) of Regulation (EC) No 882/2004 requires that sampling and analysis methods used in the context of official controls comply with relevant EU rules.

Article 12(1) 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 MSs to designate National Reference Laboratories (NRLs) for each EU Reference Laboratory (EURL) referred to in Article 32. The NRL must collaborate with the EURL, coordinate activities, organise comparative tests, ensure dissemination of information, and provide scientific and technical assistance.

Findings

DGSAN has access to laboratory capacity. The organisation and structure of the laboratory network is described in section 5.3.4.

The mission team visited the ARPA laboratory in Livorno, which has been designated for all import control samples taken by the USMAF in Livorno for analysis of mycotoxins, pesticides and Sudan Dyes. In 2009 the laboratory tested 319 import control samples, including 44 samples for mycotoxin analysis and 9 samples for Sudan Dyes. Several agreements were concluded between the ARPA and the USMAF in 2007, 2009 and 2010 regarding the analysis of samples taken by the USMAF. These agreements covered, inter alia, the turnaround time for samples. The current agreement expires at the end of 2010, and the ARPA staff stated that no investments in food analysis had been made in recent times because responsibility for food analysis is being transferred to other laboratories belonging to Tuscany’s Integrated System of Laboratories (Sistema Integrato dei Laboratori della Toscana), as referred to in Decisions of the Regional Government of Tuscany Nos 932/2008 and 26/2010. This has to do with the lack of equipment for homogenisation of samples and participation in relevant proficiency tests (see below).

No written agreement about analyses for import control samples was concluded between the USMAF in Naples and the designated laboratories.

Specific laboratory for mycotoxins

Staff
Two staff members are involved in mycotoxins analyses. They started performing analyses for mycotoxins in 2008, and stated that they had received initial training. An SOP on staff training was available.
Methods of analysis

An SOP is in place for analysis of mycotoxins, but there is no SOP for sample preparation. Samples are ground using a Retsch SM 2000 (final particle size 2 mm) and mixed by hand. The process has not been demonstrated to achieve complete homogenisation as required by Annex II.2 of Regulation (EC) No 401/2006. The process does not produce slurry, which is a recommended procedure for achieving homogeneity. The analytical procedure includes extraction and an immuno affinity column (IAC) clean-up procedure and determination using high performance liquid chromatography (HPLC) coupled with post-column derivatisation (PyridinHBr\textsubscript{3}) and fluorimetric detection. The limit of quantification is 0.1 ppb.

The laboratory also has a method for the determination of Sudan dyes using HPLC and mass spectrometry detection for confirmation.

Quality control

The laboratory is accredited to International Organisation for Standardisation (EN ISO) 17025 by the Sistema Nazionale per l’Acreditamento di Laboratori (Sinal/ACCREDIA, the National System for Laboratory Accreditation), among other things for the HPLC method for determining ochratoxin, aflatoxin B1 and total aflatoxins B1, B2, G1, G2 and Sudan Dyes for the relevant food commodities. A quality management system and an internal audit system are in place.

Standard solutions are prepared from a certified solution. A 5-level calibration curve (each level analysed in triplicates) is valid as long as 3 different concentrations of a certified control solution that are analysed each working day are within a range of ± 20%. Methods were validated in-house. Calculation of the limit of detection, limit of quantification, precision, linearity, recovery, accuracy, including estimation of measurement uncertainty, was performed during the initial validation of the method. The performance criteria meet the requirements of Regulation (EC) No 401/2006.

Currently no regular recovery checks are performed\textsuperscript{1}. Since 2007 the laboratory has not taken part in proficiency tests with all relevant matrices and toxins, namely aflatoxin in nuts and peanuts.

Reports of the ARPA Livorno laboratory are prepared in accordance with Regulation (EC) No 401/2006 and include the recovery factor and expanded measurement uncertainty. However, reports of the ARPA laboratories in Genoa and Naples that were checked at the USMAF offices in Naples did not include a reference to recovery as required by the Regulation.

Sampling

A demonstration of sampling of mace undertaken by two USMAF inspectors from Livorno was observed by the mission team. Sampling followed Regulation (EC) No 401/2006. The inspector used sampling equipment (a metal spear) and an adequate scale. From the consignment (approximately 6500 kg, 216 bags) 80 samples of 100 g were taken (i.e. 4 bags out of 10). The cuts on the bags were closed with special seals that were stamped by the inspectors. The 8 kg aggregate sample was sealed and forwarded to the laboratory.

Two more sampling procedures were observed by the mission team in the Customs area of the port of Naples:

One involved the sampling of a consignment of 25 tonnes of shelled peanuts from Brazil packed in jute sacks of 25 kg each. A number of sacks were taken from the container to a protected area to

\textsuperscript{1} In their response to the draft report the Competent Authority noted that “the recovery factors used, calculated in the course of studies to validate the methods, have proven correct”.

25
gain access to all sacks so as to allow the random sampling of at least 100 individual samples spread throughout the consignment. The inspectors used a metal spear and a metal scoop, big enough to take a sample of 200-300 g.

The second sampling in Naples concerned a consignment of 25 tonnes of Californian almonds packed in boxes. A number of boxes were taken from the container to a protected area to gain access to all boxes in order to permit the random sampling of at least 100 individual samples spread throughout the consignment. For sampling the inspectors opened the boxes and used a metal scoop big enough to take 200-300g.

In both cases the aggregate sample with a weight of 20 kg was divided into two sub-samples using a scale and finally the samples were sealed as required by Regulation (EC) No 401/2006.

The health technicians of the USMAF drew up a report on the sampling (including all data on the goods) countersigned by a representative of the importer who was present at the time of sampling. The importer was asked if he wished an additional sample to be taken, and he declined. After the sample is divided into sub-samples, these are sent to the public laboratory where the required analyses will be carried out. One copy of the report is fixed to the sack that contains the sample.

Conclusions

The laboratory for mycotoxin analysis visited is accredited to EN ISO17025 in accordance with Article 12 of Regulation (EC) No 882/2004. The performance criteria and analytical reports meet the requirements of Regulation (EC) No 401/2006, but the quality of analytical results is not sufficiently supported by data on homogeneity of sample preparation, regular recovery checks and participation in relevant proficiency tests[2].

The observed sampling procedure for aflatoxin analysis fully complied with Regulation (EC) No 401/2006.

7 Overall Conclusions

Overall, Italy has an effective and clearly defined, centralised system in place for import controls on food of plant origin. Some minor shortcomings were identified concerning the reported frequency of sampling, prior notification procedures and quality control in the laboratory visited.

8 Closing Meeting

A closing meeting was held on 14 September 2010 with representatives of the CAs. At this meeting, the audit team presented the main findings and preliminary conclusions of the mission. The representatives of the CAs provisionally accepted these findings and offered some clarifications and comments.

[2] In their response to the draft report the Competent Authority noted that “since 2001 the accreditation body in accordance with Standard EN ISO 17011 (SINAL/ACCREDIA) has constantly monitored the quality of the analytical data from the entire analytical process with regard to mycotoxins, and declared them to be adequate and compliant with standard EN ISO 17025.”
9 Recommendations

The CAs are invited to provide details of the actions taken and planned, including deadlines for their completion (‘action plan’), with a view to addressing the recommendations set out below, within twenty-five working days of receipt of this specific audit report.

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<tr>
<th>№.</th>
<th>Recommendation</th>
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<tr>
<td>1.</td>
<td>Ensure that official controls within the scope of the mission are carried out with appropriate frequency as required by Annex I of Regulation (EC) No 669/2009.</td>
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<td>3.</td>
<td>Ensure that the NRL for mycotoxins organises proficiency tests regarding mycotoxins in the relevant matrices (nuts and peanuts) for the Italian laboratory network, as required by Article 33 of Regulation (EC) No 882/2004.</td>
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<td>4.</td>
<td>Ensure that in the official laboratories the quality of analytical results is sufficiently supported by data on homogeneity of sample preparation as required by Regulation (EC) No 401/2006, as well as by regular recovery checks and participation in relevant proficiency tests.</td>
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The competent authority's response to the recommendations can be found at:

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