EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6655 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

THE CZECH REPUBLIC

FROM 02 TO 04 APRIL 2013

IN ORDER TO EVALUATE IMPORT CONTROLS OF FOOD OF NON-ANIMAL ORIGIN

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) audit in the Czech Republic, carried out from 2 to 4 April 2013, under the provisions of Regulation (EC) No 882/2004 on official food and feed controls.

The objective of the audit was to evaluate the control systems put in place for the import controls of food of non-animal origin (FNAO).

An efficient, centralised import control system was in place for import of FNAO. Detailed and updated procedures supported the qualified staff and ensured effective official controls. Good co-operation between the Competent Authorities (CAs) provides a high level of security and ensures that imported consignments will be identified and checked. The official laboratory for the analysis of import samples provides reliable results to the CA. However, minor deficiencies were noted. The CA did not always provide a completed Common Entry Document (CED) to importers. There were no dedicated places for inspection and sampling of consignments at the Designated Point of Entry (DPE) Prague Airport.

The report makes a number of recommendations to the CAs, aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

Table of Contents

Abbreviations and definitions used in this report

CA(s)	Competent Authority(ies)
CAFIA	Czech Agriculture and Food Inspection Authority
CCA(s)	Central Competent Authority(ies)
CED	Common Entry Document
CP	Control Point
DG(SANCO)	Health and Consumers Directorate-General
DPE	Designated Point of Entry
DPI	Designated Point of Import
EC	European Community
EU	European Union
EU-RL	European Reference Laboratory
FAPAS	Food Analysis Performance Assessment Scheme
FBO(s)	Food Business Operator(s)
FNAO	Food of Non–Animal Origin
FVO	Food and Veterinary Office
HPLC	High Performance Liquid Chromatography
EN-ISO/IEC	International Organisation for Standardisation
LOD	Limit of Detection
MA	Ministry of Agriculture
MANCP	Multi-Annual National Control Plan
MS(s)	Member State(s)
MU	Measurement of Uncertainty
NRL	National Reference Laboratory
PT	Proficiency Test
RASFF	Rapid Alert System for Food and Feed
TRACES	Trade Control and Expert System

1 Introduction

The audit formed part of the Food and Veterinary Office's (FVO) planned programme.

The audit took place in the Czech Republic, from 02 to 04 April 2013. The team comprised one auditor from the FVO and one expert from a European Union (EU) Member State (MS).

Representatives from the Czech Agriculture and Food Inspection Authority (CAFIA) accompanied the audit team for the duration of the audit. An opening meeting was held on 02 April 2013 with the Central Competent Authorities (CCAs) CAFIA, the Ministry of Agriculture (MA) and Customs. At this meeting, the objectives of, and itinerary for, the audit were confirmed by the audit team and the control systems were described by the authorities.

2 Objectives And Scope

The **objective** of the audit was to:

- Evaluate the implementation of EU legislation in relation to the import controls on food of non-animal origin (FNAO), in particular, implementation of Regulation (EC) No 669/2009 on increased levels of import controls; emergency measures according to Regulation (EC) No 1152/2009, Regulation (EC) No 1151/2009 and Regulation (EU) No 258/2010; requirements for official controls of Regulation (EC) No 882/2004; implementation of the Rapid Alert System for Food and Feed (RASFF);

In terms of **scope**, the audit reviewed the designation of Competent Authorities (CAs) for import controls of FNAO, their co-operation, audits and resources for performance of controls, as well as the organisation of import controls including designated places of imports (DPIs), control procedures, sampling and laboratory performance.

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

Table 1: Visits and meetings

Visits/Meetings	No	**Comments**
Competent authorities		
Central	1	MA, CAFIA, Customs at the MA in Prague
Regional	1	CAFIA, regional inspectorate in Prague
Laboratories		
Public	1	Laboratory at CAFIA , regional inspectorate in Prague
On-Site Visits		

Designated Points of Entry (DPE)/ Designated Points of Import (DPI)	2	DPE Prague Airport, DPI Rudná
Food importer(s)	1	Rudná

3 Legal Basis and Standards

3.1 Legal basis

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

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

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

3.2 Standards

Additionally, Health and Consumers Directorate-General DG(SANCO) Guidelines were relevant for this audit. A full list of applicable standards referred to in this report is provided in Annex 2.

4 Background

4.1 Audit Series

This audit is part of a series of FVO audits in the MSs of the EU on import controls of FNAO. Prior to the current audit series, two series of FVO audits on import control of FNAO were carried out. The first series took place between 2002 and 2004 and concentrated on the major importing MSs, while the second series took place between 2006 and 2008 and covered MSs not yet visited for import controls and as follow-up to recommendations made during the first series. The scope of these series covered the implementation of Regulation (EC) No 882/2004 and Regulation (EC) No 178/2002, and the implementation of emergency measures in force by that time, in particular, mycotoxin contamination and Sudan dye adulteration.

Findings of the second series of audits indicated that import controls have improved significantly, in particular, as regards sampling, sample preparation and controls on non-compliant consignments. However, during the former series, FVO teams often identified weaknesses in controls on commodities not included in the emergency measures in force but considered at risk, regarding the system of audits, RASFF notifications, performance of the laboratories and reporting of analytical results. The overview report is available on the DG (SANCO) internet site at: http://ec.europa.eu/food/fvo/specialreports/gr_2009-8328_aw_en.pdf.

The CAs of the MS subject to audit outlined in action plans how the recommendations would be addressed. These action plans are also published on the DG (SANCO) internet site together with the report.

4.2 Country Profile

The FVO has published a country profile for the Czech Republic, which describes in summary the control systems for food and feed, animal health, animal welfare and plant health and gives an overview on the state of play of the recommendations of the previous FVO mission reports. The country profile can be found at: http://ec.europa.eu/food/fvo/last5_en.cfm?co_id=CZ.

5 Findings And Conclusions

5.1 Relevant National Legislation

Legal requirements

Article 291 of the Treaty on the Functioning of the EU establishes that MSs shall adopt all measures of national law necessary to implement legally binding Union acts.

Findings

Within the scope of the audit, the following national legal acts were in force:

- Act No 110/1997 on Foodstuffs and Tobacco Products describes the responsibilities of Food Business Operators (FBOs);
- Act No 146/2002 established CAFIA and defined the scope of their responsibilities;
- Act No 17/2012 defines the duties and operational rules for Customs;
- Internal CAFIA rule No 21/2004 establishes operational rules for CAFIA.

The relevant legislation is available on the internet in Czech:
http://www.szpi.gov.cz/lstDoc.aspx?nid=11816.

An updated list of commodities to be checked under Regulation (EC) No 669/2009 is published on the internet:
http://www.szpi.gov.cz/docDetail.aspx?docid=1022975&docType=ART&nid=11754&chnum=9;

Conclusions

National legislation to implement official controls on the import of FNAO is in place.

5.2 Organisation and Implementation of Official Controls

5.2.1 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

Official controls on the import of FNAO are organised centrally under the MA by the CAFIA. The

MA is responsible for the policy decisions on import controls. The CAFIA is responsible for the import controls of FNAO. The CAFIA's regional office in Prague performs the controls at DPE Prague Airport and DPI Rudná. The Customs Services co-operate with CAFIA to ensure that only goods inspected by CAFIA will be cleared.

The laboratory of the regional CAFIA inspectorate in Prague is assigned for the analysis of import samples for mycotoxins and pesticide residues. It is the National Reference Laboratory (NRL) for mycotoxins and pesticide residues.

Further details of the structure of the CAs for import controls on FNAO are described in the FVO Country Profile: http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=CZ.

There is no delegation of official tasks.

Conclusions

There is an adequate structure and organisation in place for the implementation of official controls on the import of FNAO, as required by Article 4(1) of Regulation (EC) No 882/2004.

5.2.2 Resources for Performance of Controls

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires 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.

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

At the CAFIA Regional Inspectorate in Prague, there are four full-time staff members responsible for import controls of consignments under Regulation (EC) No 669/2009 and Regulation (EC) No 1152/2009. Food of non-animal origin under other EU or national control regimes (e.g guar gum from India or sunflower oil from Ukraine) can be checked by all CAFIA inspectors throughout the whole country.

The audit team noted that:

- there was a manual of procedure in place with regular updates;
- the last amendments to Regulation (EC) No 1152/2009 and Regulation (EC) 669/2009 were available;
- a manual of legislation and procedures was updated and available to inspectors on the intranet;
- all inspectors had personal training files;
- the inspectors interviewed demonstrated a good level of knowledge of import requirements and procedures for official controls;
- all inspectors had academic level education with a specific training for official controls;
- two of the four inspectors had participated in the BTSF training sessions on FNAO; the

reason only two participated was due to language constraints.

Conclusions

The staff has been trained and a manual of procedures was available to official staff to ensure effective and efficient controls on imports of FNAO, which was in line with Articles 4 and 6 of Regulation (EC) No 882/2004.

5.2.3 Designated Points of Import and Designated Points of Entry

Legal Requirements

Article 17 of Regulation (EC) No 882/2004, Articles 3(b) and 5 of Regulation (EC) No 669/2009 establish the definition and specific requirements for designation of DPEs by MSs.

Article 4 of Regulation (EC) No 669/2009 provides the minimum requirements for DPEs. When a DPE is not adequately equipped with all the facilities, another Control Point (CP) can be authorised by the MS for a transitional period of five years. Under Article 9, upon request of the MS, the Commission may authorise the CA of a particular DPE operating under specific geographical constraints to carry out physical checks at the premises of FBOs.

Article 2(a) and Article 6 of Regulation (EC) No 1152/2009 establish the definition and specific requirements for DPI for products subject to this Regulation.

According to Article 16(3) of Regulation (EC) No 882/2004 MSs shall ensure that physical checks are carried out under appropriate conditions and at a place with access to appropriate control facilities allowing investigations to be conducted properly.

Findings

DPE

There is one DPE in the Czech Republic at Prague airport. The audit team visited the DPE and noted that:

- there were no dedicated places for inspection or sampling available;
- the facilities were not shared with the veterinary Border Inspection Post (BIP);
- unloading equipment and storage facilities were made available by the warehouse operator;
- the CAFIA Regional Inspectorate in Prague served as an office base, but many staff members worked from home-based offices;
- equipment for sampling was transported in the inspector's car (private or official);
- if a consignment had been selected for sampling, the staff of the CAFIA Inspectorate Prague drove to the airport and samples were taken directly to the laboratory.

DPI

There is one DPI in the Czech Republic. It is assigned to the Customs office of Rudná. The audit team noted that:

- if consignments had been selected for sampling, the staff of the CAFIA Inspectorate of

Prague moved to one of the three approved importers' customs warehouses where the consignments were unloaded;
- the inspectors carried their sampling equipment and performed the sampling at the importer's premises; samples were taken directly to the laboratory;
- sampled consignments were transported to a locked space in a Customs warehouse under direct Customs supervision.

The DPE and the DPI are published on the internet:
http://www.szpi.gov.cz/docDetail.aspx?docid=1022975&docType=ART&nid=11818

Conclusions

DPEs and DPIs were designated and details made publicly available by the CA. At DPE Prague Airport there are no dedicated places for inspection and sampling which does not comply entirely with EU requirements after the transitional period ends in August 2014. This is not in line with Article 4(b) of Regulation (EC) No 669/2009 in connection with Article 19 of the same Regulation.

5.2.4 Other Places of Import Controls

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

According to Articles 5(4) and (5) of Regulation (EU) No 258/2010 the checks of products listed in this Regulation shall be carried out at CPs specifically designated by the MSs for that purpose and the list of CPs shall be made available to the public and communicated to the Commission.

According to Article 4 of Regulation (EC) No 1151/2009 controls should be performed on consignments presented for import before release.

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

Findings

The CA has designated all Czech Customs offices for checks of guar gum and Ukrainian sunflower oil. Sampling is done at the customs zone/or FBO warehouses which are approved by CAFIA. The list of CPs is published on the internet http://www.szpi.gov.cz/docDetail.aspx?docid=1022975&docType=ART&nid=11818

Conclusions

Checkpoints for sunflower oil and guar gum were designated and details made publicly available as laid down in Article 5(4) and (5) of Regulation (EU) No 258/2010 and Article 4 of Regulation (EC) No 1152/2009.

5.2.5 Prior Notification of Consignments

Legal Requirements

According to Article 17(1) of Regulation (EC) No 882/2004, for the organisation of official controls subject to Article 15(5), MSs shall require from the responsible FBO to give prior notification of their arrival and details about the consignment.

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 for prior notification requirements for products subject to these Regulations.

Article 4 of Regulation (EU) No 258/2010 requires 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

In most of the cases checked by the audit team, the CAFIA was notified in advance about the arrival of the consignments. In the case of arrivals at the airport, date and time of arrival were not in all cases listed in the Common Entry Document (CED) part I.

Conclusions

A system was in place for pre-notification of consignments, as required by the EU legislation in force.

5.2.6 Import Controls of Food of Non-Animal Origin subject to Regulation (EC) No 669/2009

Legal Requirements

Article 8 of Regulation (EC) No 669/2009 specifies official controls to be carried out by the CA on products subject to this Regulation before products are released for free circulation.

According to Article 10 of Regulation (EC) No 669/2009, release for free circulation of consignments shall be subject to the presentation by the FBOs or their representatives to the custom authorities of a CED duly completed by the CA and favourable results from physical checks, where such checks are required, are known.

Findings

Consignments arriving in the Czech Republic have to be notified to the CAFIA and Customs. For Customs clearance, the IT system "*e-import"* was used. The system recognised the combination of commodity and country of origin in a risk-profile database and flagged the necessity of an official check by the CA and presence of a CED. Commodities under Regulation (EC) No 669/2009 were not included in the risk-profile attached to "*e-import"*. Commodities, however, were flagged to be checked by the Trade Control and Expert System (TARIC), the integrated tariff system of the EU which is available to all Customs staff.

Two particular cases can occur with consignments under Regulation (EC) No 669/2009:

1. Consignments arriving at the DPE Prague: the importer notifies the CAFIA about an arriving consignment; CAFIA decides if the consignment needs to be sampled or not. CAFIA issues an *obligatory statement* to the Customs with a decision. If no samples are to be taken the consignment can be cleared upon the *obligatory statement*. The CED is completed and handed out to the importer. In the case of sampling, CAFIA will inform the Customs about the result using the *partial inspection detection* document.

2. Consignments arriving in the Czech Republic with a completed CED but before customs clearance: the importer must present the original CED to Customs before clearance. In any case, Customs would notify CAFIA and only release the consignment upon an *obligatory statement* from the CAFIA.

The audit team noted further that:

- sampling was done in warehouses of Prague Airport; there were two at the air-side of the cargo facilities;
- the samples were transported to the CAFIA's laboratory in Prague by the inspector; which is in the same building as CAFIA offices;
- the documentary check was completed within two days at latest; the analytical results are available within 10 days;
- after the receipt of the results, the CED was completed at the CAFIA offices and handed over to the importer;
- according to the CAFIA procedure, CEDs were only accepted in Czech and English language; however, the audit team noted, that other languages were also accepted by the inspectors;
- outgoing onward transportation to other MSs was not applied.

Conclusions

The import controls procedure comply with the requirements of Regulation (EC) No 669/2009.

5.2.7 Import Controls of Food of Non-Animal Origin Subject to Emergency Measures and Decision 2008/47/EC

Legal Requirements

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 products are released for free circulation.

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

Article 4 of Decision 2008/47/EC describes official controls to be carried out on products subject to this Decision.

Findings

Consignments falling under Regulation (EC) No 1152/2009 arrive in the Czech Republic only with a completed documentary check done at DPEs in other MSs. They arrive at Rudná via Bulgaria (Haskovo), Slovenia (Koper), Italy (Trieste), Greece, Germany (Bremerhaven, Hamburg) and the Netherlands (Rotterdam).

The audit team noted that:

- hazelnuts from Turkey arrived in a mixed consignment via Germany without any CED, and the CA did not investigate further; the consignment was sampled and released after favourable analytical results;
- several consignments arrived via Germany with a completed CED; the CA stated that the importer had requested onward transportation to the Czech Republic, but this was refused by the MS's CA;
- the CEDs were completed at the CAFIA office but not transferred to Customs or the importers; importers received a copy only upon request; in the case of sampling the CAFIA informs the Customs about the result with the *partial inspection detection* document;
- when receiving consignments for onward transportation the CEDs from Bulgaria and Greece were only numbered with a Customs reference; no CED numbers were available;

Conclusions

In general, the import control procedures complied with the requirements of Regulation (EC) No 1152/2009. However, no completed CEDs were handed out to the importers which is contrary to the requirements of Article 7(7) and (8) of Regulation (EC) No 1152/2009. Part I and II of the CEDs from Bulgaria for onward transportation were not linked to each other which is not in line with the procedures described in Article 7(6) of the same Regulation.

5.2.8 Sampling Frequency

Legal Requirements

According to Article 8(1)(b) of Regulation (EC) No 669/2009 the CA at the DPE shall carry out, without undue delay, identity and physical checks, including laboratory analysis, at the frequencies as set out in Annex I, and in such a way that it is not possible for feed and FBOs or their representatives to predict whether any particular consignment will be subject to such checks.

Article 7(5) of Regulation (EC) No 1152/2009, Article 5 of Regulation (EU) No 258/2010 and Article 4(1) of Regulation (EC) No 1151/2009 establish frequencies of sampling for products listed in these Regulations.

Findings

Consignments were sampled unpredictably. In some cases the frequencies were too high due to the low numbers of arrivals.

Conclusions

Sampling frequencies, laid down in the applicable EU legislation were met with small deviations

due to the low numbers of imported consignments.

5.2.9 Import Controls Beyond the Regulation (EC) No 669/2009 and Emergency Measures

Legal Requirements

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency, taking account of (a) identified risks; (b) the FBO's past record as regards compliance; (c) the reliability of any own checks that have already been carried out; and (d) any information that might indicate non-compliance.

Article 15(1) establishes that CAs shall carry out regular official controls on food and feed of non-animal origin imported into the EU.

Article 16 requires that physical checks on imports of FNAO shall be carried out at a frequency depending on the risk associated with different types of feed and food.

Findings

An annual control program for imported food was established by CAFIA and the MA. The programme covered both, checks at the point of imports and at market level as described in the Multi-Annual National Control Plan (MANCP). Non-compliances notified via the EU RASFF can trigger enforced controls (to be added to the National red list) as a result from risk assessment performed by the CAFIA. In addition to controls under EU legislation, there was a National annual plan and ad-hoc checks. Commodities selected for special checks including sampling under National rules were integrated in the red list and the red list was handed over to the Customs for inclusion into the risk profile database.

Conclusions

In accordance with Articles 15(1) and 16 of Regulation (EC) No 882/2004, a risk-based national monitoring programme on imported FNAO was in place.

5.2.10 Splitting of Consignments

Legal Requirements

Regulations (EC) No 669/2009, No 1151/2009, No 1152/2009 and No 258/2010 provide provisions for the splitting of consignments.

Findings

Procedures for splitting consignments before customs clearance were in place, but they were not applied at the time of the audit.

Conclusions

Currently, splitting of consignments is not applied in the Czech Republic.

5.2.11 Fees and Costs

Legal Requirements

Article 14 of Regulation (EC) No 669/2009 establishes that MSs shall 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 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 a non-compliance, shall be borne by the feed and FBO.

According to 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 shall be borne by the FBO.

Findings

There were no specific fees in place for documentary checks; in the case of sampling the official fees to be paid are considered based on the national legislation in force, as follows:

- approximately the equivalent of 20 EUR per hour of inspection;
- analytical costs: aflatoxins: 240 EUR, contaminants 60 EUR, pesticides 100-240 EUR.

Conclusions

Fees and costs were charged for the import controls of FNAO as required by EU legislation.

5.2.12 Sampling

Legal Requirements

Commission Regulation (EC) No 401/2006 lays down the methods of sampling and analysis for the official control on the level of mycotoxins in foodstuffs. Commission Directive 2002/63/EC establishes methods of sampling for the official control of pesticide residues. Article 11 of Regulation (EC) No 882/2004 establishes requirements for sampling and analysis.

Findings

A work instruction for sampling was available for inspectors on the intranet. There was no consignment available for sampling at the time of the audit. Inspectors and the CA showed their equipment and demonstrated the process. The audit team noted, that:

- appropriate sampling equipment such as spears and mixing utilities, bags and seals were available;
- as regards the procedure in place, it was foreseen that the inspectors mix the incremental sample to an aggregate sample; the CA undertook a practical example to show that an aggregate sample of 30 kg figs could be mixed homogeneously by the inspector with the available means; the laboratory did not mix samples before the homogenisation.

Conclusions

The sampling procedures described and demonstrated were broadly in accordance with relevant EU legislation.

5.2.13 Laboratory Performance

Article 33 of Regulation (EC) No 882/2004 requires MSs to designate NRLs for each EU reference laboratory (EU-RL) and specifies tasks for the NRL.

Article 12 of Regulation (EC) No 882/2004 requires that CAs only designate laboratories which are operational and are assessed and accredited in accordance with the standards EN ISO/IEC 17025 and EN ISO/IEC 17011.

Article 28 of Regulation (EC) No 396/2005 requires that the methods of analysis of pesticide residues shall comply with the criteria set out in the relevant provisions of EU law relating to official controls for food and feed, and that all laboratories analysing samples for the official controls on pesticide residues participate in the EU proficiency tests (PTs) for pesticide residues organised by the Commission.

Annex II of Regulation (EC) No 401/2006 provides criteria for sample preparation and for methods of analysis used for the official control of the levels of mycotoxins in foodstuffs.

Guidelines

Method Validation and Quality Control Procedures for pesticide residues analysis in food and feed, Document SANCO/12495/2011, developed under Article 28 of Regulation (EC) No 396/2005.

Findings

National Reference Laboratories

The laboratory of the CAFIA Inspectorate in Prague is the NRL for mycotoxins and pesticide residues. It organises ring-tests within its scope of analysis for Czech laboratories.

CAFIA – Inspectorate in Prague

The audit team visited the laboratory of the CAFIA Regional Inspectorate in Prague, which is responsible for the analysis of official samples of imported FNAO.

A quality management system and an internal audit system were in place.

The laboratory is accredited to EN ISO/IEC 17025. The scope of accreditation includes High Pressure Liquid Chromatography (HPLC) for several mycotoxins, including aflatoxin B1 and total aflatoxins B1, B2, G1, G2 and ochratoxin A in different matrices.

Regarding sample preparation, it became clear that laboratory staff did not mix samples to aggregate samples before splitting into sub-samples. The CA stated that the inspectors would do this during sampling. The laboratory had adequate equipment for sample homogenisation using a slurry method. The audit team observed that samples of nuts and dried fruits were sufficiently

homogenised. Studies on the homogeneity of samples were performed by the laboratory.

Standard solutions were prepared from solid substances and were regularly checked. Four-point calibration curves were prepared on a per-batch basis. Validation of Limits of Detection (LODs), limits of quantification precision, linearity, recovery, accuracy, including estimation of Measurement of Uncertainty (MU) was reviewed by the audit team. The LOD and recovery factor were in accordance with the requirements of Regulation (EC) No 401/2006.

Recovery was checked for every batch of samples. No certified reference materials were used for internal control of accuracy and precision. Control charts were prepared for assuring the quality of works. The laboratory participated in several PTs including those of the EU-RL and of the Food Analysis Performance Assessment Scheme (FAPAS) and achieved very good results (z-scores < 2).

Analytical reports were prepared in accordance with Regulation (EC) No 401/2006 and they included recovery factor and MU.

Conclusions

National laboratories for analyses of samples taken within the scope of the audit were designated in line with Article 33 of Regulation (EC) No 882/2004. The laboratory visited by the audit team which tested for mycotoxins in food was adequately staffed and very well equipped. Methods were validated and accredited. Effective quality control systems were in place.

5.2.14 Procedures for Performance and Reporting of Control Activities

Legal Requirements

Article 8 of Regulation (EC) No 882/2004 requires that CAs 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 the official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Findings

A completed and updated set of written procedures was drafted and available on the intranet. Inspectors had laptops to access their work instructions out of office. The audit team noted that:

- after completion of checks an inspection report was handed out to the FBO;
- quarterly reports on import checks were sent to the Commission on time;
- the annual report of the CAFIA is published on the internet: http://www.szpi.gov.cz/en/docDetail.aspx?nid=11452

Conclusions

Detailed procedures to ensure uniform and efficient controls were in place as required by Article 8 of Regulation (EC) No 882/2004.

Inspection reports were handed over to the FBO after completion of the checks in line with Article 9 of Regulation (EC) No 882/2004.

Quarterly reports were sent to the Commission as required by Regulations (EC) No 1152/2009, 669/2009 and (EU) No 248/2010.

5.2.15 Co-ordination and co-operation between and within Competent Authorities

Legal Requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination between CAs.

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 co-ordination and co-operation shall be ensured between the different units.

Article 24 of Regulation (EC) No 882/2004 requires that CAs and customs should co-operate closely.

Findings

There was an official co-operation agreement between Customs and the CAFIA in place (last version of 01/11/2010). Regular meetings took place at central level between the MA, CAFIA and Customs.

The audit team noted that:

- at the DPE and DPI visited Customs staff were familiar with the import procedures established by CAFIA;
- The CAFIA has been informed in cases where Customs have found foodstuffs listed under EU Regulations or on the National red list;
- Customs only released consignments with an *obligatory statement* of the CAFIA; Customs were informed by the CAFIA about new legislation;
- There was a Common Information System for Surveillance Authorities in place which was used by the CAFIA and Customs.

Conclusions

There was an efficient co-operation in place between the CAs as required by Article 4(3) of Regulation (EC) 882/2004.

5.2.16 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

The audit team examined several cases of non-compliant consignments and noted that:

- the deadline of 60 days for completion of the procedure (destruction or re-dispatch) was met;
- documentary evidence of destruction or re-dispatch was available;
- declarations were present for the country where re-dispatched consignments were sent to;
- special treatment like sorting was not applied, but would be possible in principle.

Conclusions

Procedures for non-compliant consignments are in place and comply with EU legislation.

5.3 Rapid Alert System For Food and Feed

Legal Requirements

Article 50 of Regulation (EC) No 178/2002 requires MSs to immediately notify any information relating to the existence of a serious direct or indirect risk to human health deriving from food, to the Commission under the rapid alert system.

Regulation (EU) No 16/2011 lays down the implementing measures for RASFF and establishes duties of members of the network.

Findings

The CAFIA is the National contact point for the EU RASFF. CAFIA inspectors and Customs officers had access to the notifications. RASFF notifications were sent to the Commission in cases of non-compliance where a direct or indirect for consumers had been been identified.

Conclusions

Food safety risks are immediately notified to the Commission, as required by Art. 50 of Regulation (EC) No 179/2002.

6 Overall Conclusion

An efficient, centralised import control system was in place for import of FNAO. Detailed and updated procedures supported the qualified staff and ensured effective official controls. Good co-operation between the CAs provides a high level of security and ensures that imported consignments will be identified and checked. The official laboratory for the analysis of import samples provides reliable results to the CA. However, minor deficiencies were noted. The CA did not always provide a completed CED to importers. There were no dedicated places for inspection and sampling of consignments at the DPE Prague Airport.

7 Closing Meeting

A closing meeting was held on 04 April 2013 with representatives from the CCA. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The CA provided the audit team with some clarifications and preliminary comments.

8 Recommendations

The CAs are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations as set out below, within twenty five working days of receipt of the translated draft audit report.

The CA of the Czech Republic should:

N°.	Recommendation
1.	Ensure that appropriate facilities for official controls will be in place at the DPE Prague by August 2014 as required by Article 4(b) of Regulation (EC) No 669/2009 in connection with Article 19 of the same Regulation.
2.	Ensure that Food Business Operators receive a completed Common Entry Documents (CED) for consignments in line with Article 7(7) and (8) of Regulation (EC) No 1152/2009.
3.	Ensure, that in the case of onward transportation the importers present a CED where Part I is clearly linked to Part II in line with the procedures described in Article 7(6) of Regulation (EC) No 1152/2009.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6655

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Horizontal Legislation		
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. 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. 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. 16/2011	OJ L 6, 11.1.2011, p. 7-10	Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed
Dec. 2006/677/EC	OJ L 278, 10.10.2006, p. 15-23	2006/677/EC: Commission Decision of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules
Legislation on import controls of food of non-animal origin		

Legal Reference	Official Journal	Title
Reg. 669/2009	OJ L 194, 25.7.2009, p. 11-21	Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC
Reg. 1152/2009	OJ L 313, 28.11.2009, p. 40-49	Commission Regulation (EC) No 1152/2009 of 27 November 2009 imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC
Reg. 1151/2009	OJ L 313, 28.11.2009, p. 36-39	Commission Regulation (EC) No 1151/2009 of 27 November 2009 imposing special conditions governing the import of sunflower oil originating in or consigned from Ukraine due to contamination risks by mineral oil and repealing Decision 2008/433/EC
Reg. 258/2010	OJ L 80, 26.3.2010, p. 28-31	Commission Regulation (EU) No 258/2010 of 25 March 2010 imposing special conditions on the imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins, and repealing Decision 2008/352/EC
Dec. 2008/47/EC	OJ L 11, 15.1.2008, p. 12-16	2008/47/EC: Commission Decision of 20 December 2007 approving the pre-export checks carried out by the United States of America on peanuts and derived products thereof as regards the presence of aflatoxins
Legislation on pesticide residues and contaminants		
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

Legal Reference	Official Journal	Title
Reg. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
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
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
Dir. 2002/63/EC	OJ L 187, 16.7.2002, p. 30-43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC

Annex 2 – Standards Quoted in the report

Reference number	Full title	Publication details
n.a.	Guidance document for competent authorities for the control of compliance with EU legislation on aflatoxins:	http://ec.europa.eu/food/food/chemicalsafety/contaminants/guidance-2010.pdf
EN ISO/IEC 17011	General requirements for accreditation bodies accrediting conformity assessment bodies	http://www.iso.org/iso/home.html
EN ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories	http://www.iso.org/iso/home.html
SANCO/12495/2011	Method Validation and Quality Control Procedures for pesticide residues analysis in food and feed, Document SANCO/12495/2011	http://ec.europa.eu/food/plant/plant_protection_products/guidance_documents/docs/qualcontrol_en.pdf