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FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

FINLAND

FROM 23 MARCH TO 01 APRIL 2009

IN ORDER TO EVALUATE THE OFFICIAL CONTROLS SYSTEMS IN PLACE FOR IMPORT
CONTROLS, FOOD ADDITIVES AND FOOD CONTACT MATERIALS

IN THE CONTEXT OF A GENERAL AUDIT

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

Executive Summary

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in Finland from 23 March to 1 April.

The objective of the mission was to evaluate, in the context of the import controls on food of non-animal origin, the implementation of European Parliament and of Council Regulations (EC) No 882/2004 and (EC) No 178/2002, the implementation of relevant Commission Decisions concerning mycotoxin contamination and Sudan dye adulteration, and the implementation of Community legislation in the area of food additives (FAs) and food contact materials (FCMs).

The relevant EC Directives within the scope of this mission has been transposed into national law.

In relation to import controls, the requirements of Commission Decision 2006/504/EC in terms of frequency of controls and of Commission Decision 2005/402/EC regarding Sudan dyes were met. However, a few shortcomings were identified in relation to the non-rejection of consignments not accompanied by the health certificate (Article 3(4) of Commission Decision 2006/504/EC) and inadequate assessment of the official documentation (Article 10(2)(e) of Regulation (EC) No 882/2004) for a food consignment subject to Commission Decision 2006/504/EC.

Procedures on HACCP principles were not always adequately assessed (Article 10(2)(d) of Regulation (EC) No 882/2004) and written material was not always examined (Article 10(2)(e) of Regulation (EC) No 882/2004), in particular documentation on the specifications regarding purity criteria. In addition, the nitrites used in one of the companies visited did not comply with the requirements of Part C of Annex III to Directive 95/2/EC.

The level of GMP implementation in FCM manufacturers is very low (Commission Regulation (EC) No 2023/2006).

There is no monitoring of consumption of FAs (Article 8 of Directive 94/35/EC, Article 6 of Directive 94/36/EC and Article 7 of Directive 95/2/EC).

The laboratory visited in the context of this mission is adequately staffed and performs well. However, in relation to sample preparation the aggregate sample is not mixed before being divided into 3 equal laboratory samples (Commission Regulation (EC) No 401/2006).

Overall, there is an official control system in place in relation to import controls, FAs and FCMs in Finland which is mainly implemented in accordance with the relevant EC legislation. However, some shortcomings, relating to import procedures, the assessment of FAs and procedures on HACCP principles, and limited GMP implementation in FCM manufacturers, have been identified which might hamper the effective implementation of the official control system.

The report makes a number of recommendations to the competent authorities in Finland to address the shortcomings identified.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
BADGE	2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether
BFDGE	bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ether
CA	Competent Authority
CCA	Central Competent Authority
CCP	Critical Control Point
CHEK	Proficiency testing scheme in the Netherlands
CIRCA	Communication & Information Resource Centre Administrator - European Commission
CN	Combined Nomenclature
CP	Control Point
CRL	Community Reference Laboratory
CRM	Certified Reference Material
DEHA	di-2-(ethylhexyl) adipate
DEHP	Phthalic acid, bis (2-ethylhexyl) ester
DIBP	Phthalic acid, dibutyl ester
DPI	Designated Point of Import
EDI	Electronic Data Interchange
ESBO	Epoxidised soybean oil
EU	European Union

EVIRA	Finnish Food Safety Authority
FA	Food Additives
FAPAS	Food Analysis Performance Assessment Scheme, UK
FBO	Food Business Operator
FCM	Food Contact Materials
FINAS	Finnish National Accreditation Body
FVO	Food and Veterinary Office
GC-MS	Gas Chromatography-Mass Spectrometry
HACCP	Hazard Analysis Critical Control Points
HPLC	High Performance Liquid Chromatography
ICP	Inductively Coupled Plasma
ISO	International Organisation for Standardisation
ITX	Isopropylthioxanthone
JRC-IMRR	Joint Research Centre — Institute for Reference Materials and Measurements
LC-MS	Liquid Chromatography-Mass Spectrometry
LIMS	Laboratory Information Management System
LOD	Limit of Detection
LOQ	Limit of Quantification
MAF	Ministry of Agriculture and Forestry
MFCA	Municipal Food Control Authority

MS	Member State
MTI	Ministry of Trade and Industry
NBC	National Board of Customs
NCP	National Contact Point
NRL	National Reference Laboratory
OJ	Official Journal of the European Union
OTA	Ochratoxin A
PAA	Primary Aromatic Amine
PVC	Polyvinyl Chloride
RASFF	Rapid Alert System for Food and Feed
SANCO	Health and Consumers Directorate-General
SEM	Semicarbazide
SOP	Standard Operating Procedure
SPO	State Provincial Office
TLC	Thin Layer Chromatography
UV-VIS	Ultraviolet-visible spectrophotometry
VALVIRA	National Supervisory Authority for Welfare and Health

1 INTRODUCTION

The specific audit took place in Finland from 23 March to 1 April 2009. The mission team comprised 2 inspectors from the Food and Veterinary Office (FVO) and 2 Member State experts. The specific audit was undertaken as part of the FVO's planned mission programme and was carried out as a component of a General Audit, as prescribed in Article 45 of 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.

The inspection team was accompanied during the specific audit by a representative from the central competent authority (CCA) the Finnish Food Safety Authority (EVIRA).

An opening meeting was held on 23 March 2009 with EVIRA and representatives of the Ministry of Agriculture and Forestry (MAF), Customs, the National Supervisory Authority for Welfare and Health (VALVIRA) and the State Provincial Offices (SPOs). At this meeting, the objectives of and itinerary for the specific audit were confirmed by the inspection team, and additional information required for the satisfactory completion of the specific audit was requested.

2 OBJECTIVES OF THE MISSION

The objective of the specific audit was to evaluate the implementation of :

- European Parliament and Council Regulation (EC) No 882/2004,
- European Parliament and Council Regulation (EC) No 178/2002, and
- Commission Decisions imposing special conditions on the import of certain products concerning mycotoxin contamination and Sudan dyes adulteration in foodstuffs,
- Community legislation in the area of food additives (FA), in particular the transposition and implementation of Directives 89/107/EEC, 94/35/EC, 94/36/EC, 95/2/EC and related legislation concerning the purity of food colours, sweeteners and food additives other than colours and sweeteners,
- Community legislation in the area of food contact materials (FCM), in particular the implementation of European Parliament and Council Regulation (EC) No 1935/2004 and related legislation with regard to regenerated cellulose film, plastic materials and ceramic articles.

This was the first FVO specific audit to Finland for this purpose. It formed part of a wider series of missions to Member States (MSs) to evaluate control systems and operational standards in these three sectors.

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

Competent Authority visits		5	Comments
Competent authority	Central	1	EVIRA, in the presence of Customs, MAF, VALVIRA and SPOs
	Regional	2	SPOs Western and Southern Finland

	Local	2	Municipal Food Control Authorities: Hämeenlinna and Tampere

Laboratory visits	1	Comments
Customs Laboratory	1	National reference laboratory for mycotoxins and FCM. It is also an official laboratory for food additives.
Visits to premises	6	
FCM manufacturers	2	Plastics and ceramics FCMs
FA producers	2	FA mixtures for meat companies
User of FAs/FCMs	1	Food processor which uses FAs and FCMs
Importer of food of non-animal origin	1	Importer of nuts, spices and dried fruits
Other sites	1	
Port of Helsinki	1	Vuosaari Harbour. Main point of import for food of non-animal origin (nuts and dried fruits)

3 LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of Community law and in particular:

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

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

4 BACKGROUND

4.1 BACKGROUND TO THE MISSION

Article 50 of Regulation (EC) No 178/2002 requires that information on foodstuffs and feedingstuffs found to have public health implications is disseminated as notifications through the

Rapid Alert System for Food and Feed (RASFF) to all MS and when relevant to the exporting country.

4.1.1 Mycotoxins

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

In fact, there were 992 RASFF messages for mycotoxins in 2005, 874 in 2006, 754 in 2007 and 936 in 2008. Implicated products included peanut and peanut products, pistachios, hazelnuts, Brazil nuts, almonds, dried fruits, spices, coffee and cereals. For Sudan dyes, there were 183 RASFF notifications in 2005, 50 in 2006, 30 in 2007 and 25 in 2008.

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

Seventeen MS were visited and three of these were the subject of additional follow-up inspections.

This series of missions identified weak controls at the import stage in some MS. In particular, the following major problems were identified:

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

4.1.2 Food contact materials

As regards food contact materials, 570 notifications, mainly concerning materials originating from Third Countries and to a lesser extent in Member States, have been notified through RASFF in the last three years. These break down as follows: 192 alerts in 2006, 172 in 2007 and 206 in 2008.

The following hazards were reported: primary aromatic amines (PAA), semicarbazide (SEM), di(2-ethylhexyl) adipate (DEHA), formaldehyde, heavy metals (lead, cadmium, chromium, nickel, iron, manganese or zinc), excessive total migration, organoleptic properties, isopropyl thioxantone (ITX) and phthalates (DEHP, DBP).

4.1.3 Food Additives

"Food additive" is defined as a substance not normally consumed as food in itself and not normally used as a characteristic ingredient of food. It is added to food intentionally for technological reasons. Community legislation establishes a "positive list" of additives authorised for use in foodstuffs, usually specifying the maximum content thereof allowed in food or setting the permitted limit at a level necessary to achieve the technological purpose without misleading the consumer. Before authorisation, food additives have to undergo appropriate toxicological testing and evaluation, leading to approval or rejection and to establishment of the maximum permitted levels in foodstuffs. This evaluation takes into account any cumulative, synergistic or potentiating effect of

use thereof and the phenomenon of human intolerance to substances foreign to the body. It is forbidden to use unauthorised additives in foodstuffs and to apply additives to foodstuffs without authorisation for each specific application.

4.2 PUBLIC HEALTH INFORMATION

4.2.1 Mycotoxins

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

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

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

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

Therefore, EU legislation establishes:

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

4.2.2 Sudan dyes

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

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

4.2.3 Food Contact Materials

Primary aromatic amines

Annex V to Commission Directive 2002/72/EC lays down the general specification for plastics that primary aromatic amines (PAAs) should not migrate into food or food simulant in detectable quantities. Some PAAs are considered human carcinogens. They can be formed primarily from isocyanates used in glues, adhesives in laminates and azodyes used as colours. There may also be other sources.

Lead and cadmium from ceramic ware

Council Directive 84/500/EEC lays down migration limits for lead and cadmium from ceramic ware into 4% acetic acid. This Directive requires a declaration of compliance for ceramic articles and

appropriate documentation to demonstrate that they comply with the migration limits for lead and cadmium. The manufacturer or the importer into the Community should make the documentation available to the national competent authorities on request. It must contain the results of the analyses carried out, the test conditions and the name and address of the laboratory that performed the tests.

Formaldehyde

Directive 2002/72/EC lays down a specific migration limit of 15 mg/kg for formaldehyde, a monomer used to manufacture melamine kitchenware.

DEHA

DEHA is used as a plasticiser in polyvinyl chloride (PVC) cling films and other PVC applications. Directive 2002/72/EC lays down a specific migration limit of 18 mg/kg of food for DEHA. Certain cling films exceeded the migration limit for DEHA, especially into meat.

SEM

Directive 2002/72/EC authorises use of azodicarbonamide as a blowing agent in plastic materials and articles intended to come into contact with foodstuffs. New findings have shown that azodicarbonamide decomposes into semicarbazide when heated during production of foamed gaskets and during sterilisation of sealed glass jars. The European Food Safety Authority (EFSA) Scientific Panel on food additives, flavourings, processing aids and materials in contact with food concluded that SEM was undesirable in baby food and recommended that it would be prudent to reduce exposure to SEM as swiftly as technological progress safely allows. Commission Directive 2004/1/EC amending the above-mentioned Directive 2002/72/EC suspends use of azodicarbonamide from the (incomplete) list of additives fully harmonised at Community level.

4.2.4 Food Additives

The quantity of food additives in foodstuffs and application of food additives to specific product groups has to be monitored by the competent authorities in the Member States to ensure maximum consumer safety.

The most common infringement of the relevant EU legislation since 2004 has been use of unauthorised Sudan dyes, which were classified as category 3 carcinogens by the International Agency for Research on Cancer. Sulphites are also frequently used as preservatives in excess of the legal limits. This group of substances can trigger asthma, urticaria, itching and even anaphylaxis in rare cases. Other main analytical targets in foodstuffs which are routinely monitored by the competent authorities are sweeteners, nitrates/nitrites, antioxidants, flavour enhancers and thickeners.

5 FINDINGS AND CONCLUSIONS

5.1 LEGISLATION

Findings

As stated in the country profile (DG SANCO 7592/2007) the designation of CAs and their respective duties in the field of food control are laid down in the Finnish Food Act No 23/2006.

The MAF is currently responsible for drafting legislation and transposing EU law in the context of

this mission, in particular the Unit for Food Safety of the Department of Food and Health. The role of the Ministry of Trade and Industry (MTI) in drafting food legislation has been transferred to the MAF since 2008. Staff of the MTI involved in this area were also transferred to the MAF.

The Advisory Committee on Foodstuffs under the MAF plays an important role in giving opinions on new EU and national legislation. The task of this Committee is to handle matters relating to food safety and consists of 15 subcommittees dealing among other things with FAs, FCMs and contaminants. These subcommittees comprise representatives of all the relevant authorities and of stakeholders (food industry, food trade and catering sector, consumer issues and primary production).

All legislation is made available to the public on the MAF's website. EVIRA produces a compendium of legislation for CAs and publishes a monthly magazine where information on new legislation is described. This magazine is circulated to the SPOs, the MFCAs and Customs.

The mission team was informed that all EC Directives concerning FCMs and FAs have been transposed into Finnish law. They are transposed by means of Decrees.

There is additional national legislation in place which lays down specific migration limits for heavy metals on metal wares and ceramics.

EVIRA is responsible for receiving applications referred to in Articles 9-12 of Regulation (EC) No 1935/2004 where the approval of plastic recycling process is concerned; MAF is responsible for receiving other applications, and EVIRA and MAF have been designated as the contact point for the European Commission and the EFSA in line with the provisions of Article 13 of the Regulation.

There have been no national authorisations of FAs under Article 5 of Directive 89/107/EEC since 1999. If an application was made, MAF would be responsible for authorising the FA in question.

Conclusions

Responsibilities for drafting and transposing legislation in the context of this mission, and granting authorisations of FAs under Article 5 of Directive 89/107/EEC, are clearly defined.

Legislation is well disseminated and publicly available.

The EC Directives relevant to this mission have been transposed into Finnish law. Additional national legislation covers FCMs not harmonised at Community level.

5.2 REQUIREMENTS ALONG THE FOOD CHAIN FOR IMPORT CONTROL, FOOD ADDITIVES AND FOOD CONTACT MATERIALS

5.2.1 Organisation of import controls

Legal requirements

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

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

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

thereto.

Findings

The import procedure starts when operators notify the consignment to be imported via Customs but before this import declaration takes place, importers can make an advance inquiry to the Customs Consumer Protection Inspector on the possibility of sampling in the case of products subject to Commission Decisions. When an entry declaration is lodged the Customs electronic clearance system (ITU) identifies the food commodities listed by the relevant Commission Decisions and asks for further requirements (e.g. health certificate, sampling); it flags those which are considered risky by Customs. Once the declaration is processed the Customs EDI (electronic data interchange) processor requires the Customs Consumer Protection Inspector to carry out a documentary check on the goods concerned. If sampling is required the inspector will issue a sampling order and a transfer permit will be issued by the EDI processor to allow the movement of the goods from the port to the importer's warehouse. A Customs Sampling Unit undertakes the identity check and sampling, and the samples are then brought to the Customs Laboratory. When the analytical results are provided, the Enforcement Unit of the Customs Laboratory informs the EDI processor of the analytical results. If the results are in compliance with EC legislation, Customs officials complete the form in Annex III to Commission Decision 2006/504/EC and the products are then released onto the market.

In the case of non-compliance, the EDI processor receives a message electronically from the above Enforcement Unit explaining why the consignment has been rejected. Customs then informs the importer in writing and asks the importer what they are going to do with the rejected consignment (see point 5.2.5).

Conclusions

There is an adequate official import control procedure in the context of this mission.

5.2.2 Frequency of controls

5.2.2.1 Foodstuffs imported from certain third countries submitted to special conditions

Legal requirements

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

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

Audit findings

In reply to the pre-mission questionnaire, the mission team obtained data on import controls on foodstuffs of non-animal origin for 2007 and 2008 from Finnish Customs. This included products subject to Commission Decision 2006/504/EC. The data are presented in Annex II (Tables 1 and 2). The mission team observed that the frequency of controls on foodstuffs affected by the above Decision is in compliance with the required frequency.

With regard to Commission Decision 2005/402/EC, the official control by Customs included a

check on the analytical report, as required by the EU legislation; in the absence of such reports, consignments were detained and reports requested. Samples were also taken.

Conclusions

The frequency of controls was in accordance with Commission Decision 2006/504/EC.

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

5.2.2.2 Foodstuffs imported from certain third countries not subject to special conditions

Legal requirements

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

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

Audit findings

The Customs Enforcement Unit of the Customs Laboratory is responsible for developing the official food control plan in relation to import controls on food of non-animal origin, including FCMs, taking into account the food control programme (EVO) developed by EVIRA, specific EU programmes (e.g. pesticide residues), RASFF notifications, potential risks and the results of samples taken at the point of import. The draft plan is developed in consultation with other units of the Customs Laboratory. Once it is drafted, the plan is submitted to the Control Department of the Board of Customs for comments. Once it is approved, a copy is sent to EVIRA. The plan contains a list of food products and FCMs subject to an increased level of control, including those subject to Commission Decisions. The country of origin and the frequency of sampling are also described.

The frequency and place of sampling for products subject to an increased level of official control but not included in Commission Decision 2006/504/EC are indicated in the Customs official control plan and in the Customs ITU system (see point 5.2.1).

In 2007, 23 samples of peanuts, spices and basmati rice from several third countries were analysed for aflatoxins and 48 samples of the above products were also analysed for aflatoxins in 2008 (see Table 3 of Annex II).

Conclusions

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

5.2.3 Types of checks on food of non-animal origin

Legal requirements

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

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

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

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

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

Audit findings

All Finnish Customs offices are Designated Points of Import (DPIs) through which foodstuffs covered by Commission Decision 2006/504/EC may be imported into Finland. The mission team was informed that the main DPI for nuts and dried fruits subject to the above Decision is Vuosaari Port.

The mission team evaluated a demonstration sampling of a shelled peanut consignment consisting of 360 bags of 50 kg each (total weight 18 tonnes). The sampling was carried out by the Customs Sampling Unit. The container had been unloaded into a covered warehouse with adequate space for full unloading. Sampling spears were used to take 100 incremental samples of 300 g each from a random distribution of sampling points to result in a 30 kg sample distributed in 4 bags of 7.5 kg each. The 4 bags were labelled and sealed. An identity check was also carried out by the samplers before sampling.

Despite the existence of a Commission guidance document, Customs had prepared a sampling manual. In addition, EVIRA issued guidelines for sampling concerning *Fusarium* toxins to SPOs and MFCAs in 2007.

Conclusions

A covered area was available for unloading and sampling of consignments in accordance with Article 4(2)(c) of Commission Decision 2006/504/EC and Article 16(3) of Regulation (EC) No 882/2004.

The sampling equipment available for the inspectors is adequate and the sampling was carried out in accordance with the requirements of Commission Regulation (EC) No 401/2006.

5.2.4 Import of foodstuffs for further sorting or other physical treatment

Legal requirements

Article 4 of Commission Regulation (EC) No 1881/2006 provides that groundnuts, nuts, dried fruit and maize not complying with the appropriate maximum levels of aflatoxins can be placed on the market under certain conditions.

Audit findings

To date, there had been no imports of the above food commodities for sorting, or other physical treatment, before human consumption and there are no establishments for this kind of treatment in Finland.

Conclusions

No consignments for further sorting are imported into Finland.

5.2.5 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.

Article 3(4) of Commission Decision 2006/504/EC stipulates that when a consignment is not accompanied by the results of the sampling and analysis and the health certificate, the consignment must be re-dispatched to the country of origin or destroyed.

Audit findings

When a food consignment does not comply with EU food law, a number of measures can be taken, such as re-dispatch to the country of origin, special treatment for use as feed or destruction.

In the case of re-dispatch of the consignment to the country of origin, Customs issues a decision in writing on the basis of the application from the importer. In this case, the consignment to be returned must be loaded under Customs control and sealed.

The mission team was informed that one or two consignments of products subject to Commission Decision 2006/504/EC that requires a health certificate were not accompanied by this health certificate and were released onto the market after sampling and analysis were made. These consignments were not rejected and subsequently either re-dispatched to the country of origin or destroyed as required by Article 3(4) of the above Decision.

The second possibility is that the non-compliant consignment can be used as feed. Two examples of rejected consignments contaminated with ochratoxin A in rye were shown to the mission team. The importer applied to Customs for authorisation to use the products as feed. Customs then contacted EVIRA, who in turn drafted an opinion on the possibility of using them as feed. This opinion was sent to the Enforcement Unit of the Customs Laboratory, which sent instructions for the consignment to be released as feed.

Customs can also order the destruction of the rejected consignment. The destruction takes place when requested by the importer or if the product may pose a serious health hazard. The destruction is carried out under the supervision of Customs and the importer receives a destruction protocol.

Conclusion

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

In very few cases, consignments of products subject to Commission Decision 2006/504/EC that requires a health certificate were not accompanied by this health certificate and were not rejected as required by Article 3(4) of Commission Decision 2006/504/EC.

5.2.6 Right of appeal against decisions on consignments

Legal requirements

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

Article 14(6) of Regulation (EC) No 178/2002 provides that, where any food which is unsafe is part of a consignment of food of the same description, it shall be presumed that all the food in that consignment is also unsafe, unless — following a detailed assessment — there is no evidence that the rest of the consignment is unsafe.

Annex II to Regulation (EC) No 401/2006 on mycotoxins lays down the requirements for the replicate samples (enforcement, defence and reference).

Audit findings

The mission team was informed that in the case of non-compliant consignments, the food business operators (FBOs) have the right to apply for a second opinion. This right is described in section 73 of Food Act No 23/2006. In the context of mycotoxin analysis, the defence sample is taken from the homogenised laboratory sample following the requirements of Annex II to Regulation (EC) 401/2006. In this case, the defence sample has to be analysed in an accredited laboratory chosen by the importer.

If the results of the defence and the enforcement sample were different, the reference sample would be analysed, but this situation had never yet occurred.

Conclusions

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

The defence sample is taken in accordance with the requirements of Annex II to Regulation (EC) No 401/2006.

5.2.7 Declaration of compliance

Legal requirements

Article 16 of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food requires FCMs to be accompanied by a written declaration stating that they comply with the rules applicable to them.

Article 9 of Commission Directive 2002/72/EC as amended relating to plastic materials and articles intended to come into contact with foodstuffs requires that at the marketing stages other than the retail stages, plastic materials and articles which are intended to be placed in contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004.

Article 2a of Council Directive 84/500/EEC as amended relating to ceramic articles intended to come into contact with foodstuffs requires that at the marketing stages up to and including the retail stages, ceramic articles which are not yet in contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004.

Audit findings

In the context of the declaration of compliance the mission team visited two FCM manufacturers,

one for plastics and one for ceramics, and one user of FCMs.

In the 2 manufacturing companies, the declaration of compliance was checked by means of a check list developed by EVIRA. This check list requires, among other things, information about the company and its activities. It also describes how to assess the company's quality assurance system and its implementation. In relation to the declaration of compliance, the check list includes all the above legal requirements. The check list was used extensively by the inspectors in the three companies visited and complied with the above legal requirements.

Conclusions

Adequate assessments of the declaration of compliance were carried out in respect of the three companies visited.

5.2.8 Control at premises visited including hazard analysis and critical control points (HACCP)

Legal requirements

Article 10 of Regulation (EC) No 882/2004 lays down that official controls shall, in general, be carried out using appropriate control methods and techniques.

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

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

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

Article 18 of Regulation (EC) No 178/2002 establishes traceability requirements in food and feed.

Article 17 of Regulation (EC) No 1935/2004 establishes traceability requirements in FCM.

Audit findings

With regard to the implementation of HACCP principles by FBOs and the assessment of food safety procedures based on HACCP principles by MFCA officials, including monitoring of FAs by the companies and traceability requirements, the mission team visited 6 companies, namely 2 producers of FA mixtures, 2 FCM producers, 1 user of FAs and 1 importer and processor of nuts and dried fruits in three municipalities. All the establishments were categorised on the basis of risk.

The company visited (a producer of FA mixtures), which is under the supervision of the Hämeenlinna MFCA, is inspected once a year according to the risk assessment. The company has been certified to ISO-9001 and 22001. The inspection was well organised and focused on traceability, formulation, labelling, procedures based on HACCP principles and general hygiene requirements. The team was informed that the inspector had never requested full access to the recipe of the products and therefore did not fully assess how the company ensured that the quantities of FAs used when making the mixture followed the requirements of the recipe. The specifications on purity criteria regarding FAs used in foodstuffs provided by the FA supplier were not assessed by the inspectors.

The inspection carried out on the producer of FA mixtures in the city of Helsinki focused on traceability, formulation, labelling, procedures based on HACCP principles and general hygiene requirements. The company did not identify any critical control point (CCP) in its process and the HACCP assessment plan by the inspector did not require the need for CCPs either. The last official inspection was undertaken in November 2008 and a number of control points (CPs) were identified in the process. During the inspection, the mission team observed that the inspector had requested full access to the recipe of the products during the previous visits. However, the instructions (e.g. procedures for calibration and maintenance of scales used for weighing ingredients) and records of process control for these CPs were not checked. The specifications on purity criteria regarding FAs used in foodstuffs provided by the FA supplier were not assessed by the inspectors.

The mission team also visited a company importing and processing nuts, dried fruits and spices. The company is inspected three times a year. During the inspection, the inspector checked relevant documentation on the goods imported, the traceability of the food products and the HACCP plan. However, the HACCP plan was not fully assessed as the inspector did not check the critical limits, the monitoring procedures at CCPs and corrective actions. In relation to import control, the mission team checked the documentation on a consignment of US sliced almonds and noticed that the document required by Annex III to Commission Decision 2006/504/EC was missing and that this absence had not been identified by the inspector.

In the municipality of Tampere, the company (a user of FAs/FCMs) visited had procedures based on HACCP and no CCPs were identified by the company. The assessment of these procedures by the inspector did not indicate the need for such CCPs. The inspection was well organised and checklists for both topics were used by the inspectors. Regarding FCMs, the storage conditions and traceability were assessed in line with the relevant EC requirements. Regarding FAs, the inspector did not check the specifications on purity criteria provided by the FA supplier or the implementation of some instructions related to CPs, in particular monitoring of the weight of FAs used in the products. As the company makes meat products (e.g. sausages) some FAs are used, such as nitrites. However, the mission team found that the nitrites used by the company for food production were not bought by the company in a mixture with salt or a salt substitute as required by Part C of Annex III to Directive 95/2/EC on FAs other than colours and sweeteners. This issue was not identified by the inspector during the inspection.

At the two FCM manufacturers visited, the inspectors assessed the traceability of the FCMs produced following the requirements of Regulation (EC) No 1934/2004. However, one of the two manufacturers visited, which is one of the biggest in Finland, had been operating for many years and was only inspected in March 2009¹

Conclusions

The assessment of procedures on HACCP principles in some companies was not fully carried out in accordance with Article 10(2)(d) of Regulation (EC) No 882/2004.

The implementation of some companies' instructions (CPs) relating to FAs was not adequately assessed.

The nitrites used by one company did not follow the requirements of Part C of Annex III to Directive 95/2/EC on FAs other than colours and sweeteners. This issue was not identified by the inspector.

Traceability requirements regarding FCMs were adequately assessed.

Up to the time of the mission, no tasks related to official control had been carried out in one FCM company visited (Article 10 of Regulation (EC) No 882/2004).

There was inadequate assessment of the written material in one case (official documentation not

fully completed for an almond consignment and lack of checking of the specifications on purity criteria regarding FAs used in foodstuffs).

5.3 GOOD MANUFACTURING PRACTICE FOR FOOD CONTACT MATERIALS

Legal requirements

Article 3 of Regulation (EC) No 1935/2004 requires FCM to be manufactured in compliance with good manufacturing practice (GMP).

Commission Regulation (EC) No 2023/2006 lays down the rules on good manufacturing practice for the groups of materials and articles intended to come into contact with food.

Audit findings

From September to December 2008, EVIRA established a pilot project on GMP implementation in FCM companies. Eighteen MFCAs and a total of 27 companies (24 FCM and 3 FBO operators) under the supervision of these MFCAs participated in this project. In addition, 4 FCM samples were taken regarding BADGE compounds. In the same context 26 foodstuffs which had been in contact with lacquer-coated metal cans were also inspected for BADGE compounds. No non-compliant samples were found.

The outcome of this project was presented to the mission team and indicated that 87% of FCM operators had a GMP in place, and it was of a high standard in 17% of the companies. The mission team was informed that the compliance with GMP was considered satisfactory in 70% of the companies and 60% of them had a certified quality system (e.g. ISO 9001, ISO 22000).

EVIRA has participated in a Nordic joint project on developing horizontal guidelines for in-house control and traceability, including GMP, and a vertical guideline for paper and cardboard in contact with food.

In the Hämeenlinna municipality, 5 (1 as part of the pilot project) out of 15 FCM producers were assessed by the MFCA with regard to GMP implementation. The remaining FCM companies have not been assessed yet.

In the Tampere municipality, 8 (4 as part of the pilot project) out of 27 FCM producers were assessed by the MFCA with regard to GMP implementation. The remaining FCM companies have not been assessed yet.

The two FCM companies visited had a quality assurance system in place and the assessment of GMP and its implementation were assessed by the inspectors by using a check list (see also point 5.3.8). There is a specific section relating to the quality management plan on the check list which indicates how to assess it. The assessment was made in line with the requirements of Regulation (EC) No 2023/2006.

Conclusions

Procedures on GMP have been implemented in 70% of the FCM companies.

The assessment of GMP in the companies visited was adequate.

5.4 MONITORING SYSTEMS FOR THE CONSUMPTION AND USE OF ADDITIVES

Legal requirements

European Parliament and Council Directives 94/35/EC (Article 8), 94/36/EC (Article 6) and 95/2/EC (Article 7) require each Member State to monitor the consumption and usage of FA.

Audit findings

EVIRA is in charge of the monitoring system for the use and consumption of FAs. With regard to consumption of FAs, the Product Safety Unit of EVIRA is responsible for collecting the data and the Risk Assessment Unit is responsible for calculating the intake. In this area, no further monitoring of the consumption of FAs has been carried out since 2000. The mission team was informed that the monitoring system is under discussion since there is not going to be a common methodology at Community level in the near future.

Regarding the use of FAs, the Control Management Unit has the task of gathering control data from the MFCAs, Customs and VALVIRA in relation to the number of FA samples. In 2007, the MFCAs took 131 FA samples, of which 16 were non-compliant, and Customs took 685 FA samples, 28 of which did not comply with the EC requirements.

Conclusions

There has been no monitoring of the consumption of FAs since 2000.

There is a monitoring system in place for the use of FAs.

5.5 LABORATORY SERVICES

Legal requirements

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

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

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

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

Article 24 of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food requires the Community reference laboratory for FCMs and national reference laboratories established as laid down in Regulation (EC) No 882/2004 to assist MSs by contributing to a high quality and uniformity of analytical results.

Annex II to Commission Regulation (EC) No 401/2006 lays down the methods of analysis for the official control of the levels of mycotoxins in foodstuffs.

Audit findings

General organisation

Currently, there are 3 FCM and 8 FA laboratories designated to perform official control analysis in Finland. All these laboratories are approved by EVIRA and as a prerequisite the laboratories have to be accredited to ISO 17025 by the national accreditation body (FINAS). The mission team was informed that the Customs Laboratory is the main laboratory for testing FCMs, FAs and mycotoxins as it analyses more than 90% of official samples taken. The remaining FCM and FA laboratories perform very limited official analysis.

In the context of this mission, the NRL for mycotoxins and FCMs is the Customs Laboratory. However, when questioned about the role of the NRL as described in Article 33(2) of Regulation 882/2004 the laboratory stated that this role was under discussion. The mission team was informed that currently no dissemination of information from the CRL to the official national laboratories takes place and no comparative tests between the official national laboratories are being organised.

In Tampere MFCA, the mission team was informed that some official FA samples (nitrites) were to be analysed by a private laboratory. A contract had been concluded between the municipality and the laboratory in this regard. However, the laboratory was approved by EVIRA for nitrites in water.

Laboratory visited

The mission team visited the Customs Laboratory, where the areas of FAs, FCMs and mycotoxins were evaluated. The laboratory employs 75 staff and has a number of units, including an enforcement unit, a sampling and inspection unit, and two analytical units: Food I (FAs, contaminants, pesticide residues) and Consumer Goods (FCMs, cosmetics, toys), that come under the scope of this mission.

The laboratory performs mainly official control analyses and Customs technical examinations. The laboratory also carries out private analysis but the number of these analyses is low (10-15%).

The laboratory has been accredited according to ISO 17025 by FINAS since 1993 and the accreditation visit takes place once every 1.5 years. The last visit by FINAS was made in March 2009 and no essential non-compliances were detected during that visit. The accreditation scope covers most important methods of FAs, mycotoxins and FCM analyses. The laboratory is approved by EVIRA for carrying out official control analyses.

A quality manager has been appointed for the laboratory. Internal audits are carried out by the laboratory's quality team. All analytical methods are audited once every two years. New methods, devices and personnel are always subjected to audits.

A general evaluation was made of the laboratory's system for sample reception and processing. In the sample reception area, samples are brought in by the officials. Samples are then given a unique code and sent to the laboratory accompanied with the sampling report filled in by the sampling officers. Data concerning samples are entered in the laboratory information management system (LIMS), and a work sheet is issued for the analysts.

The results of the analyses are normally written manually onto the work sheets and subsequently entered into the LIMS database. When the result of the analysis shows that permitted concentration limits are exceeded, the analysis is repeated from the beginning by another person to confirm the result. The test reports issued by the laboratory contain all the essential data about the analysis. If non-compliance is detected, the laboratory's enforcement unit issues a non-compliance decision as an annex to the laboratory test report containing the results.

The mission team observed that there are sufficient quality control procedures in place and that the results of participation in proficiency testing schemes (FAPAS, CHEK, JRC-IRMM) were

considered satisfactory.

With regard to FA analysis, the 'Food I unit' has 2 chemists and 4 technicians who devote 50% of their working time to FA testing. The technicians took part in HPLC training in 2008 but no specific training for food additive analysis has been provided.

The list of analytical methods includes the determination of most important FAs. There are 5 methods that have been accredited and the remaining methods are validated.

Overall, the number of samples analysed for FAs was 829 in 2008, including 706 official control samples. With regard to non-compliances, 13 samples were found non-compliant on account of the non-authorized use of FAs, 8 exceeded the maximum permitted legal limits, and 27 samples lacked the requisite labelling. No tests were carried out regarding purity of FAs.

In addition, six samples of guar gum were tested for pentachlorophenol in 2008 and no non-compliant samples were identified.

The mission team checked 3 SOPs: the determination of water-soluble food colours by TLC and HPLC methods, and the determination of Sudan dyes by the LC/MS method.

Water-soluble food colours are always detected qualitatively by the TLC method. Only when suspicions arise that maximum permitted limits may possibly be exceeded, which is evaluated visually, is quantitative analysis by HPLC carried out. The HPLC method is accredited for the determination of the following three colours: E110, E122 and E124. The method was validated for the determination of the above three colours in soft drinks and confectionery in the year 2003. The limit of quantification (LOQ) is 0.1 mg/kg, the recovery factor varies from 90.1 to 91.8%, and the expanded measurement uncertainty is between 10 and 20%. If needed, six other synthetic colours in addition to the above three colours can be determined together quantitatively by the HPLC method.

The LC/MS method for determination of Sudan dyes enables Sudan I, II, III and IV and Para Red to be detected. The SOP is well documented and the limit of detection (LOD) for Sudan dyes is 0.1-1 mg/kg. For Para Red the LOD is 0.3-3 mg/kg depending on the sample matrix.

The 'Food II unit' is responsible for aflatoxin analysis. There are 3 technicians and 1 chemist involved in mycotoxin analyses. The staff took part in HPLC training in 2008; no special training in mycotoxin analysis has been available.

In the context of this mission, there are two methods for mycotoxin analysis (aflatoxins B1, B2, G1 and G2; Ochratoxin A) which are accredited by FINAS.

The mission team checked the SOP for the determination of aflatoxins, including sample preparation. Registration of the sample is the same as explained above. With regard to sample preparation the mission team observed that the aggregate sample, which consists of 4 or 5 opaque plastic bags containing altogether 30 kg for aflatoxin analysis, is not mixed before being divided into 3 equal laboratory samples as required by Commission Regulation (EC) No 401/2006. Each laboratory sample is then finely ground using the slurry method. From the homogenised material, 5 replicate samples are taken (enforcement, trade and reference purposes, and two more for laboratory purposes). The defence, the reference and the two laboratory samples are kept frozen.

The analytical method is based on standard SFS-EN 14123 (immunoaffinity column cleanup, HPLC with post-column derivatisation) and enables the content of aflatoxins B1, B2, G1 and G2 in food to be determined. The performance criteria follow the requirements laid down in Annex II to Commission Regulation (EC) No 401/2006. Quality control measures are in place and the results of proficiency tests were good.

The Consumer Goods unit is responsible for FCM analysis. There are 10 staff (4 chemists, including the head of section, 1 physicist and 5 laboratory assistants) working in this unit. One third

of their work is devoted to FCMs. Training records were checked and showed sufficient training.

There were 818 samples analysed for FCMs (651 for import control and 167 for market control). 315 samples were ceramics, 98 were plastics and the remaining FCMs were mainly metallic wares. There were 9.5% non-compliant samples identified, relating to the migration of heavy metals in ceramic and metal wares, PAA in nylon kitchen utensils, formaldehyde in melamine and volatile compounds in silicone.

In the context of this mission, the scope of accreditation covers the analysis of specific migration of lead and cadmium from ceramic ware, specific migration of formaldehyde from plastic ware, and overall migration into aqueous simulants from plastic materials. The laboratory also uses other in-house methods which are not accredited but validated. These in-house methods are: a method for determining specific migration of PAA from nylon kitchen utensils, a method for determining specific migration of BADGE and BFDGE from coated cans, a method for determining phthalates content in gaskets, a method for determining ITX content, a method for determining ESBO and phthalates content and a method for determining specific migration of bisphenol A.

The laboratory is equipped with all the necessary instruments for FCM analysis (ICP, HPLC, UV-VIS spectrophotometer, GC/MS, LC/MS/MS).

During the last few years the laboratory has participated in international proficiency testing schemes (for determining overall migration into aqueous simulants, 95% ethanol, olive oil, specific migration of PAA, for determining overall migration into 3% acetic acid, for determining specific migration of lead and cadmium from ceramic ware) with good results. In 2008, the laboratory also participated in an interlaboratory comparison organised by the JRC for determining phthalates and ESBO, with good results.

The mission team checked the determination of the surface area of kitchen utensils and the use of migration cells.

The mission team also checked the method for determining specific migration of lead and cadmium from ceramics, including the control chart for lead and cadmium, the validation report and the determination of measurement uncertainty for this method. The performance of this method complied with the requirements of Council Directive 84/500/EEC, as amended.

Conclusions

All laboratories designated to perform official control are approved by EVIRA and accredited to ISO 17025.

In the context of this mission, the Customs Laboratory has been designated as the NRL for mycotoxins and FCMs as required by Article 33 of Regulation (EC) No 882/2004.

The laboratory is adequately staffed and well equipped. The most important methods are accredited and the non-accredited methods are validated. The laboratory performance is considered good.

The aggregate sample for aflatoxin analysis is not mixed before being divided into 3 equal laboratory samples as required by Commission Regulation (EC) No 401/2006.

5.6 RAPID ALERT SYSTEM FOR FOOD AND FEED

Legal requirements

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

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

Audit finding

The national contact point (NCP) for food and feed for the Commission RASFF system is EVIRA. Incoming information via CIRCA is evaluated by EVIRA and disseminated to the relevant CAs. This information is usually submitted by e-mail.

Information from the CAs to the NCP is forwarded electronically. If the CAs find out during a food inspection that food commodities including FCMs pose a serious risk to health, they notify the NCP by completing a notification form and attaching all available documentation.

EVIRA has also developed a guideline on the implementation of Articles 19 and 20 of Regulation (EC) No 178/2002, entitled 'Guideline to FBOs on withdrawal of products and on notification to authorities and to consumers'.

With regard to the issue of benzophenone and 4-methylbenzophenone, the Finnish CA contacted the company concerned immediately after the RASFF alert. The person responsible from the company affirmed that batches of the samples in question were not distributed in Finland. This information is being cross-checked by contacting the RASFF teams in some MSs. No information has been received yet from those MSs. The mission team was informed that no samples have been taken as EVIRA is waiting for the final EFSA opinion.

The mission team checked some RASFF files (e.g. non-compliant samples of preservatives, food colours, aflatoxins in almonds, PAA in nylon kitchen utensils, and lead and cadmium in ceramic wares) and found that they met the requirements of the above EC legislation.

Conclusion

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

6 OVERALL CONCLUSIONS

Overall, there is an official control system in place in relation to import controls, FAs and FCMs in Finland which is mainly implemented in accordance with the relevant EC legislation. However, some shortcomings, relating to import procedures, the assessment of FAs and procedures on HACCP principles, and limited GMP implementation in FCM manufacturers, have been identified which might hamper the effective implementation of the official control system.

7 CLOSING MEETING

A closing meeting was held on 1 April 2009 at EVIRA's premises. Representatives of MAF, Customs, VALVIRA and SPOs were present. At this meeting, the main observations and initial conclusions were presented by the mission team. The Finnish side provisionally accepted the observations and initial conclusions presented during that meeting with some general comments.

8 RECOMMENDATIONS

Nº.	Recommendation
1.	Ensure that import controls are performed in accordance with Commission Decision 2006/504/EC, in particular that food consignments not accompanied by a health certificate are rejected and subsequently either re-dispatched to the country of origin or destroyed when required by Article 3(4) of the above Decision.
2.	Ensure that official controls adequately assess HACCP principles as provided for in Article 10(2)(d) of Regulation (EC) No 882/2004.
3.	Ensure that food business operators use food additives (nitrites) that meet the requirements of Part C of Annex III to Directive 95/2/EC.
4.	Ensure that official controls adequately include the examination of written material as required by Article 10(2)(e) of Regulation (EC) No 882/2004, in particular the examination of the specifications regarding purity criteria and official documentation related to consignments subject to Commission Decision 2006/504/EC.
5.	Ensure that FCM manufacturers implement GMP as required by Commission Regulation (EC) No 2023/2006.
6.	Continue to implement the monitoring system for the consumption of FAs as required by European Parliament and Council Directives 94/35/EC (Article 8), 94/36/EC (Article 6) and 95/2/EC (Article 7).
7.	Ensure that the aggregate sample is mixed before being divided into three equal laboratory samples as required by Commission Regulation (EC) No 401/2006.

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

http://ec.europa.eu/food/fvo/ap/ap_fi_2009-8149.pdf

ANNEX 1 - LEGAL REFERENCES

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

Legal Reference	Official Journal	Title
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Dec. 2005/402/EC	OJ L 135, 28.5.2005, p. 34-36	2005/402/EC: Commission Decision of 23 May 2005 on emergency measures regarding chilli, chilli products, curcuma and palm oil
Dec. 2008/433/EC	OJ L 151, 11.6.2008, p. 55-56	2008/433/EC: Commission Decision of 10 June 2008 imposing special conditions governing the import of sunflower oil originating in or consigned from Ukraine due to contamination risks by mineral oil
Dec. 2008/352/EC	OJ L 117, 1.5.2008, p. 42-44	2008/352/EC: Commission Decision of 29 April 2008 imposing special conditions governing guar gum originating in or consigned from India due to contamination risks of those products by pentachlorophenol and dioxins
Reg. 1935/2004	OJ L 338, 13.11.2004, p. 4-17	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
Dir. 2007/42/EC	OJ L 172, 30.6.2007, p. 71-82	Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (Codified version)
Dir. 84/500/EEC	OJ L 277, 20.10.1984, p. 12-16	Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs
Dir. 82/711/EEC	OJ L 297, 23.10.1982, p. 26-30	Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs
Dir. 85/572/EEC	OJ L 372, 31.12.1985,	Council Directive 85/572/EEC of 19 December 1985 laying down the list of simulants to be used

Legal Reference	Official Journal	Title
	p. 14-21	for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs
Dir. 78/142/EEC	OJ L 44, 15.2.1978, p. 15-17	Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs
Dir. 80/766/EEC	OJ L 213, 16.8.1980, p. 42-46	Commission Directive 80/766/EEC of 8 July 1980 laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs
Dir. 81/432/EEC	OJ L 167, 24.6.1981, p. 6-11	Commission Directive 81/432/EEC of 29 April 1981 laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs
Dir. 93/11/EEC	OJ L 93, 17.4.1993, p. 37-38	Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers
Dir. 2002/72/EC	OJ L 220, 15.8.2002, p. 18-58	Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs
Reg. 1895/2005	OJ L 302, 19.11.2005, p. 28-32	Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food
Dir. 89/107/EEC	OJ L 40, 11.2.1989, p. 27-33	Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption
Dir. 94/35/EC	OJ L 237, 10.9.1994, p. 3-12	European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in

Legal Reference	Official Journal	Title
		foodstuffs
Dir. 94/36/EC	OJ L 237, 10.9.1994, p. 13-29	European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs
Dir. 95/45/EC	OJ L 226, 22.9.1995, p. 1-45	Commission Directive 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs
Dir. 95/31/EC	OJ L 178, 28.7.1995, p. 1-19	Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs
Dir. 95/2/EC	OJ L 61, 18.3.1995, p. 1-40	European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners
Dir. 96/77/EC	OJ L 339, 30.12.1996, p. 1-69	Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners
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

- i Section 5.2.8. In their response to the draft report the Finnish Authorities informed that “even though the municipal authority has not performed a physical audit of the manufacturer until March 2009, a representative of the manufacturer has been in telephone and email contact with EVIRA experts in earlier years and received information and advice”.