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Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SPAIN

FROM 04 TO 14 JUNE 2013

IN ORDER TO EVALUATE THE CONTROLS FOR CONTAMINANTS IN FOOD

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 the Food and Veterinary Office audit in Spain, carried out from 4 to 14 June 2013 under the provisions of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004.

The objectives of the audit were to:

- *verify that the official controls for contaminants in food are organised and carried out in accordance with the relevant provisions of Regulation (EC) No 882/2004, and the Multi-Annual National Control Plan (MANCP) prepared by Spain;*
- *evaluate the implementation of EU legislation in the area of food contaminants*
- *gather information about the results of investigations undertaken on food contaminants as specified in Commission Recommendations.*

In Spain all aspects of official controls on contaminants are under the responsibility of the Autonomous Communities (ACs). Both ACs visited, operate control systems for contaminants which include sampling plans and official controls of food processing establishments but not at primary production level. Contaminant sampling plans are not risk-based but are designed taking into account the capacity of official laboratories, in particular the methods available. The laboratories have the competence and capacity to analyse samples for contaminants. However, their performance is weakened by a lack of some validated methods and instructions on sample quantity for contaminants analysis. Staff performing official controls have a good knowledge of contaminants' issues but do not always have access to adequate sampling equipment.

The report makes some recommendations to the Competent Authorities aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

Table of Contents

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ACs	Autonomous Community(ies)
AESAN	*Agencia Española de Seguridad Alimentaria y Nutrición,* Spanish Food Safety and Nutrition Agency
CA(s)	Competent Authority(ies)
CCA	Central Competent Authority
CNA	*Centro National de Alimentacion*, National Food Centre
CP	Country Profile
DG (SANCO)	Health and Consumers Directorate-General of the European Commission
DGSP	*Direccion General de Salud Publica*, Directorate General for Public Health
DON	Deoxynivalenol
ENAC	*Entidad Nacional de Accreditatión*, Spanish National Accreditation Body
EP	European Parliament
EU	European Union
EURL	European Union Reference Laboratory
FBO(s)	Food Business Operator(s)
FNAO	Food of Non-Animal Origin
FVO	Food and Veterinary Office
GAP	Good Agriculture Practices
GHP	Good Hygiene Practice
HACCP	Hazard Analysis and Critical Control Points
HPLC-FLD	High Performance Liquid Chromatography with Fluorescence Detection
LAA	*Laboratorio Arbitral Agroalimentario*, Agri-Food Arbitral Laboratory
MAGRAMA	*Ministerio de Agricultura, Alimentación y Medio Ambiente,* Ministry of Agriculture, Food and Environment
MANCP	Multi-Annual National Control Plan
3-MCPD	3-monochloropropane-1,2-diol
MS(s)	Member State(s)
NRL(s)	National Reference Laboratory(ies)
OTA	Ochratoxin A
PAHs	Polycyclic Aromatic Hydrocarbons
PCBs	polychlorinated biphenyls
PTs	Proficiency Tests
RASFF	Rapid Alert System for Food and Feed
SCIRI	*Sistema Coordinadado de Intercambio Rápido de Información,* Coordinated System for Rapid Exchange of Information

1 Introduction

The audit formed part of the Food and Veterinary Office's (FVO) planned programme and was carried out in accordance with Article 45 of Regulation (EC) No 882/2004 of the European Parliament (EP) 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 audit took place in Spain from 04 to 14 June 2013. The team comprised two auditors from the FVO and one expert from a European Union (EU) Member State (MS).

Representatives from the Central Competent Authority (CCA): Spanish Food Safety and Nutrition Agency (*Agencia Española de Seguridad Alimentaria y Nutrición,* AESAN) under the Ministry of Health, Social Services and Equality (*Ministerio de Sanidad, Servicios Sociales e Igualdad*) accompanied the FVO team for the duration of the audit. An opening meeting was held on 04 June 2013 with representatives from the AESAN, Ministry of Agriculture, Food and Environment (*Ministerio de Agricultura, Alimentación y Medio Ambiente,* MAGRAMA), the Autonomous Community (AC) of Valencia and, *via* video link, the ACs of Murcia, Castilla y Leon, Extremadura, Catalunya, Aragón, La Rioja and Galicia. At this meeting, the objectives of, and itinerary for, the audit were confirmed by the FVO team and the control system was described by the authorities.

2 Objectives

The objectives of the audit were to:

- verify that the official controls for contaminants in food are organised and carried out in accordance with the relevant provisions of Regulation (EC) No 882/2004, and the Multi-Annual National Control Plan (MANCP) prepared by Spain;
- evaluate the implementation of EU legislation in the area of food contaminants
- gather information about the results of investigations undertaken on food contaminants as specified in Commission Recommendations.

In terms of scope, the audit assessed the organisation, implementation and enforcement of contaminant controls including the national control and monitoring plans, the performance of officially designated laboratories, as well as consideration of relevant Commission Recommendations, guidance and standards.

This audit did not cover the implementation of measures aimed at the control of contaminants in live animals and animal products as required by Council Directive 96/23/EC.

In pursuit of these objectives, the following sites were visited:

Table 1: Audit visits and meetings

Visits/Meetings		Comments
Competent Authorities		
Central	1	AESAN
ACs level	2	Directorate General for Public Health of the Ministry of Health of the Castilla y Léon AC and the Valencia AC; Directorate General for Agriculture and Livestock Production of the Ministry of Agriculture of the ACs of Castilla y Léon and Valencia

Inspectors		
ACs level	11	Discussions held during the visits to supervised food processing establishments, cereals grower and leafy vegetables producer
Laboratories		
Public	3	The laboratory of the National Food Center (*Centro National de Alimentacion*, CNA) The Public Health Laboratory in Burgos The Public Health Laboratory in Valencia
Establishments		
Food processors	6	One major bakery One flour mill One fruit juice producer One smoked meat processing establishment One importer of dried fruits and cereals One coffee processing establishment
Establishments growing products of plant origin	2	One leafy vegetables producer One establishment growing wheat and barley

3 Legal Basis

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 EP 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, the standards and Commission recommendations, as listed in Annex 2, were relevant for this audit. Reference to the specific provisions of these documents is provided at the begining of each section.

4 Background

4.1 Audit Series

This audit to Spain is part of a series of FVO audits to the MSs of the EU regarding the implementation of national measures aimed at the control of contaminants in food in accordance with the requirements of Regulation (EC) No 1881/2006. The reports on these audits are available on the Health and Consumers Directorate-General of the European Commission (DG (SANCO)) internet site at: http://ec.europa.eu/food/fvo/ir_search_en.cfm

4.2 Country Profile

The FVO has published a Country Profile (CP) for Spain, which describes in summary the control systems for food and feed, animal health, animal welfare and plant health. The CP can be found at: http://ec.europa.eu/food/fvo/country_profiles_en.cfm

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

Royal Decree No 475/1988 of 13 May 1988 on maximum levels of contaminants in food establishes maximum allowable levels of aflatoxins in food at the level of 10µg/kg for the sum of aflatoxins B_1, B_2, G_1 and G_2 and at the level of 5µg/kg for aflatoxin B_1. For certain foodstuffs these levels are higher than those laid down in the Annex to Commission Regulation (EC) No 1881/2006. The Decree is published on the AESAN website.

The information note of 12 June 2013 by the AESAN General Secretariat regarding the possible contradiction between Royal Decree No 475/1988 and Commission Regulation (EC) No 1881/2006 was provided to the audit team during the closing meeting. It states, *inter alia,* that the Scientific Committee of the AESAN advised maintaining the validity of Royal Decree No 475/1988 to ensure sufficient consumer protection with regard to mycotoxin levels in tiger nuts the tubers of which are widely consumed in certain regions of Spain but are not covered by EU legislation and that EU law supersedes national legislation. However, no explanation is provided on the AESAN website.

Royal Decree No 1424/1983 of 27 April 1983 provides for maximum levels for heavy metals in edible salt.

Legislation in the context of this audit, including Commission Recommendations is made available to the public on the AESAN website.

Conclusions

Relevant legislation is publicly available and accessible to the Competent Authorities' (CAs) inspectors. National legislation provides for additional requirements for certain contaminants in foodstuffs.

5.2 Official Control Systems

5.2.1 Competent Authorities

Legal requirements

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

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination and co-operation 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 33(1) of Regulation (EC) No 882/2004 requires MSs to designate at least one National Reference Laboratory (NRL) for each Community reference laboratory.

Findings

Central level

The AESAN is the CCA responsible within the context of this audit for the co-ordination of controls on contaminants and food hygiene after the primary production phase and excluding import controls.

The MAGRAMA is responsible for the co-ordination of official controls at primary production level. However, these controls do not cover verification of FBO's compliance with the general hygiene provisions for primary production of Food of Non-Animal Origin (FNAO) and associated operations laid down in Article 4.1 and in Annex I, Part A of Regulation (EC) No 852/2004.

The AESAN is the National Contact Point for the Rapid Alert System for Food and Feed (RASFF) with regard to foodstuffs.

The detailed structure of CAs, their responsibilities and instruments for co-ordination are described in Part A point 4 and in Annex II to the 2011-2015 MANCP.

Autonomous Communities level

Castilla y Léon

The Directorate-General for Public Health (*Direccion General de Salud Publica*, DGSP) under the Ministry of Health of the AC Castilla y Léon is the CA responsible for food safety issues. It operates the sampling plan for contaminants and carries out inspections in food processing establishments which cover contaminant issues.

The Directorate-General for Agricultural Production and Rural Development of the AC Castilla y Léon is the CA responsible for controls on primary production. However, these controls do not cover verification of FBO's compliance with the general hygiene provisions for primary production of FNAO and associated operations laid down in Article 4.1 and in Annex I, Part A of Regulation (EC) No 852/2004.

Valencia

The Sub Directorate-General for Food Safety under the DGSP of the Ministry of Health of the AC of Valencia is responsible, *inter alia*, for the planning and implementation of official controls in food processing establishments and contaminants sampling programme.

The Sub Directorate-General for Agri-Food Safety under the General Directorate for Agricultural and Animal Production of the Ministry of Agriculture, Fish, Feed and Water of the AC of Valencia is responsible *inter alia* for the traceability and follow-up of non-compliant nitrate results in leafy vegetables and controls on primary production. However, these controls do not cover verification of FBO's compliance with the general hygiene provisions for primary production of FNAO and associated operations laid down in Article 4.1 and in Annex I, Part A of Regulation (EC) No 852/2004.

Conclusions

The CAs involved in food contaminant controls are designated and their areas of responsibility are clearly defined in line with the requirements of Article 4(1) of Regulation (EC) No 882/2004. However, official controls do not cover verification of compliance with general hygiene provisions for primary production of FNAO laid down in Article 4.1 and in Annex I, Part A of Regulation (EC) No 852/2004.

5.2.2 Resources for Performance of Official Controls

Legal basis for controls

Legal requirements

Article 4(2)(e) of Regulation (EC) No 882/2004 requires that the necessary legal powers to carry out controls are in place and there is an obligation on Food Business Operators (FBOs) to undergo inspection by the CAs.

Article 8(2) of the above Regulation requires that CAs have the necessary powers of access to food business premises and documentation.

Findings

The legal basis for controls is described in point 6.1 of the 2011-2015 MANCP. It lays down that CAs have the necessary legal powers to carry out controls on contaminants in food.

Conclusions

Legal provisions are in place to ensure that CAs have the necessary legal powers to carry out controls on contaminants in food.

Staffing provisions and facilities

Legal requirements

Article 4(2)(c) of Regulation (EC) No 882/2004 requires the CAs to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available, and that staff performing controls are free from any conflict of interest.

Findings

Staff resources available for official controls are described in the CP for Spain and are updated in the annual report on the implementation of official controls.

Appropriate and properly maintained facilities are available at the offices of the CAs visited, including those at laboratories.

At regional level, there are technicians (pharmacists and veterinarians) assigned to perform all food safety controls, which include official controls for contaminants.

At both regions visited the CAs does not have sampling equipment available for taking samples for mycotoxin analysis from bulk lots (or big bags). The FBO's facilities or equipments are used for

official sampling whenever such facilities are available.

Adequate provisions are in place as described in the MANCP, to ensure public servants avoid conflicts of interest.

Conclusions

Adequate staff provisions and facilities are in place to perform controls in the context of this audit. However, a lack of sampling equipment for taking samples for mycotoxins undermines the operational criteria for controls on contaminants.

Preventive measures are in place to ensure that staff carrying out official controls are free from conflicts of interest.

Staff qualifications and training

Legal requirements

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

Findings

The responsibility for staff training is with the ACs. However, certain training on contaminants is provided at central level. In 2011 the Sub Directorate-General for Food Risk Management of the AESAN organised a one day training course on persistent organic pollutants and heavy metals and a more general one day training course on contaminants took place in June 2013.

Castilla y Léon

The most recent training courses on contaminants took place in 2011 and covered two days training on food sampling, two days training on surveillance and control of food processing establishments which also included two hours training on sampling, and 25 hours training on MANCP. 30 participants attended each of these.

Training on food sampling, including sampling for contaminants is scheduled to take place in October 2013.

Valencia

Three training programmes on mycotoxins in the food chain took place in 2006, 2007 and 2009, each consisting of 25 hours for 30 participants and two training programmes on organic persistent pollutants took place in 2007 and 2008, each consisting of 25 hours for 30 participants. A new series of training programmes for contaminants are planned for 2013.

There were 12 training programmes on Hazard Analysis and Critical Control Points (HACCP) and supervision of auto-control systems in food processing establishments of 115 hours each and one of 190 hours with 375 inspectors trained. The audit team noted as a good practice that after finishing the theoretical module of HACCP training inspectors accompany their experienced colleagues on control visits for additional practical training.

At both ACs visited, the majority of inspectors met in the food establishments visited demonstrated a good knowledge of HACCP principles and contaminants issues. They were able to adequately

assess the scope of FBO's own checks on contaminants.

Conclusions

The CAs provide training and the staff met demonstrated knowledge in carrying out official controls on food hygiene and contaminants.

5.2.3 Official Controls on Contaminants Along the Food Chain

Planning of controls on contaminants

Legal requirements

Article 3 of Regulation (EC) No 882/2004 requires MSs to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency. In doing so they must take account of identified risks that may influence feed and food safety, animal health or animal welfare, past records of operators, the reliability of operators' own-checks, and any information on non-compliance. Official controls shall be carried out at any of the stages of the production and processing chain. In general, such controls are to be carried out without prior warning, except where prior notification of the FBO is necessary.

Article 4 of Regulation (EC) No 852/2004 requires FBOs carrying out primary production and those associated operations listed in Annex I to comply with the general hygiene provisions laid down in part A of Annex I.

General procedures for contaminants in food are laid down in Council Regulation (EEC) No 315/93. Commission Regulation (EC) No 1881/2006 lays down maximum levels for contaminants in food.

Consideration may also be given to EU recommendations on the monitoring of the presence of and on the prevention and reduction of certain contaminants in foodstuffs.

Findings

Central level

There is a General Register of Food Establishments in Spain operated by the AESAN. In line with the AESAN area of competence it does not cover primary production and establishments selling their production directly to the end consumer.
General provisions for official controls on contaminants in food are provided in section III.5 of the MANCP.

The assessment of contaminants related risks is within the responsibility of the ACs. All official samples collected under the AC sampling plans are tested in laboratories available within the respective AC.

Castilla y Léon

Official controls cover inspections on general hygiene provisions in food processing establishments, audits of auto-control systems operated by the FBOs and planned sampling activities. A Co-ordinated Regional Protocol for Integrated Official Control within the Food Chain covers, *inter*

alia, a sampling plan for contaminants.

Contaminant sampling plans are designed annually. The CAs stated that different risk factors (e.g. vulnerable groups of consumers, risk associated with the identified hazard (i.e. contaminant), and the number of non-compliant results in the preceding year) are considered during the planning of the sampling programme. However, the CAs could not provide the evidence that the risk analysis is documented and that all groups of contaminants listed in Commission Regulation (EC) No 1881/2006 were considered during the planning process.

The scope of testing matches the availability of methods in the AC laboratories (see section 5.2.5) and is limited by the laboratory capacity and availability of technical staff. It covers nitrate in vegetables and baby foods, aflatoxins and Ochratoxin A (OTA) in spices and in coffee, lead, cadmium and tin in vegetables. The possibility of sending samples to a laboratory in another region had not been considered up to the time of the audit. The CAs stated that there are no financial constraints.

When a new method is being developed, official but single, so called "prospective" samples are collected. This has the benefit of reducing economic impact. However, if any of those samples is found non-compliant, a new official sample from the same lot enabling the FBO a supplementary expert opinion must be taken.

Possibility for suspect sampling exists in the plan description. However, there are no guidelines when or if it is advisable, to take samples for contaminants' analysis based on suspicion. No suspect samples were taken under the contaminants sampling plan since 2010.

Turnaround times for providing sample testing reports are not agreed between the CA and laboratories. However, such turnaround times are established within the laboratories' quality management systems and the audit team did not note any delays with regard to reporting test results by the AC's laboratories.

Controls in food processing establishments are focussed on the assessment of HACCP based systems which cover contaminant issues. Organisation of these controls follows documented procedures and covers control visits to assess traceability, HACCP-based systems, own testing results and verification against horizontal legislation in force including those on contaminants. Adequate checklists are available.

Valencia

Under the food sanitary surveillance programme the guide on drafting sampling plans for food safety monitoring purposes was prepared in 2010. It targets, *inter alia,* compilation of sampling plans for the official control of chemical contaminants in foodstuffs and includes tables, sampling schemes and explanations. Planning of sampling for contaminants is not risk-based but targets monitoring of contaminants occurrence.

Sampling plans for contaminants are included in the annual program of sanitary surveillance of foodstuffs. It provides sampling distribution product- and Public Health Department-wise, total number of samples, indication of sample quantity, applicable sampling legislation, laboratory name, turnaround time and the list of applicable legislation.

All samples have the status of official single control samples. In the case of a non-compliant result the decision to suspend marketing of the product may be taken, but sanctions may be imposed only when a new official sample enabling the FBO a supplementary expert opinion is collected from the same lot and found to be non-compliant.

The sampling plan covers all contaminants listed in Commission Regulation (EC) No 1881/2006.

However, since not all methods are accredited in the AC laboratories, the scope of testing is focussed on those contaminants for which accredited methods are available.

Turnaround times of 7 to 20 days (depending on the contaminant group) were established and are monitored. Although in 2012 certain progress was observed compared to 2011, these turnaround times were frequently not met and reached 68% at the most.

Planning of official controls is facilitated through the "Manual for applying the official control procedures in industry/food processing establishments". It provides for general rules for inspection, inspection/audit of hygiene and traceability pre-requisites and auditing of HACCP based systems.

Conclusions

There is no evidence that all groups of contaminants listed in Commission Regulation (EC) No 1881/2006 were considered during the planning of the contaminant sampling plan for Castilla y Léon. The AC of Valencia operates monitoring of all contaminant groups laid down in Commission Regulation (EC) No 1881/2006. In both ACs visited the scope of sampling is not risk based but depends on laboratory capacity (see section 5.2.5). Planning of routine official controls is risk-based and follows the written procedures.

Implementation of controls on contaminants

Legal requirements

Articles 3 and 4 of Regulation (EC) No 882/2004 deal with the general obligations with regard to the organisation of official controls. Community methods of sampling for the official control of contaminants in food are laid down in several parts of EU legislation: Commission Regulation (EC) No 1882/2006 (nitrates); Commission Regulation (EU) No 252/2012 (dioxins and dioxin-like polychlorinated biphenyls (PCBs)); Commission Regulation (EC) No 333/2007 (certain chemical elements, 3-monochloropropane-1,2-diol (3-MCPD), benzo(a)pyrene); Commission Regulation (EC) No 401/2006 (mycotoxins).

Article 10(2)(d) of Regulation (EC) No 882/2004 requires official controls on food to include, *inter alia*, assessment of procedures on good manufacturing practice, good hygiene practice (GHP) good farming practices and HACCP, taking into account the use of guides established in accordance with EU legislation.

Article 7 of Regulation (EC) No 852/2004 requires that MSs encourage the development of national guides to good practice for hygiene and for application of HACCP principles.

Article 8(1)(c) of Regulation (EC) No 852/2004 stipulates that guides to GHP for primary production activities should be developed having regard to the recommendations set out in Part B of Annex I of that Regulation.

Findings

Instructions on sample collection are available and provide reference to applicable EU legislation.

In both ACs visited all inspectors are considered qualified to take samples. However, in Valencia, priority is given to those verifying the HACCP based systems.

Samples are collected from all levels of the food chain except primary production and sampling plans are fully implemented.

In both ACs visited standardised sampling forms are used to record, *inter alia*, the date of sampling,

the name of the product sampled, its origin, lot identification data, lot size and the number of incremental samples taken.

During the visit to the Burgos laboratory the audit team noted sample clustering. All 2013 samples for nitrate in infant foods were collected and arrived at the laboratory on two dates. Moreover, although sample size in the instruction for inspectors is indicated as 3x350g, 12 out of 15 samples stored at the laboratory consisted of one jar of 230g and were accepted for testing.

When a sample is found to be non-compliant, a follow-up inspection is ordered. If non-compliance is found in official prospective sample (Castilla y Léon) or official control sample (Valencia), a new official sample enabling the FBO a supplementary expert opinion must be taken. However, the audit team noted that the lots identified were not available for sampling due to the lapse of time between the taking of the first sample and the attempt to take the official sample enabling the FBO a supplementary expert opinion.

Sampling and testing within the sampling plans for contaminants is financed from public resources; as well as inspection related costs in the case of non-compliance.

Considering the implementation of Commission Recommendations on contaminants, acrylamide is tested in the Valencia laboratory and ethylcarbamate in the Agri-Food Arbitral Laboratory (*Laboratorio Arbitral Agroalimentario*, LAA).

Good agricultural and hygiene practices

A Code of Good Practices to prevent and reduce contamination with OTA in paprika was drafted by the AESAN in collaboration with the industries and ACs. This Code was approved by the Institutional Committee and published in 2010 on the AESAN website for comments.

As refers to GHP, it is considered that the food industry is responsible for taking the initiative of developing national guidelines. However, to facilitate the process, in 2010 the Institutional Committee approved the "Procedure for the study and development of national guides for GHP and for the application of HACCP principles". Within the context of the audit and in line with this procedure by the Institutional Committee, the Guide on the application of HACCP in the fruit juice industry was approved.

Different CCAs, some ACs and different stakeholders collaborated within the Standardization Technical Committee of the Spanish Association for Standardisation and Certification in the development and adoption of a voluntary quality standard, UNE 155300, called Good Agricultural Practices (GAP) for fresh fruits and vegetables.

The MAGRAMA convenes annually to attribute aid co-financed from European funds and aimed at the training of professionals in rural areas. GAP are among the subjects for training.

Controls at visited premises

The audit team visited a major bakery, mill and cereal grower in Castilla y León and a leafy vegetables producer in Valencia, a fruit pulp and juice producer, a smoked meat products producer, a dried fruit processor and a coffee processor in Valencia.

The audit team observed and verified official controls for contaminants carried out by the CAs and verified control records and information provided by the FBOs.

At all seven food processing establishments visited official controls were carried out regularly, the HACCP-based systems in place covered contaminants issues and were verified by inspectors.

The establishments visited rarely considered contaminants as a hazard which needs to be controlled

as a Critical Control Point under their HACCP based system. However, all FBOs visited were aware of contaminant related risks and had taken steps to prevent their occurrence e.g. by requesting raw material specifications from their suppliers, sampling and carrying out own-checks of raw materials and their final products to avoid placing contaminated foodstuffs on the market. All FBOs visited had a HACCP-based system in place and operated certified quality management systems.

The smoked meat producer using direct smoking process had devised a HACCP-based system and all relevant hazards linked to the smoking process were taken into account and monitored. A validation of the smoking process was performed in 2009 and covered the assessment of benzo(a)pyrene levels. However, no verification of the sum of four Polycyclic Aromatic Hydrocarbons (PAHs) levels was undertaken by the FBO after the introduction (in 2012) of new requirements in EU legislation and the need to revalidate the smoking process was not identified during control visits carried out by the CAs.

In the documentation of the HACCP-based systems at the bakery and the dried fruit processor visited there were no clear links between the identified hazards of chemical contaminant occurrence and actions undertaken by the FBOs to control these hazards. Moreover, the suppliers control at the bakery visited did not cover PAHs and dioxins in fats and oils and this was not noticed by the inspector in charge.

At the coffee processor visited the HACCP-based system was developed under the supervision of the inspector in charge. It covered screening of OTA content in incoming lots and monitoring of storage conditions. The levels of OTA and acrylamide in the final produce were verified with the pre-defined frequency.

Controls on primary production level

Primary producers are inspected by the agricultural offices of the regions in the framework of cross compliance audits and the use of pesticides surveillance programmes. In the Valencia region additionally the amount of nitrogen fertilizers used is checked in vulnerable areas. However, controls on general hygiene provisions foreseen in Article 4.1 of Regulation (EC) No 852/2004 and having impact on contaminants related risks in FNAO, are not performed, see section 5.2.1. The CAs were of the opinion that there are no requirements for such controls in EU legislation.

Castilla y Léon

The GAP guidelines were developed and are available in a printed version to the farmers.

The audit team visited a farmer who grows cereals on approximately 86 ha. He explained that after harvest he transports the grains directly to a private trading company. He reported that he had never encountered problems or price reductions with the trading company relating to increased levels of mycotoxins or heavy metals. The CA in charge reported that they never took samples of the farmer's produce for heavy metals or mycotoxins verification. They explained that the region is too dry for the development of mycotoxins and that there are no industries in the area from which emissions could potentially contaminate the produce. Air and soil are regularly checked for heavy metals by the Ministry of Environment and no alarming results were known. Controls on general hygiene provisions are not performed (see section 5.2.1).

Valencia

The Ministry of Agriculture has developed and officially published GAP guidelines. They are available in a printed version to farmers, additionally on the website (including an online calculator

for fertilisation) and the printed versions are spread via regular training courses for farmers and co-operatives.

The audit team visited a farmer (in the first year of conversion to organic production) growing nearly 30 types of vegetables on approximately 10 ha. Leafy vegetables such as spinach and lettuce are produced on approximately 1.5 ha. He reported that he had never encountered problems with contaminants with his produce. The audit team checked his organic fertilisation and it was found compliant with the GAP requirements. The farmer never took samples for nitrate or heavy metals analysis. The CA in charge reported that they never took samples of the farmer's produce for heavy metals or nitrates verification. Controls on general hygiene provisions were not performed (see section 5.2.1).

Conclusions

Sampling plans are implemented as foreseen notwithstanding certain sample clustering and inadequate sample size noted in Castilla y Léon. All food processing establishments visited were controlled with adequate frequency. Also all FBOs visited took measures to avoid contaminants in their produce. However, official controls on FBO's obligations concerning hygiene requirements (Article 4.1 of Regulation (EC) No 852/2004) and GHP at primary production level are not carried out. Therefore the CAs cannot ensure that measures to avoid contamination of foodstuffs at that level are in place.

5.2.4 Sampling

Legal requirements

Article 11 of Regulation (EC) No 882/2004 establishes general requirements for sampling. Article 8 of Regulation (EC) No 1881/2006 requires that the sampling for the offcial control of the levels of contaminants in foodstuffs shall be performed in accordance with the methods set out in Regulation (EC) No 401/2006 (mycotoxins), Regulation (EC) No 1882/2006 (nitrates), Regulation (EU) No 252/2012 (dioxins and dioxin-like PCBs). Article 1 of Regulation (EC) No 333/2007 stipulates that sampling for the official control of the levels of chemical elements, 3-MCPD and benzo(a)pyrene in foods shall be carried out in accordance with the Annex to that Regulation.

Additionally, the Commission Guidance document for CAs for the control of compliance with EU legislation on aflatoxins is relevant to this audit.

Findings

The audit team observed two official sampling exercises, one at a grain mill for flour in the Castilla y Léon region and one for almonds at the dried fruit processor in the Valencia region. The sampling was performed by the Public Health inspectors.

The lot of flour consisted of approximately 25 tons of flour in bulk. The FBO transported the lot through a system of pipes in a defined time and every 30 seconds an incremental sample was taken from the pipe with an electronic sampler. In total 100 incremental samples were taken, each of 350 g. The aggregate sample (35 kg) was homogenized with a custom made mixer and divided into 3 sub samples. The samples were sealed and a sampling report was drafted. The observed sampling was fully in line with Regulation (EC) No 401/2006.

Official sampling of almonds was observed by the audit team at a company specialised in importing, processing and packing of dried fruits and nuts. The lot, which was subject to official

sampling weighed 1971 kg. It consisted of 4 pallets with 704 boxes each containing 14 packs of roasted and salted almonds of 200 g. The inspector took 40 incremental samples in a representative way. The observed sampling was fully in line with Regulation (EC) No 401/2006.

In the laboratory in Valencia the audit team checked the reports of the last 10 samples that arrived for analysis on mycotoxins. Five reports were fully in line with Commission Regulation 401/2006 in terms of the number of incremental samples taken. However, three reports of samples on peanuts and rice indicated a reduced number of incremental samples. The CA stated that the number of incremental samples was reduced to limit the economic damage. The remaining two reports indicated that only one incremental sample was taken in the case of a lot of hazelnuts (325kg) and for baby food at retail stage. No clarifying details were provided in the reports. The CA stated that they will follow-up on the issues highlighted.

Conclusions

The observed sampling was in line with the requirements of Commission Regulation No 401/2006. However, reducing the number of incremental samples may compromise the representativeness of the sample taken.

5.2.5 Laboratory Performance

Legal requirements

Requirements for designating laboratories are laid down in Article 12(1) of Regulation (EC) No 882/2004. Requirements pertaining to the capacity and capability of laboratories are described in Article 4(2)(c) of Regulation (EC) No 882/2004. Requirements for accreditation of laboratories are laid down in Articles 12(2) and (3) of Regulation (EC) No 882/2004. Requirements for designation of NRLs for each EU Reference Laboratory (EURL) as well as tasks of NRLs are laid down in Article 33 of Regulation (EC) No 882/2004.

Criteria for sample preparation and performance parameters for methods of analysis used for the official control of the levels of contaminants in foodstuffs as well as results reporting requirements are laid down in the annexes to Regulation (EC) No 401/2006 (mycotoxins), Regulation (EC) No 1882/2006 (nitrate), Regulation (EU) No 252/2012 (dioxins and dioxin-like PCBs) and Regulation (EC) No 333/2007 (chemical elements, 3-MCPD, benzo(a)pyrene).

Additionally, the Commission guidance document “Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation” is relevant to this audit.

Findings

The CNA under the AESAN is the NRL for mycotoxins and PAHs.

Regarding the tasks of a NRL, the CNA disseminates technical and general information about mycotoxins and PAHs to the official laboratory network. The NRL provides on assistance service to the laboratories of the autonomous regions. It organises annual workshops which cover latest developments in analytic and regulatory area, Codex Alimentarius, current alerts, EU legislation concerning mycotoxins and PAHs.

The CNA does not organise any Proficiency Tests (PTs) for routine laboratories as a need for such tests was not identified during workshops. The information on commercially organised PTs and access to the participation in EURL PTs is offered instead. However, this is on the condition that a

routine laboratory agrees to reveal its registration number to the NRL. So far only a small number of laboratories took this opportunity.

The LAA under the MAGRAMA is designated as NRL for heavy metals in all matrices.

The LAA organises twice a year co-ordination meetings for control laboratories with the aim of harmonising analytical methods and providing new method proposals. Three times a year ring tests for chemical elements in feed and food are organised covering a range of heavy metals except tin. In addition, each year the NRL provides one day training on selected aspects of heavy metals analysis and prepared two documents on sample preparation which have been published on the MAGRAMA website. It disseminates information on relevant scientific publications and provides responses to individual queries raised by official control laboratories.

The Castilla y Léon region has four laboratories involved in contaminants analysis. The audit team was informed that their responsibilities were divided and defined to increase effectiveness, see Table 2.

In Castilla y Léon no methods are available for testing official samples for fumonisins, deoxynivalenol (DON), zearalenone, patulin, lead, melamine and PAHs in all matrices.

Table 2: Official laboratories involved in testing for contaminants in the AC of Castilla y Léon

Name	Scope of testing in food	Accredited methods for contaminants
Public Health Laboratory Burgos	nitrate, tin	nitrate in infant foods, tin
Public Health Laboratory Soria	mycotoxins	aflatoxins in spices, OTA in coffee and food
Public Health Laboratory León	heavy metals	cadmium in fruits, mercury in foodstuffs (except oils and fats) and alcoholic beverages
Public Health Laboratory Salamanca	nitrate	nitrate in vegetables, nitrate in infant foods

The Valencia region has two laboratories (in Valencia and Alicante) involved in contaminants analysis.

The audit team visited the CNA laboratory and two AC laboratories: in Burgos and in Valencia.

The laboratories visited are located in adequate facilities and are equipped with state of the art instruments.

CNA, Madrid

With regard to official samples, the CNA has so far received only mycotoxin reference samples which are exclusively from import controls. In addition, three samples of oil were submitted by other CAs based on suspicion.

There were no specific standards on defining sample acceptance/rejection criteria and no specific requirements with regard to minimum sample quantity for contaminants analysis.

The laboratory is accredited within a flexible accreditation system. There were no methods validated for DON in cereals and derived products. Regarding PAHs, the PAHs recommended in the

EU have been validated, although the sum of benzo(a)pyrene, benzo(a)anthracene, benzo(b)fluoranthene and chrysene in foodstuffs is not evaluated yet. However, having the flexible accreditation scope and current method development stage, the laboratory is able to validate these methods at short notice in case an official sample is received.

Laboratory records were well maintained, immediately available and traceable.

Sample homogenisation for mycotoxins was carried out thoroughly and according to the requirements of Regulation (EC) No 401/2006. Samples were first ground on a commercially available mincer (originally for meat) or other milling devices, then the complete ground sample was mixed with water to a so called slurry with a disperser tool. Finally the obtained slurry was mixed again in a common household mixing machine. The homogenisation process was validated for peanuts in shell and dried figs on naturally contaminated samples and the coefficients of variation were within acceptable ranges for both matrices. For the year 2013 the laboratory scheduled the validation of the homogenisation of pistachios in shell, though this is dependent on the availability of natural contaminated samples. The statistical representativeness of the four samples used for the homogenisation study was discussed.

Validation files, for the High Performance Liquid Chromatography with Fluorescence detection (HPLC-FLD) method for OTA in wheat flour and the HPLC-FLD method for PAHs in olive oils, were examined by the audit team. Both methods were thoroughly validated and in compliance with the method performance criteria of Regulations (EC) No 401/2006 (mycotoxins) and (EC) No 333/2007 (PAHs).

Checks of recovery and precision are carried out regularly to verify method performance. Control charts are based on the original validation data and maintained. The laboratory successfully participated in PTs for mycotoxins and PAHs.

The way of reporting laboratory results was precisely clear and in line with the requirements of Regulation (EC) No 401/2006.

Public Health Laboratory Burgos

Instructions on sample admission requirements were available. The samples were registered and therefore provided with a bar-code and an internal laboratory number. However, the laboratory was not able to show documentation for rejection of samples of a lower quantity for testing than that prescribed in the Annex to Regulation (EC) No 1882/2006 (nitrates). The minimum sample size requested by the laboratory is 250 g. In contrast to that, the legislation requires a minimum amount of 1 kg sample. Out of 30 test reports for nitrate in baby foods verified by the audit team, the adequate sample size was indicated only in nine reports.

Validation files for the Ion-Exchange Chromatography method for nitrates and the Isotope dilution Inductively Coupled Plasma Mass Spectrometry method for tin, were examined by the audit team. Both methods were fully validated and within the method performance criteria specified in Regulation (EC) No 1882/2006 and Regulation (EC) No 333/2007 respectively.

Regarding the analysis of nitrate, standard solutions for calibration of instruments, as well as for recovery checks were prepared from a certified solution. Calibration of instruments with twelve point standard calibration was performed every six month. To verify the former calibration 3 calibration points were checked in each sequence running.

For nitrate in infant food there were no Certified Reference Materials or control materials available in the laboratory. For internal quality control purposes a recovery of a sample spiked with certified nitrate solution was used in each sequence running and a control chart was maintained. However, the control chart was based on all available results for three different spiking levels which lead

automatically to a broader acceptance range. Furthermore, for spiking experiments even two-months-old samples were used without re-analysing their natural nitrate level.

The laboratory reporting procedures for nitrate did not follow the requirements as laid down in Regulation (EC) No 1882/2006 concerning the indication of recovery level and information, whether the results were corrected for recovery. In contrast, the test report form for tin analysis was in line with legislative requirements.

Since 2011 the laboratory successfully participated in PTs for nitrates in infant foods and for tin in canned foods.

Public Health Laboratory Valencia

The laboratory has in total 71 Full Time Equivalent staff and accepts only public samples. It processes annually about 780 samples for contaminants in food on the basis that certain samples are tested for more than one analyte.

The laboratory is accredited according to the International Organisation for Standardisation Standard 17025 by the Spanish National Accreditation Body (*Entidad Nacional de Accreditatión*, ENAC) with a fixed accreditation scope.

There are no accredited methods available for the analysis of mycotoxins in infant food and in spices, for OTA in coffee, heavy metals in FNAO and melamine. Methods for nitrate in infant food and patulin in fruit juice were assessed by ENAC and the laboratory was awaiting the update of its accreditation scope. However, the laboratory tests for all contaminants listed in Commission Regulation (EC) No 1881/2006.

The Standard Operating Procedure for sample reception was available, as well as a list stipulating minimum sample quantities for different matrices. However, in the case of mycotoxins and 3-MCPD the minimum sample quantities were much lower than those required in the Annexes to Regulation (EC) No 401/2006 (mycotoxins), and Regulation (EC) No 333/2007 (3-MCPD).

The samples are registered electronically within a Laboratory Information Management System with a unique number.

Cereal and nut samples for mycotoxins are ground in two turns due to the capacity of a grinder, filled in plastic bags and subsequently mixed by turning plastic bags of 4kg each. Next a laboratory sample of about 1kg is prepared by taking about 50 ml aliquots from both plastic bags. Neither the homogeneity of grinding, nor laboratory sample preparation procedure were verified. This practice is not in line with the requirements stipulated in Article 2 and Annex II to Regulation (EC) No 401/2006.

The validation file for the HPLC Mass Spectrometry method for patulin was examined by the audit team. Fourteen different juice samples spiked at 5, 50 and 100 µg/kg were used to validate this method and calculation method performance parameters. However, the laboratory accepted all results of the validation study although seven were not compliant with the recovery range stipulated in Commission Regulation (EC) No 401/2006.

Quality control checks at two spiked levels are performed with each assay series and control charts are maintained. However, results were re-calculated after each assay series so underperformance of the method could not be noticed.

With regard to mycotoxins and nitrate the reporting routines follow the requirements as laid down in Regulation (EC) No 1882/2006 and Regulation (EC) No 401/2006 concerning information as to whether the results were corrected for recovery.

The laboratory regularly participates in PTs organised mainly by commercial providers. It also took part in PTs organised by the EURL. Results were satisfactory.

Conclusions

All NRLs are designated. All laboratories visited perform well in PTs. Official laboratories have no methods for certain contaminants listed in Regulation (EC) No 1881/2006 and some methods in use are not validated. The lack of sample acceptance criteria poses the risk that samples of inadequate quantity are admitted for analysis and consequently results cannot be legally binding. Sample preparation for mycotoxin analysis does not always comply with legislative requirements.

5.2.6 Other Contaminant Control Programmes

Findings

The audit team noted that all seven food processors visited operated annual testing for contaminants of their final products to determine if the levels of these contaminants do not exceed the maximum levels stipulated in EU legislation.

Conclusions

Other contaminant control programmes run by FBOs assist in ensuring the safety of foodstuffs.

5.2.7 Procedures for Performance and Reporting of Control Activities

Legal requirements

Article 3 of Regulation (EC) No 882/2004 requires official controls to be carried out without prior warning, except where prior notification of the FBO is necessary.

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 official controls, the methods applied, the results obtained and any action to be taken by the FBOs concerned. At least in cases of non-compliance a copy of the report must be given to the FBO.

Findings

At both ACs visited there were procedures in place and check-lists available for inspectors covering different aspects of official controls and actions to be taken upon receipt of non-compliant results of laboratory analysis. The audit team saw examples confirming that this procedure was followed and that results of controls are documented.

In all laboratories visited there are no procedures stipulating sample acceptance criteria to prevent samples of an inadequate quantity to be registered and accepted for testing (see sections 5.2.3.2 and 5.2.5).

Conclusions

There are procedures and instructions in place for official controls of FNAO. However, shortcomings were identified in relation to instructions in laboratories on sample acceptance criteria.

5.2.8 Enforcement Measures

Measures in case of non-compliance

Legal requirements

Article 54 of Regulation (EC) No 882/2004 lays down the principles to be followed in the application of national enforcement measures and actions to be taken in cases of non-compliance.

Implementing measures for the RASFF are laid down in Commission Regulation (EU) No 16/2011.

Findings

Central level

Measures to be taken in case of non-compliance are described in Part B of the MANCP, in section III Programmes of Official Control in Food Processing Establishments and in part III.5 Control on contaminants in foodstuffs. The measures may be applied to establishments (e.g. temporary suspension of the activity) or to products (e.g. activation of an alert, withdrawal from the market).

It is up to the AC to establish procedures to be followed in case of non-compliance depending on the place where sampling took place and taking into account the nature of the hazard, the origin of the product and its distribution nationwide and internationally.

FBOs are obliged to notify the CAs if they have non-compliant results in their own-check programmes.

The RASFF notification is issued only in the case when an identified non-compliance has implications for another MS. Otherwise non-compliant results are notified through the Coordinated System for Rapid Exchange of Information (*Sistema Coordinadado de Intercambio Rápido de Información*, SCIRI). Both systems are managed by the AESAN based on information provided by CAs of the ACs.

There were no RASFF or SCIRI notifications on contaminants in FNAO in the two years prior to the audit although nine samples were found non-compliant for mycotoxins and heavy metals in the Castilla y Léon region and four in Valencia during that period. The CAs stated that all non-compliances were identified either in official prospective samples of perishable products or the area of their distribution was restricted to the AC where the sample was taken.

Castilla y Léon

The audit team verified two non-compliances for nitrate identified under the 2011 Sampling plan.

In both cases, excessive concentrations of nitrate were found in spinach and samples were analysed promptly after sampling.

Valencia

The audit team verified two cases of non-compliance identified under the 2012 Sampling Plan.

In the case of a sample of spinach containing a concentration of nitrate exceeding the Maximum Level a follow-up investigation was performed and the primary producer adequately traced it back. However, the lack of the lot number on the laboratory test report created difficulties in verifying the traceability. The whole investigation lasted from 21/11/2012 to 20/03/2013 and the CA of Murcia did not take control samples to verify the nitrate level.

Excessive concentration of aflatoxins (B_1 and sum) was found in an unshelled peanuts sample collected at retail level. The FBO was informed about the non-compliant result and inspection of the FBO's traceability system was performed by the CAs. However, they did not verify, if the whole lot was sold to the retailer from which the non-compliant sample had been taken.

Conclusions

The CAs took action when non-compliances were identified. However, actions were sometimes delayed and could not provide evidence that the operator remedied the situation.

Sanctions

Legal requirements

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

Findings

The legal basis for sanctions and penalty procedures are described in the CP for Spain.

In the context of this audit, sanctions have been imposed by the Castilla y Léon CAs in cases of excessive concentration of OTA found in coffee and nitrate in spinach.

Conclusions

Legal and administrative measures are in place to impose sanctions as required by Article 55 of Regulation (EC) No 882/2004 and sanctions are applied when needed.

5.2.9 Verification Procedures and Audit

Legal requirements

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

Findings

The responsibility for carrying out audits is with the ACs. In the ACs visited, no audits were carried out on contaminants up to the time of this audit.

Both ACs visited, have procedures in place for supervision of inspectors' performance while carrying out official controls on food processing establishments.

Conclusion

There is a verification system in place within the meaning of Article 8(3) of Regulation (EC) No 882/2004.

6 Overall Conclusions

In Spain all aspects of official controls on contaminants are under the responsibility of the ACs. Both ACs visited, operate control systems for contaminants which include sampling plans and official controls of food processing establishments but not at primary production level. Contaminant sampling plans are not risk-based but are designed taking into account the capacity of official laboratories, in particular the methods available. The laboratories have the competence and capacity to analyse samples for contaminants. However, their performance is weakened by a lack of some validated methods and instructions on sample quantity for contaminants analysis. Staff performing official controls have a good knowledge of contaminants' issues but do not always have access to adequate sampling equipment.

7 Closing Meeting

A closing meeting was held on 14 June 2013 with representatives from all the CAs concerned. At this meeting the audit team presented the main findings and preliminary conclusions of the audit. The authorities made some comments on the findings and preliminary conclusions and asked for legal interpretation of EU legislation concerning official controls on general hygiene requirements at primary production of FNAO. The FVO audit team informed the authorities that the relevant Commission services would be informed and the formal opinion would be transmitted.

8 Recommendations

N°.	Recommendation
1.	Ensure that hygiene provisions in primary production of FNAO are controlled to meet requirements laid down in Article 4 and in Annex I, Part A of Regulation (EC) No 852/2004.
2.	Ensure that staff performing official controls in the area of contaminants have access to adequate sampling equipment as required by Article 4.2(d) of Regulation (EC) No 882/2004 so they can perform official controls efficiently, effectively and in line with specific EU legislation on contaminants.

N°.	Recommendation
3.	Ensure risk-based planning of contaminant sampling plans as required by Article 3 of Regulation (EC) No 882/2004 taking into consideration all contaminant groups listed in Commission Regulation (EC) No 1881/2006.
4.	Ensure that the CAs have access to an adequate laboratory capacity for contaminants analysis and in particular, to ensure that analytical methods needed for the analysis of official samples of contaminants listed in Commission Regulation (EC) No 1881/2006 are available, validated and are demonstrably fit for purpose by meeting method performance criteria as defined in applicable Community legislation e.g. Commission Regulation (EC) No 401/2006 (mycotoxins) and Commission Regulation (EC) No 333/2007 (3-MCPD, PAHs).
5.	Ensure that samples taken for official control purposes and accepted by laboratories for the analysis of mycotoxins and nitrates have an adequate weight/quantity and are representative of the lot which has been sampled, as stipulated in Annex I to Commission Regulation (EC) No 401/2006 and Commission Regulations (EC) No 1882/2006.
6.	Ensure that sample preparation for the official control of the levels of mycotoxins in foodstuffs comply with the criteria set out in Annex II to Commission Regulation (EC) No 401/2006.

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=2013-6661

Annex 1 - Legal References

Legal Reference	Official Journal	Title
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. 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. 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
Reg. 1882/2006	OJ L 364, 20.12.2006, p. 25-31	Commission Regulation (EC) No 1882/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs

Legal Reference	Official Journal	Title
Reg. 252/2012	OJ L 84, 23.3.2012, p. 1-22	Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in 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

Annex 2 – Recommendations And Standards Quoted In The Report

Reference number	Full title	Publication details
2007/196/EC	Commission Recommendation of 28 March 2007 on the monitoring of the presence of furan in foodstuffs	OJ L 88, 29.3.2007, p. 56
2007/331/EC	Commission Recommendation of 3 May 2007 on the monitoring of acrylamide levels in food	OJ L 123, 12.5.2007, p. 33
2010/133/EU	Commission Recommendation of 2 March 2010 on the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits and on monitoring of ethyl carbamate levels in these beverages	OJ L 52, 3.3.2010, p. 53
2010/161/EU	Commission Recommendation of 17 March 2010 on the monitoring of perfluoroalkylated substances in food	OJ L 68, 18.03.2010, p. 22
2010/307/EU	Commission Recommendation of 2 June 2010 on the monitoring of acrylamide levels in food	OJ L 137, 3.6.2010, p. 4
None	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
None	Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation	http://ec.europa.eu/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf