EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6658 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

PORTUGAL

FROM 29 APRIL TO 08 MAY 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 Portugal, carried out from 29 April to 08 May 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 evaluate the implementation of national measures, aimed at the control of contaminants in food in accordance with the requirements of Regulation (EC) No 1881/2006.

There are separate Competent Authorities (CAs) responsible for controls on contaminants: the General Directorate for Food and Veterinary Affairs is the Central Competent Authority (CCA) responsible for food processing and the Authority for Food and Economic Security (ASAE) for controls on the market.

The CCA has not yet implemented effective controls on food of non-animal origin since it assumed this responsibility in 2012. It does not have staff trained to control establishments processing food of non-animal origin, control procedures, access to adequate sampling equipment and designated laboratories.

The ASAE operates a system for the official controls of contaminants in foods on the market which is risk based, covers major contaminant groups listed in Commission Regulation (EC) No 1881/2006 and it is the only form of physical control on contaminants in Portugal.

The National Reference Laboratory is designated only for heavy metals and it does not perform its duties as required by Article 33 of Regulation (EC) No 882/2004. The scope of testing in the ASAE laboratory does not yet cover the full range of contaminants due to the lack of certain validated methods.

The lack of clear division of competence between CAs involved and a lack of co-ordinated approach to official controls combined with communication problems undermine the effectiveness of controls on contaminants.

The report makes a number of 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
ASAE	*Autoridade de Segurança Alimentar e Económica*, Authority for Food and Economic Security
CA(s)	Competent Authority(ies)
CCA	Central Competent Authority
DEPO	*Divisão de Estudos e Planejamento Operacional,* Division of Research and Operational Planning
DGAV	*Direcção-Geral de Alimentação e Veterinária*, General Directorate for Food and Veterinary Affairs
DG (SANCO)	Health and Consumers Directorate-General of the European Commission
DGV	*Direcção-Geral de Veterinária,* Directorate-General for Veterinary Issues
DON	Deoxynivalenol
DRAP	*Direcção Regional de Agricultura e Pescas*, Regional Directorate for Agriculture and Fisheries
EP	European Parliament
EU	European Union
EURL	European Union Reference Laboratory
FAO	Food of Animal Origin
FBO(s)	Food Business Operator(s)
FNAO	Food of Non-Animal Origin
FTE	Full Time Equivalent
FVO	Food and Veterinary Office
GAP	Good Agriculture Practice
GHP	Good Hygiene Practice
GPP	*Gabinete de Planeamento e Política,* Policy and Planning Office
HACCP	Hazard Analysis and Critical Control Points
HPLC	High Performance Liquid Chromatography
INIAV	*Instituto Nacional de Investigação Veterinária,*The National Institute of Agricultural and Veterinary Research
LNIV	*Laboratório Nacional de Investigação Veterinária,* National Veterinary Research Laboratory
LOQ	Limit of Quantification
MAMAOT	*Ministério da Agricultura, do Mar, do Ambiente e do Ordenamento do Território,* Ministry of Agriculture, Sea, Environment and Spatial Planning
MANCP	Multi-Annual National Control Plan
ML	Maximum Level
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
PNCA	*Plano Nacional de Colheita de Amostras,* National Sampling Plan
PTs	Proficiency Tests
RASFF	Rapid Alert System for Food and Feed
RD	Regional Directorate(s)
TC(s)	Third Country(ies)
ZEA	Zearalenone

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 Portugal from 29 April to 08 May 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): General Directorate for Food and Veterinary Affairs (*Direcção-Geral de Alimentação e Veterinária*, DGAV) under the Ministry of Agriculture, Sea, Environment and Spatial Planning (*Ministério da Agricultura, do Mar, do Ambiente e do Ordenamento do Território,* MAMAOT) accompanied the FVO team for the duration of the audit. An opening meeting was held on 29 April 2013 with representatives from the DGAV and the Authority for Food and Economic Security (*Autoridade de Segurança Alimentar e Económica,* ASAE) under the Ministry of Economy and Employment. 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 Portugal;
- 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	2	DGAV, ASAE
Regional	2	ASAE Regional Office in Coimbra and Lisbon
Inspectors		
Regional Directorate for Agriculture and Fisheries (*Direcção Regional de*	6	discussions held during the visits to supervised food processing establishments, cereals grower and leafy vegetables producer

Agricultura e Pescas, DRAP)		
ASAE	6	discussions held during the visits to supervised food processing establishments and sampling performed
Laboratories		
Public	2	The ASAE laboratory The laboratory of National Institute of Agricultural and Veterinary Research (*Instituto Nacional de Investigação Veterinária,* INIAV)
Establishments		
Food processors	5	One vegetable oil processing establishment One baby food processing establishment One smoked meat processing establishment One juice and canned vegetables producer One major bakery
Establishments growing products of plant origin	3	One lettuce packing establishment with subcontracted lettuce growers One establishment growing maize, wheat, barley, peanuts and vegetables One rice grower

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 Portugal 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 for Portugal, which describes in summary the control systems for food and feed, animal health, animal welfare and plant health. The country profile 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

There is no additional national legislation in place on national limits for food contaminants.

Legislation in the context of this audit is made available to the public on the DGAV website. In addition, the DGAV and the DRAPs staff can access legislation through the link to Eur-Lex from the DGAV website. However, the audit team noted that the DGAV webpage for foods for special dietary uses provided a link to the non-amended version of Commission Regulation (EC) No 1881/2006. An example was presented during the audit that the non-amended version of Commission Regulation (EC) No 1881/2006 was used by one of DRAP's team of inspectors.

The ASAE website does not provide access to legislation on contaminants. Nevertheless, the ASAE inspectors can access legislation through the ASAE's intranet which also provides links to national and European databases.

Conclusion

Relevant legislation is publicly available and accessible to the Competent Authorities (CAs) inspectors.

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.

Findings

At central level there are separate CAs responsible for contaminant controls: the DGAV is the CCA

responsible for primary production/food processing and the ASAE for controls on the market.

The DGAV was established in April 2012, following the adoption of Regulatory Decree No 31/2012 of 13 March 2012, by taking over the competencies of the former Directorate-General for Veterinary Issues (*Direcção-Geral de Veterinária,* DGV), the Directorate-General for Agriculture and Rural Development and, partly, the Policy and Planning Office (*Gabinete de Planeamento e Política,* GPP). The DGAV operates under the Secretary of State for Food and Agreefood Research of the MAMAOT and has five regional branches located in each of the five regions.

The DGAV's mission is to manage the food safety system in Portugal. The tasks of the DGAV are defined in Article 2 of Regulatory Decree No 31/2012 and within the scope of the audit relate to the development, co-ordination, evaluation and implementation of official control plans on the production and processing of foodstuffs.

The detailed structure of the DGAV is established through Ordinance No 282/2012 of the MAMAOT. Two of the DGAV's directorates are relevant in the context of this audit: the Directorate for Food and Nutrition which is responsible for the implementation of legislative acts and policies applicable to food ingredients, agricultural, industrial and environmental food contaminants and the Food Safety Directorate which is responsible for the development, co-ordination and implementation of official controls along the food chain.

The five DRAPs are regional services under the Secretary of State for Agriculture and Rural Development of the MAMAOT. They are responsible, *inter alia,* for carrying out on-the-spot inspections of establishments processing Food of Non-Animal Origin (FNAO). For the implementation of the MANCP, the DRAPs activities are co-ordinated by the DGAV based on informal agreement between the two responsible Secretaries of State. The DGAV is awaiting clarification with regard to the division of competences for regional structures of the DGAV and the DRAPs. However, no time frame was decided for this decision.

The DRAP's inspectors are also responsible for carrying out inspections on cross-compliance which, in Portugal, includes general hygiene provisions for primary production of FNAO and associated operations as laid down in Article 4 and in Annex I, Part A of Regulation (EC) No 852/2004.

The ASAE is the CA in charge of official controls on contaminants in foods on the market. It operates the National Sampling Plan (*Plano Nacional de Colheita de Amostras,* PNCA) which includes, *inter alia,* sampling for contaminants and carries out inspections in food processing establishments which may include contaminant issues.

In February 2012 the Portuguese authorities informed the Commission that in order to avoid overlapping of responsibilities, the DGV and ASAE were drafting a memorandum of understanding. Although information is exchanged on an ad-hoc basis no memorandum of understanding has been established between the DGAV and the ASAE.

The Strategy, Communication and International Affairs Directorate of the DGAV is the National Contact Point for the Rapid Alert System for Food and Feed (RASFF).

The General Inspectorate for Agriculture, Sea, Environment and Spatial Planning under the MAMAOT is the authority responsible for planning and performance of systematic external audits in the area of food safety.

The audit team noted communication problems between CAs and the lack of a co-ordinated approach to hygiene controls including those on contaminants carried out by different CAs.

Conclusions

The CAs involved in food contaminant controls are designated but their areas of responsibility are not clearly defined. The lack of a clear division of competence between CAs involved and a co-ordinated approach to official controls, combined with communication problems, undermine the effectiveness of controls on contaminants.

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

Findings

Regulatory Decree No 31/2012 defines the mission and tasks of the DGAV.

Decree-Law No 133/2006 lists CAs (including the DGAV's predecessor DGV) responsible for controls on the implementation of EU Hygiene Regulations. Article 6(f) of the same decree-law stipulates that impeding or creating barriers to official controls, particularly by disallowing access to buildings, premises, facilities etc. or to any documentation and records deemed necessary to the CA for assessing the situation constitutes an offence punishable by a fine.

The ASAE has a new organic law published in Decree No 194/2012 of 23 August 2012 which provides the CA with the necessary legal powers to carry out controls, including the powers of access to food business premises and documentation.

Decree No 139/2008 of 21.06.2008 of the Ministry of Science, Technology and Higher Education transfers certain tasks, including those related to laboratory activities, to the Department of Chemical Industry Technologies of the ASAE which comprises the ASAE laboratory (see section 5.2.5).

The representative from the ASAE stated that there is an obligation on FBOs to undergo inspection by the CA and that FBOs are obliged to notify the CAs if they have non-compliant results in their own-check programmes.

Conclusion

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

At central level of the DGAV no specific staff are assigned to contaminant controls in FNAO. The available staff are responsible for the planning and supervision of hygiene controls including contaminants listed in Commission Regulation (EC) No 1881/2006 both in Food of Animal Origin (FAO) and FNAO.

At regional level, there are technicians assigned to perform all food safety controls, which include official controls on contaminants.

The representative from the DGAV stated that in 2011-2012, the planned frequency of controls in FNAO processing establishments was not reached due to the shortage of staff and financial resources for controls.

There are 9 inspectors in DRAPs who are involved both in official controls of FNAO processing establishments and cross-compliance checks covering hygiene checks at primary production level.

The staff resources of ASAE remain as described in the Country Profile. There are 50 Full Time Equivalent (FTE) staff at the ASAE laboratory out of which seven analysts are involved in contaminants analysis.

The INIAV laboratory visited comprised in total 3 FTE staff for the analysis of Polycyclic Aromatic Hydrocarbons (PAHs).

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

Both the DGAV and DRAPs do not carry out sampling for contaminants in the context of this audit and they have no sampling equipment suitable for taking samples for mycotoxins from bulk lots (or big bags). The audit team was informed that feed sampling is outsourced and this approach may be considered for food in future.

Adequate provisions are in place as described in the Country profile (see chapter 1), to ensure public servants avoid conflicts of interest.

Conclusions

The CCA is in the process of re-allocating resources for controls including controls on contaminants. A lack of adequate sampling equipment may further delay reaching the operational criteria for controls on contaminants.

The ASAE has adequate staff provisions and facilities to perform controls in the context of this audit.

Preventive measures are in place to ensure that staff carrying out official controls are free from any

conflict 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 representative from the DGAV stated that due to the reorganization, the CCA is not yet fully qualified to carry out controls of FNAO including those on contaminants.

DGAV staff have never received training on contaminants in FNAO and specifically not on sampling for contaminants in FNAO.

The training of DRAP staff on the procedures for performing official controls of FNAO was organised through participation of the DRAP inspectors in hygiene controls carried out jointly with the GPP inspectors and included theoretical training on contaminants.

With regard to training on Hazard Analysis and Critical Control Points (HACCP), all 11 (DGAV, DRAP and ASAE) inspectors met by the audit team received this training; however, some of this training took place in 2008.

Out of the four DRAP inspectors, five DGAV inspectors and two ASAE inspectors met in the food establishments visited, the majority had difficulty in adequately performing the control on contaminants through the HACCP plan e.g. to assess if the scope of own checks was satisfactory in different types of establishments.

The annual training on sampling for the ASAE samplers involved in sampling for the PNCA is centrally organised. It covers 15 hours of lectures and 3 hours of practical exercise.

Conclusions

The DGAV staff have not received adequate training on contaminants. Although certain training in the fields of HACCP and controls on FNAO was provided to the DRAP inspectors, it was considered insufficient and it did not cover sampling for 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 could also be taken of EU recommendations on the monitoring of the presence of and on the prevention and reduction of certain contaminants in foodstuffs.

Findings

Controls on contaminants are performed within the framework of the PNCA operated by the ASAE and hygiene inspections are carried out independently by the DGAV/DRAPs and the ASAE.

Controls performed by the DGAV and DRAPs

Before November 2012, official controls on hygiene in FNAO were carried out by the GPP in co-operation with the DRAPs. They were focussed on the assessment of HACCP based systems which covered contaminant issues. Organisation of these controls followed the procedures described in the P2 Plan on Food Hygiene Control and covered control visits to assess traceability, HACCP-based systems and verification against horizontal legislation in force, including those on contaminants. The P2 Plan was developed by the former GPP in May 2009 and has not been revised since.

At the time of the audit, the planning of official controls on hygiene in FNAO to be performed by the DGAV was not finalised due to re-organisation. At the closing meeting, the DGAV presented a preliminary plan of measures related to the controls of FNAO.

The DGAV stated that no sampling for contaminants is foreseen even in the case of suspicion of a contaminants occurrence.

Both the DGAV and the DRAP inspectors met by the audit team during visits to food processing establishments confirmed that during routine official controls they never undertook sampling for contaminants.

The DGAV does not have their own official laboratory. Although informal arrangements exist with private laboratories which are accredited and have been used by the GPP for import control purposes, none of them was formally designated by the DGAV for contaminant analysis in FNAO.

In the case of baby food for infants and young children, the CA operates a certification system for market authorisation which is obligatory for FBOs. On-line applications are assessed against risk criteria and a decision is made as to the scope of evaluation of documentation provided. In the case of high risk, a full evaluation is performed. This includes the assessment of test results for contaminants provided by the FBO. The CA is considering extending this form of control to other foodstuffs.

The DGAV has not initiated regular controls on hygiene and contaminants in FNAO processing establishments and was not in a position to indicate the number of such controls planned for 2013.

With regard to contaminants, according to the P2 Plan on Food Hygiene Control procedures, routine

inspections on food processing/distributing establishments shall cover the documentary assessment of raw materials and own testing results against the requirements of Regulation No (EC) 1881/2006. However, there are no check lists or detailed instructions available for the DGAV and DRAP inspectors on the scope and depth of official controls on contaminants.

At the closing meeting, the DGAV informed the audit team that on the day before, a circular letter to the regional services was sent. The letter indicated the need for official controls to include verification of the measures taken by the FBOs to ensure that contaminant levels in their products comply with the requirements as laid down in Commission Regulation (EC) No 1881/2006. The checklist used was amended to include contaminant issues. However, the letter referred only to contaminants in FAO so in the context of this audit was relevant only with regard to PAHs.

None of the Commission's Recommendations on contaminants was implemented.

The PNCA

The ASAE operates the PNCA on the market which includes the monitoring of contaminants. The PNCA is risk based and the following criteria are considered in order to calculate the targeted number of samples: risk associated with the identified hazard (i.e. contaminant), the number of non-compliant results in the preceding year and the annual national consumption of the foodstuff. A statistical approach for detecting non-compliances with a chosen level of confidence has not been applied to date.

The ASAE Food Risk Division (which belongs to the Food Risk and Laboratory Division) prepares monthly sampling plans taking into account currently available resources of the ASAE laboratory (see section 5.2.5). Based on this information the Division of Research and Operational Planning (*Divisão de Estudos e Planejamento Operacional*, DEPO) prepares the orders for the Regional Units.

With regard to contaminants the PNCA covers approximately 250 samples a year on the basis that some of them might be tested for more than one contaminant at a time. The PNCA covers foodstuffs of national, MS and Third Country (TC) origin available on the Portuguese market. The DEPO decides on the type of FBO where the samples should be collected and indications are given to avoid brand repetition. The place of sampling is left to the discretion of the sampler.

In terms of the scope the contaminants tested, the PNCA covers those contaminants for which methods exist in the ASAE laboratory (see section 5.2.5).

An overview of the number of samples tested for contaminants within the PNCA since 2009 is presented in Table 2.

Table 2: Number of samples tested within the PNCA in 2009-2012

Scope of testing	Number of tested samples			
	2009	2010	2011	2012
Nitrate in horticultural products and spices	74	34	39	70
Nitrite in horticultural products and spices	0	31	0	0
Aflatoxins in nuts, dried fruits and derived products	70	4	62	42
Aflatoxins in fruits, fruit juices, canned fruits	2	0	0	0

Aflatoxins in cereals and cereal based foods	21	36	11	26
Aflatoxins in spices	0	6	0	24
Aflatoxins in oils and fats	7	15	0	0
Aflatoxins in dietary foods for special medical purposes	1	0	0	0
OTA* in cereals and derived products	71	34	0	5
OTA in dried vine fruits	27	30	10	18
OTA in coffee and energy drinks	25	33	5	18
OTA in vine and derived products	0	47	0	16
OTA in fruits, fruit juices, compotes, canned fruits	1	0	0	6
OTA in dietary foods for special medical purposes	1	0	0	2
OTA in spices	0	0	0	24
ZEA** in cereals and derived products	18	1	0	8
ZEA in refined maize oil	1	0	0	2
Fumonisins in cereals and derived products	14	0	0	0
Lead in fruits, fruit juices, concentrated fruit juices	4	0	0	0
Lead in wine, aromatized wine and derived products	0	52	0	16
Lead in ready to eat products	0	2	0	0
Lead in horticultural products and legumes	17	0	0	0
Lead in energy drinks	2	0	0	0
Cadmium in fruits, fruit juices, concentrated fruit juices	25	0	0	0
Cadmium in wine, aromatized wine and derived products	0	1	0	0
Cadmium in ready to eat products	0	2	0	0
Cadmium in horticultural products and legumes	19	0	0	0
Benzo(a)pyrene in oils and fats	31	11	0	0

* OTA – Ochratoxin A, **ZEA – Zearalenone

Inspections carried out by the ASAE

The ASAE carries out controls on FNAO processing and retail establishments based on the number of selection criteria including *inter alia* the following: non-compliance in the PNCA, other types of non-compliance, risk posed by the activity and possible impact on public health and/or consumer confidence.

An overview of inspections carried out by the ASAE is provided in **Table 3**. The figures indicate controls on FNAO in food processing establishments and both FAO and FNAO at retail level. These controls cover hygiene requirements as described in Regulation (EC) No 852/2004.

Table 3. Number of controls performed by the ASAE in 2009-2012

Year	Type of controls		Number of controls	%
2012	Planned		229	51
	Non-planned	RASFF	74	16
		Non-compliant results	119	26

		Complaints	30	7
2011	Planned		623	70
	Non-planned	RASFF	39	4
		Non-compliant results	138	16
		Complaints	86	10
2010	Planned		474	67
	Non-planned	RASFF	35	5
		Non-compliant results	111	16
		Complaints	83	12
2009	Planned		316	67
	Non-planned	RASFF	43	9
		Non-compliant results	26	6
		Complaints	84	18

For 2013, the ASAE has planned 55 controls of FNAO processing establishments and retail outlets. It should be noted that this figure can be largely exceeded due to unplanned surveillance operations performed by the ASAE in this area based on reports, complaints and interventions.

Conclusions

Controls within the framework of the PNCA, operated by the ASAE, are the only form of physical controls on contaminants in Portugal as, within the framework of controls performed by the DGAV, sampling for contaminants is not foreseen.

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. EU methods of sampling for the official control of contaminants in food are laid down in Commission Regulation (EC) No 1882/2006 (nitrate); 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

The PNCA

The instruction called "Sample Collection Normative" is made available for samplers. It provides instructions on which contaminants can be tested for in different food products, tables for calculating the number of incremental samples to be taken depending on the weight of the lot, sample coding system and other practical information.

At the time of the audit the 2013 PNCA was not officially approved, however, its implementation started in line with the procedures. With regard to contaminants, the January-May sampling covered aflatoxins in dried fruit, nitrate in spinach, OTA in coffee and dried fruits, dioxins in non-branded oils, patulin in fruit beverages, and melamine in composite food products.

Sampling for the PNCA is performed by the ASAE sampling technical staff, who collect samples from wholesalers or retail markets.

A standardised sampling form is used to record, *inter alia*, the date of sampling, the name of the product sampled, its origin, lot identification data, lot size and the quantity of the samples taken.

All samples collected under the PNCA are tested in the ASAE laboratory which was appointed to carry out food analyses through Order No 14720/2009 of the Ministry of Economy and Innovation.

Analytical reports are sent to the Food Risk Division of the ASAE and the compliant results are notified to the FBO involved.

When a sample is found non-compliant, test results are sent to the DEPO who prepare operational orders for the Regional Directorates (RDs) to perform a follow-up inspection(s) and/or additional sampling.

The audit team noted that the batch sizes were not always correctly indicated in the sampling forms and that Request for Laboratory Analysis forms, which are sent to the laboratory, have no box to indicate the size of the batch. This procedure excludes the possibility for the laboratory to verify if the sample quantity corresponds to the lot size as required in legislation. This shortcoming was partially removed by the ASAE during the time of the audit. Instructions were issued to technical staff to indicate the size of the lot on the sampling form and to the laboratory to reject samples of inadequate quantity. However, the proof that Request for Laboratory Analysis forms were amended was not provided to the audit team (see section 5.2.4).

Regarding the implementation of the requirements of Article 2 of Regulation (EC) No 1881/2006 requiring the application of the process factor in the case of the testing of dried, diluted or compound foodstuffs, no instructions were issued as to how to determine compliance with the maximum limits in the case of such foodstuffs. However, examples were seen that the rules stipulated in Article 2 were followed by the ASAE laboratory to ascertain compliance with the legal limit.

Sampling and testing within the PNCA is financed from public resources. However, in the case of non-compliance, costs of any further sampling and testing have to be covered by the FBO if the case is lost in court.

Controls at visited premises

The audit team visited a baby food producer controlled by the DRAP and DGAV technicians, a major bakery, a vegetable oil processor, a fruit pulp and juice producer and a lettuce cutting plant –

all controlled by DRAP food control technicians, a major rice producer and a cereals and vegetable producer controlled by DRAP cross-compliance technicians, and a smoked meat products producer controlled by the DGAV technicians. The ASAE inspectors were present at the bakery visited.

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

The technicians generally correctly identified contaminant related risks in the HACCP-based system operated by the FBOs visited. However, the majority of technicians had difficulty in verifying if measures in place were adequate to manage the risks related to contaminants.

The establishments visited never considered contaminants as a hazard which need 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. requesting raw material specifications from their suppliers, sampling and carrying out own-checks of incoming lots to avoid placing contaminated foodstuffs on the market. All FBOs visited had a HACCP based system in place.

At the bakery visited, the HACCP-based plan was developed and, with regard to contaminants, followed the requirements previously defined by the GPP. An arrangement exists to send quarterly results of own laboratory checks to the DRAP with a copy to the DGAV headquarters. However, this arrangement was agreed only with the establishment which was visited.

Out of six food processing establishments visited, two were never visited for official control purposes within the context of this audit, two others were last visited in 2009, one was visited in 2010 and one is frequently visited because the FBO is involved in meat processing. The HACCP-based plan was verified in four of those establishments.

Controls on primary production level

Primary producers are inspected by DRAPs only within the framework of cross compliance audits. However, specific checks regarding contaminants are not performed. DRAP has developed the guide on Good Agriculture Practices (GAP) which is available on the internet.

The first organisation visited was a co-operative of 600 farmers operating on approximately 10000 ha. Approximately 8000 ha of grain (corn, wheat, barley) and 2000 ha of vegetables (potatoes, broccoli, onions etc.) are under cultivation. All vegetable farms are certified by a private sector scheme related to GAP. The co-operative takes samples for analysis in an accredited laboratory for all relevant contaminants (nitrate, heavy metals and mycotoxins). The audit team analysed the analytical reports and concluded that the self control system of the co-operative for contaminants is considered adequate.

The second entity visited has contracted 30 farmers with approximately 100 ha for producing fresh lettuce and spinach for fast food businesses. About 80% of the farmers are certified by a private sector scheme related to GAP, the remaining 20% are on the way to get certified. The company takes samples for analysis in an accredited laboratory on nitrate and the relevant heavy metals from each farmer once a year. Additionally, they request own sampling and analysis from their farmers. The audit team analysed the analytical reports and concluded that the self control system of the company for contaminants is adequate.

The third entity visited was a group of 40 shareholders that are producing rice on approximately 5300 ha. The company takes samples for analysis in an accredited laboratory for all relevant contaminants (heavy metals and mycotoxins) from each silo after drying. For baby rice, additional

samples for PAHs analysis are taken. The audit team analysed the analytical reports and concluded that the self control system of the company for contaminants is adequate.

Conclusions

The majority of food processing establishments visited were not subject to official controls with adequate frequency. However, all FBOs visited took measures to avoid contaminants in their produce. There are no official controls of contaminants at primary production level. However, the FBOs visited were all operating comprehensive self control systems to monitor the relevant contaminants.

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 (nitrate), 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 ASAE usually takes samples at wholesale and retail level.

The audit team observed two official sampling exercises at supermarkets, one for peanuts and one for hazelnuts.

Both sampling exercises were conducted by a team of two specialised samplers from the ASAE. All four samplers were very experienced and received training on sampling 2-3 times per year.

The lot of peanuts consisted of approximately 120 bags of 1kg each. The samplers decided to take two bags from the surface of the lot as a sample. At a later stage the samplers consulted the sampling instructions of the ASAE and realised that the sample should be 3kg. The deficiency was corrected by sending a supermarket employee to fetch a third bag. However, details about the corrective measure were not recorded in the sampling protocol.

The lot of hazelnuts consisted of approximately 5 kg of unpacked nuts in shell. The samplers took a representative sample of 2.14 kg from different places of the lot and sealed it.

After both sampling exercises, a sampling report was drafted, signed by the samplers and the representative from the supermarket. Only the report from the peanut sampling contained information regarding the lot size. A Request for Laboratory Analysis form is filled in to accompany the sample to the laboratory and in case of non-compliant results a copy of the sampling report is sent for risk assessment. The audit team checked after the sampling exercise the last 20 sampling reports (ten from the ASAE Lisbon and ten from other regions in Portugal) of samples on contaminants of FNAO. No report contained detailed information about the lot size. This

shortcoming was partially corrected by the ASAE during the time of the audit. (see section 5.2.3.2).

The CA stated that the forms of the sampling protocols were introduced in 2012 and that there is confusion regarding the definition of the lot size. The samplers add a copy of the documents of all produce that entered the supermarket for the definition of the lot size. However, this could lead to wrong interpretations of the correct sample size because these lots could be split or parts could be sold to consumers.

Conclusions

The observed sampling was in general in line with the requirements of Commission Regulation No 401/2006. However, some shortcomings were noted with regard to the ascertaining and reporting of the lot size and reporting of unusual events during sampling.

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 (EC) No 1883/2006 (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 NRLs for PAHs and mycotoxins are not designated as required by Article 32 of Regulation (EC) No 882/2004.

The audit team noted that the ASAE laboratory participated in Proficiency Tests (PTs) organised by the EURL for mycotoxins but is not listed as an NRL on the EURL webpage. The ASAE laboratory declared that it was requested by the former GPP to become the NRL for mycotoxins in FNAO and the former GPP was asked to clarify the situation, however, such clarification has not been provided and the laboratory was never formally designated as the NRL.

The National Veterinary Research Laboratory (Laboratório Nacional de Investigação Veterinária, LNIV) is the NRL for heavy metals in all matrices. The audit team verified in the ASAE laboratory visited that the LNIV does not perform the NRL duties towards other official laboratories in Portugal as required by Article 33 of Regulation (EC) No 882/2004.

As sampling for contaminants has not yet been foreseen within the controls on FNAO carried out by

the DGAV, this CA has no laboratory network established for contaminant analysis (see section 5.2.3.1). The former GPP used some private laboratories for contaminant controls but no formal designation or contracts with those laboratories had been signed.

Within the ASAE, there is the ASAE laboratory responsible, *inter alia,* for analysing samples for official controls of contaminants under the PNCA. There are two laboratory units involved in the testing of samples which are relevant within the context of this audit. There is the laboratory for physical-chemical testing and the laboratory for testing beverages and vine (also vine products). The ASAE laboratory also accepts samples from other customers.

The audit team visited two laboratory units of the ASAE laboratory in Lisbon and a laboratory division of INIAV in Lisbon.

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

The ASAE laboratory Lisbon

The ASAE laboratory has in total 50 FTE staff. There are two staff members for heavy metals, three for mycotoxins, two for nitrate and one co-ordinator. Staff qualification is 5 years at university except for one staff member who has a master's degree.

The laboratory is equipped with two High Performance Liquid Chromatography (HPLC) instruments for mycotoxin analysis and one for nitrate. Additionally, there are two atomic absorption spectrometers for heavy metals analysis.

The ASAE laboratory is accredited according to the International Organisation for Standardisation Standard 17025 by the Portuguese Accreditation Institute with a fixed accreditation scope.

There are no accredited methods available for the analysis of fumonisins, T2 and HT2, Patulin, 3-MCPD and melamine. For methods of analysis for Deoxynivalenol (DON) and ZEA the validation had not been finalised before the time of the audit, and for Patulin, work on validation was due to commence in May 2013. The laboratory is accredited for the testing of benzo(a)pyrene but the method was found non-operational at the time of the audit due to lack of gas supply. No method for the remaining three PAHs as listed in Regulation (EC) No 1881/2006 was validated or even in operating status.

The laboratory was not able to demonstrate that it has procedures in place for the rejection of samples of a lower quantity for testing than that prescribed in the Annexes to Regulation (EC) No 401/2006 (mycotoxins), Regulation (EC) No 1882/2006 (nitrates) and Regulation (EC) No 333/2007 (heavy metals). However, the Request for Laboratory Analysis forms in use do not provide information on the lot size to the laboratory (see sections 5.2.3.2 and 5.2.4).

The samples are registered electronically within a Laboratory Information Management System. The samples are assigned with a unique number by the sample collector and sealed with a numbered seal. During the registration another unique number is assigned to the sample for internal use in the laboratory.

Validation files for the HPLC methods for nitrate and for OTA were examined by the audit team. Ten replicates at two spiking levels were used to validate these methods. The calculation of the Limit of Detection and the Limit of Quantification (LOQ) follows the calibration curve approach. However, the method for OTA was not validated for baby foods, spices and grape juice matrices.

For OTA analysis the calibration of instruments with five calibration standards was performed. With

every assay series, two standards were measured to check the stored calibration. One standard concentration is close to the LOQ and a second standard concentration is close to the highest calibration point. These standards are prepared independently from the calibration which is good practice.

In the case of nitrate analysis the same procedure is followed. The shelf life of the nitrate stock solution was given as six months by the laboratory. The adequacy of that period has never been checked. However, the validity of the stored calibration is controlled with two independent standards and a 10% tolerance interval is allowed. If this range is exceeded the method will be calibrated with freshly prepared standards.

There were no Certified Reference Materials available. For quality control purposes in the case of OTA and nitrate, the laboratory uses a control material from the PTs provider. However, these checks are done only once a year.

The recovery for the OTA method is also checked only once a year. For that, a specific matrix (coffee, raisins and cookies) is spiked in-house with two different concentrations of the standard solution. The frequency of checks is not in line with the principles of good laboratory practice. The results of quality checks are monitored in a table, not graphically.

It is laboratory policy to participate annually in PTs for each method in use. The 2012 PTs report for nitrate was checked by the audit team. The laboratory adequately monitors the results of its participation in PTs. All other results of the laboratory's participation in PTs organised by the EURL or by the commercial provider were satisfactory.

With regard to nitrate and mycotoxins, the reporting routines did not 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 audit team noted that this information is missing in the examples of test reports verified during the audit. This shortcoming was corrected during the time of the audit and the laboratory identified a computer problem that had led to this failure.

INIAV laboratory division, Lisbon

The audit team visited the INIAV laboratory division for chemical analysis in Lisbon. Since 2010, this laboratory belongs to the MAMAOT. The audit team was informed by the head of the division and the CA that the laboratory is not involved in testing samples for official control purposes. Only research studies on PAHs in food are carried out.

The laboratory is not accredited and building of the quality management system was not a priority due to the lack of a sufficient number of samples.

The HPLC method for PAHs is validated for research purposes only, the scope and depth of validation is not in line with the requirements of Regulation (EC) No 333/2007.

Since 2011 the laboratory has participated in PTs carried out by the EURL with satisfactory results.

Conclusions

The lack of NRLs for mycotoxins and PAHs is not in line with the requirement of Article 33(1) of Regulation (EC) No 882/2004. The only existing NRL – for heavy metals – did not undertake the NRL duties as required by Article 33 of Regulation (EC) No 882/2004. The CCA has no designated laboratories for contaminant analysis in FNAO as required by Article 12 of Regulation (EC) No 882/2004. In the ASAE laboratory there are no methods for a number of contaminants as listed in

Regulation (EC) No 1881/2006. Methods in use in the official laboratory are validated and accredited (except the methods for DON and ZEA) and its performance in PTs was good. However, the lack of sample acceptance criteria in that laboratory poses the risk that samples of inadequate quantity are admitted for analysis and results cannot be legally binding.

5.2.6 Other Contaminant Control Programmes

Findings

The audit team noted that all six food processors as well as the rice producer 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. Additionally, all the FBOs visited by the audit team, which were involved in primary production, operated comprehensive self control systems to monitor the relevant contaminants (see 5.2.3) and the majority of their growers were certified by private sector GAP schemes.

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 must be given to the FBO.

Findings

Although the procedures for official controls in FNAO as developed by the GPP in the P2 Plan on Food Hygiene Control were available, these procedures were not formally approved for implementation by the DGAV and the DGAV has not yet developed its own procedures and instructions for official controls of FNAO. At the closing meeting of the audit, the DGAV presented a preliminary strategy related to official controls of FNAO, including contaminants (see section 5.2.3.1).

At the ASAE there is a procedure in place on actions to be taken upon receipt of non-compliant results of laboratory analysis concerning food safety and the audit team saw examples confirming that this procedure was followed.

In the ASAE laboratory, 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

The DGAV has no procedures and instructions for official controls on contaminants in FNAO. The ASAE have procedures in place for performing and reporting control activities. However, shortcomings were identified in relation to instructions in laboratories on sample acceptance criteria.

5.2.8 Enforcement Measures

Measures in the 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

When a sample taken during official controls for analysis of contaminants in FNAO is found non-compliant in the ASAE laboratory, the analytical report is sent to the Food Risk Division which performs the risk assessment. The case is directed to the Control Division which orders an on the spot follow-up inspection. This inspection is carried out by the RD Operational Department of the ASAE. The information on the results of the investigation and sanctions are reported to the headquarters and the RASFF notification process may be initiated. The FBO concerned may be requested to inform the CA on withdrawal from the market or other measures taken by him following the detection of the foodstuff considered unsafe.

In 2011, Portugal initiated RASFF notification No 2011.1182 referring to pistachio nuts from Iran contaminated with aflatoxins. No other RASFF notifications on contaminants in FNAO originated from Portugal in the four years prior to the audit although 22 samples in total were found non-compliant under the 2009-2012 PNCA out of which 15 were for nitrate in horticultural products, six for aflatoxins and one for OTA in dried fruits.

The CA explained that some RASFF notifications were not launched due to the ASAE understanding that RASFF notifications should be launched only with regard to those products, for which traceability data indicate the risk of being dispatched to other MSs or TCs.

The audit team verified two cases of non-compliance identified under the PNCA in 2012.

In the case of a sample of spinach containing a concentration of nitrate exceeding the Maximum Level (ML) an investigation followed the above described procedure and a fine was imposed on the FBO who cancelled the contract with the spinach producer. However, the sample was tested one month after its collection and the follow-up inspection took place five months after the laboratory report had been issued.

Excessive concentration of aflatoxins was found in a fig sample collected at a supermarket. The sample was taken on 6 December and the laboratory report was ready on 17 December followed by

the technical opinion issued on 14 January and an inspection ordered to be performed during 15-28 February. The control visit revealed that the lot was sold before the inspection started.

Conclusions

Measures undertaken by the CA to address non-compliances were generally adequate but a long time span between the date of the laboratory report and follow-up investigations undermines the effectiveness of corrective actions. RASFF notifications were not launched, which is not in line with Article 50 of Regulation 178/2002.

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 EU 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

Decree-Law No 28/84 of 20 January 1984 is the main legislative supporting instrument for sanctions imposed by the DGAV.

In the case of a minor offence, an administrative proceeding may be initiated either by the DGAV or the ASAE but only the ASAE has the police powers.

With regard to controls carried out by the ASAE, when a minor offence is identified only an administrative procedure is launched. When non-compliance is classified as a crime – public prosecution is initiated.

In the context of this audit, sanctions have been imposed only by the ASAE services.

Conclusions

Both the DGAV and the ASAE have the legal basis and administrative measures in place to impose sanctions as required by Article 55 of Regulation (EC) No 882/2004.

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

Although in the P2 Plan on Food Hygiene Control used by the former GPP there are measures foreseen for the verification of inspectors' performance during official controls and the DGAV has experience in the supervision of its inspectors working in the FAO sector, the DGAV verification procedures for the FNAO sector were neither finalised nor implemented.

The performance of the ASAE food samplers is verified on the spot every quarter by their direct supervisor but no records are maintained.

There is no possibility in place to verify the PNCA sample quantity at laboratory level as the Request for Laboratory Analysis forms sent to the laboratory do not contain information regarding the lot size.

The ASAE laboratory reports on test results clearly indicate if the tested sample conforms to the requirements as laid down in Regulation (EC) No 1881/2006. However, there are no procedures in place to verify if the method of reporting laboratory results is in line with the requirements of the relevant legislation.

According to the information provided by the Internal Audit Department of the DGAV there were no audits on contaminants in FNAO carried out up to the time of the audit. The Internal Audit Department of the DGAV will carry out audits on contaminants in FNAO during the next Multiannual Audit Plan (2014 – 2018).

Conclusions

There are no procedures in place for the verification of the effectiveness of the DGAV controls and on sampling under the PNCA operated by the ASAE.

There is an audit system in place within the meaning of Article 4(6) of Regulation (EC) No 882/2004.

6 Overall Conclusions

There are separate CAs responsible for controls on contaminants: the DGAV is the CCA responsible for food processing and the ASAE for controls on the market.

The CCA has not yet implemented effective controls on food of non-animal origin since it assumed this responsibility in 2012. It does not have staff trained to control establishments processing food of non-animal origin, control procedures, access to adequate sampling equipment and designated laboratories.

The ASAE operates a system for the official controls of contaminants in foods on the market which is risk based, covers major contaminant groups listed in Commission Regulation (EC) No 1881/2006 and it is the only form of physical control on contaminants in Portugal.

The NRL is designated only for heavy metals and it does not perform its duties as required by Article 33 of Regulation (EC) No 882/2004. The scope of testing in the ASAE laboratory does not yet cover the full range of contaminants due to the lack of certain validated methods.

The lack of clear division of competence between CAs involved and a lack of co-ordinated approach to official controls combined with communication problems undermine the effectiveness

of controls on contaminants.

7 Closing Meeting

A closing meeting was held on 8 May 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 did not express disagreement and made some comments on the findings and preliminary conclusions.

8 Recommendations

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

N°.	Recommendation
1.	Ensure that areas of responsibility of CAs involved in contaminant controls are clearly defined and their competences divided to meet the requirements of Article 4(1) of Regulation (EC) No 882/2004.
2.	Ensure efficient and effective co-ordination and co-operation between all CAs involved in official controls on food to meet the requirements of Article 4(3) of Regulation (EC) No 882/2004.
3.	Ensure that all staff responsible for official controls of FNAO receive appropriate training and instructions on contaminants and, in particular, in the area of risk assessment related to contaminants in FNAO and sampling, as required by Article 6 and Annex II of Regulation (EC) No 882/2004 and are kept up to date so that they can perform their tasks competently as required by Article 4 of the same Regulation.
4.	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.
5.	Ensure that controls on FNAO processing establishments are carried out regularly, on a risk basis and with appropriate frequency to meet the requirements of Article 3(1) of Regulation (EC) No 882/2004.
6.	Ensure that hygiene provisions in primary production of FNAO are subject to official controls in order to meet requirements laid down in Article 4 and in Annex I, Part A of Regulation (EC) No 852/2004.
7.	Ensure that all NRLs relevant for contaminant controls are designated as required by

N°.	Recommendation
	Article 33 of Regulation (EC) No 882/2004 and actively fulfil their duties.
8.	Ensure that NRLs perform their duties as required in Article 33 of Regulation (EC) No 882/2004.
9.	Ensure the designation of laboratories that may carry out the analysis of official samples for contaminants in FNAO in line with the requirements of Article 12 of Regulation (EC) No 882/2004 and to ensure adequate laboratory capacity as laid down in Article 4.2(c) of the same Regulation.
10.	Ensure that samples accepted by the laboratory for the analysis of mycotoxins and nitrate have an adequate weight/quantity to be 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.
11.	Ensure that all analytical methods needed for the analysis of official samples for contaminants are validated and are demonstrably fit for purpose by meeting method performance criteria as defined in applicable EU legislation e.g. Commission Regulation (EC) No 401/2006 (mycotoxins) and Commission Regulation (EC) No 333/2007 (3-MCPD, PAHs).
12.	Ensure that official controls on contaminants in FNAO are carried out in accordance with documented procedures as required by Article 8(1) of Regulation (EC) No 882/2004.
13.	Ensure procedures for the verification of the effectiveness of official controls as required by Article 8 of Regulation (EC) No 882/2004.

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=2013-6658

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