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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

POLAND

FROM 05 TO 12 JUNE 2012

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

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

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Poland, carried out from 5 to 12 June 2012, under the provisions of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004.

The objective of the audit was to evaluate the implementation of EU legislation in the area of food contaminants, 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 prepared by Poland and gather information about the results of investigations undertaken on food contaminants as specified in Commission Recommendations.

It was concluded that there is an operational system in place for controls of contaminants in food within the scope of this audit. However, it does not cover primary production of plant products before harvesting and all contaminants/foodstuffs under Regulation (EC) No 1881/2006. The control system is facilitated by a monitoring plan covering non regulated contaminants/foodstuffs. Shortcomings in the planning and a lack of co-ordination between and within Competent Authorities weaken the effectiveness of the control system. Inconsistencies in the sampling procedures applied and a lack of adequate training and instructions on sampling and official controls of contaminants in food and deficiencies in the assessment of the Hazard Analysis Critical Control Points plans decrease quality and consistency of official controls.

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
CA(s)	Competent Authority(ies)
CCA	Central Competent Authority
CP	Country Profile
CRM	Certified Reference Material
DON	Deoxynivalenol
EN/ISO IEC	European Norm /International Organisation for Standardisation
EU	European Union
EURL	European Union Reference Laboratory
FAAS	Flame Atomic Absorption Spectroscopy
FAO	Food of Animal Origin
FBO(s)	Food Business Operator(s)
FCM	Food Contact Material
FNAO	Food of Non-Animal Origin
FVO	Food and Veterinary Office
GAP	Good Agricultural Practices
GC/MS	Gas Chromatography/Mass Spectrometry
GFAAS	Graphite Furnance Atomic Absorption Spectroscopy
GHP	Good Hygiene Practice
HACCP	Hazard Analysis and Critical Control Points
HGAAS	Hydride Generation Atomic Absorption Spectroscopy
HPLC	High Performance Liquid Chromatography
3-MCPD	3-Monochloropropane-1,2-diol
MPPSI	Main Plant Protection and Seed Inspection
MS(s)	Member State(s)
MSI	Main Sanitary Inspectorate
NFNI	National Food and Nutrition Institute
NIPH-NIH	National Institute of Public Health- National Institute of Hygiene
NRL	National Reference Laboratory
OTA	Ochratoxin A
PAH	Polycyclic Aromatic Hydrocarbons
PCA	Polish Centre for Accreditation
PCB(s)	Polychlorinated Biphenyl(s)
PPP(s)	Plant Protection Product

PT(s)	Proficiency Test(s)
RASFF	Rapid Alert System for Food and Feed
SSI	State Sanitary Inspection
VI	Veterinary Inspection
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 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 from 5 to 12 June 2012. 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) – the Main Sanitary Inspectorate (MSI) did not accompany the audit team for the duration of the audit. An opening meeting was held on 5 June 2012 with representatives from the MSI, the Veterinary inspection (VI), the Main Plant Protection and Seed Inspection (MPPSI), the National Institute of Public Health - National Institute of Hygiene (NIPH-NIH) and the National Food and Nutrition Institute (NFNI).

At this meeting, the objectives of, and itinerary for, the audit were confirmed by the audit 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 prepared by Poland;

- 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 reviewed the designation of the Competent Authorities (CAs) for the official control of food contaminants, their co-operation, audits and resources for the performance of controls, as well as the organisation of the controls including national control programmes for food contaminants, control procedures, consideration of Commission guidance documents, sampling and laboratory performance.

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

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

Table : Audit visits and meetings:

Visits/Meetings		Comments
Competent Authorities		
Central	2	Opening and closing meeting with MSI, Main Veterinary Inspectorate, MPPSI, NIPH-NIH and NFNI
Regional	2	Competent Voivodship authorities (of the SSI, VI, MPPSI) in two Polish regions (Malopolskie and Podlaskie)
Local	4	Discussions held during the visits to food establishments
Laboratories		
Public	2	NIPH-NIH and Voivodship SSI laboratory in Podlaskie Voivodship
Establishments		
Food mill	1	One mill for production of wheat and rye flour
Food processors	2	One establishment for processing smoked meat One establishment for processing nuts
Farmer growing food products of plant origin	2	One co-operative of farmers growing cereals, and one farmer growing cabbage

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 European Parliament and of the Council.

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

3.2 Standards

Additionally, the standards and EU recommendations contained in Annex 2 were relevant for this audit. Reference to specific provisions of these documents is provided at the beginning of each section.

4 Background

4.1 Audit Series

This audit undertaken in Poland is the third in a series of audit audits to 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.

4.2 Country Profile

The FVO has published a Country Profile (CP) for Poland, 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

There is no additional national legislation in place on national limits for food contaminants. The legislation is disseminated from central level to regional level by letters or during training courses.

All legislation in the context of this audit is made available to the public on the SSI and VI web pages.

Conclusions

There is no national legislation in place regarding maximum levels for contaminants in food. The EU legislation is properly disseminated and publicly available.

5.2 Organisation and Implementation of Official Controls

5.2.1 Designation of Competent Authorities

Legal requirements

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

Article 33 of the Regulation (EC) No 882/2004 requires MSs to designate National Reference Laboratories (NRLs) for each EU reference laboratory.

Findings

The main responsible CAs in the context of this audit are the SSI and the VI. The MPPSI has a limited role in the context of this audit.

The SSI is responsible for the official controls of contaminants of all processors of food of non-animal origin (FNAO) and in retail facilities. The VI carries out controls on environmental and industrial contaminants in facilities processing food of animal origin (FAO). Both the SSI and the VI carry out controls on contaminants in establishments where composite foodstuffs are processed.

Regarding official controls of the primary production of FNAO, the SSI is responsible for the controls of post harvest operations, including transport. The primary production of plant products before harvesting is not supervised in the context of this audit by any of the CAs from the point of view of implementation of Good Agricultural Practices (GAP) and of food hygiene requirements established in Annex I of Regulation (EC) No 852/2004. The CAs informed the audit team, that no CA was designated for official controls in the context of this audit at primary production before harvesting[1].

At the primary production level of FNAO the MPPSI carries out official controls on the use of Plant Protection Products (PPPs). MPPSI controls and certifies plant produce under the national agricultural integrated system. Participation in this system obliges farmers to test fresh produce for nitrates and heavy metals and to ensure full traceability of the products.

Within the SSI, the enforcement of official controls on food contaminants is within the responsibility of 16 Voivodship SSI Inspectorates and subordinated Poviat SSI Inspectorates.

The SSI has nominated 16 integrated laboratories for the official controls of contaminants and the VI has designated 7 laboratories (including two NRLs). However, the VI has no laboratory designated for Polycyclic Aromatic Hydrocarbons (PAH) in FAO. The VI informed the audit team, that they do not use SSI designated laboratories. All laboratories used in the context of the official controls are accredited to the European Norm /International Organisation for Standardisation (EN/ISO IEC) 17025.

The NIPH-NIH is sub-ordinated to the Ministry of Health and acts as the NRL for the SSI. The NIPH-NIH prepares and sends an annual proposal for a "Plan for sampling and testing of food in the framework of official controls and monitoring for the SSI" concerning tests for contaminants in food.

There are nine NRLs designated in the context of this audit, however, there is no NRL for PAH[2]. The audit team was informed, that new legislation is currently being prepared, which will designate

1 In their response the competent authorities noted that in a document dated 22 August 2012 (ref: GIS-BŻ-UE-420-41/KN/12/1, Annex 1) the Main Sanitary Inspector requested the Minister for Agriculture and Rural Development to take action aimed at resolving the problem of controls on contaminants in plant products at primary production level before harvesting in the framework of official food controls, rather than through a voluntary system - Integrowana Produkcja (Integrated Production).Negotiations are currently under way concerning the designation of one department (agriculture or health) as the Competent Authority with the consequent responsibilities. The department concerned will conduct official controls for contaminants at primary production level before harvesting.

2 In their response the competent authorises noted that the NIPH-NIH laboratory has been acting as a NRL for PAH under Regulation 882/2004 since 2006 (the Regulation from the Minister for Health in 2004 establishing NRLs did not cover PAH at the time). The Laboratory's scope of activity also includes food of animal origin that is on the market. On 19 June 2012 the Minister for Health signed the Regulation on the list of reference laboratories, in which the NIPH-NIH was designated as the PAH reference laboratory (Journal of Laws 2012, item 728).

the NIPH-NIH as the NRL for PAH. The legislation is expected to come into force in July 2012.

Conclusions

The CAs in the context of this audit are clearly designated. However, there is no CA designated for controls of general hygiene provisions in primary production before harvesting. There are official laboratories and NRLs designated for the controls of contaminants in food. However, currently no NRL for PAH analysis has been designated.

5.2.2 Resources for Performance of Controls

5.2.2.1 Legal basis for controls

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires that the necessary legal powers to carry out controls are in place and there is an obligation on food business operators (FBOs) to undergo inspection by the CAs. Article 8 of the above Regulation requires that CAs have the necessary powers of access to food business premises and documentations.

Findings

The CAs have the necessary legal powers to carry out controls, including powers of access to food business premises and documentation.

The legal basis to undertake official control activities in the scope of this audit for all CAs is provided in Articles 73-78 of the Act of 25 September 2006 on Food Safety and Nutrition.

The competences of the SSI are provided for in the State Sanitary inspection Act of 14th March 1985 (Journal of laws 2006 item 851 as amended).

The competences of the VI are provided for in Article 3 of the Act of 29 January 2004 on Veterinary Inspection (Journal of Laws No 33, item 287 as amended).

The MPPSI has a legal basis for its activities in the Act from 18th December 2003 on the Protection of Plants and Act of 26 June 2003 on Seed Material.

Conclusions

The CAs have the legal basis for carrying out official controls of contaminants in food.

5.2.2.2 Staffing provision and facilities

Legal requirements

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

Findings

At the central level of the SSI there are two full time equivalents involved in the context of this audit. At the Voivodship level there are 427 officials (274 of them are at official laboratories), who deal with food safety issues including contaminants in food controls. At Poviat level there are 2162 officials, of which 50 are at laboratories.

At the Voivodship level of the VI there are 66 officials involved in the context of this audit and 613 officials at Poviat level.

There is no staff member exclusively assigned to controls in the context of this audit which are carried out along with other food safety controls.

The equipment used by the SSI official met in the Podlaskie Voivodship – metal probe, paper bags and balances - was appropriate for sampling cereal products for mycotoxin analysis.

The same kind of metal probe was used by the SSI staff met in the Malopolskie Voivodship. However, the equipment was not appropriate for big bags (1250 kg) of peanuts sampled for mycotoxin analysis. See also chapter 5.2.4.

Conclusions

The inspectors have access to sampling equipment. However, the equipment is not always fit for the purpose (see also chapter 5.2.4.).

5.2.2.3 Staff qualifications and training

Legal requirements

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

Findings

In the last two years the SSI organised 63 training courses that included some information on contaminants in food. In total 16 training courses were organised at the central level of the SSI and in the framework of the NIPH-NIH and other organisations. All training provided information on new methods, legislation and sampling. The information was disseminated via a cascade training system to the staff at the Voivodship and Poviat level.

In the Podlaskie SSI Voivodship the audit team was informed that the training needs are established on the basis of requests from Poviats, new legislation and reports from official controls.

In the Malopolskie Voivodship the audit team was informed by the SSI, that training needs are established *inter alia* on the basis of questionnaires used for the evaluation of the training courses provided and also on the basis of the needs identified in connection with implementation of new legislation and results of the audits undertaken.

The SSI Poviat staff met in the Podlaskie Voivodship participated in internal training courses, which included training sessions on the HACCP. Participation in external training courses was very limited; they did not receive any training on official controls of FNAO at primary production.

In the Malopolskie Voivodship one official from the Poviat SSI level participated in an external training course on contaminants in 2011. However, the knowledge received was not transmitted to the other staff in the Voivodship. In the Malopolskie Voivodship meetings are organised at least

twice a year to transmit the information received at central level to the Poviat level. The last training on sampling was organised in 2006. In May 2012 a training course was organised on controls at primary production after harvest. In April 2012, staff from the Voivodship participated in a training course organised by the central level of the SSI on contaminants in food and the knowledge acquired was transmitted via the cascade system to staff from the Poviats in May 2012. All inspectors met in this Voivodship participated in internal training on the procedures based on the HACCP principles.

The VI plans training courses at the end of each year and all inspectors can apply to participate. In 2011 the VI organized two training sessions on chemical hazards in the production of FAO and on sampling for chemical testing and interpretation of results.

The VI inspector met in Malopolskie Voivodship had participated in a two-year post graduate course, which included training on contaminants in food and procedures based on the HACCP principles.

The SSI staff has secondary level education or university degree in chemistry, food chemistry, pharmacology, biology, biotechnology, food or nutrition technology, public health and environment protection.

Inspectors at Voivodship and Poviat level have access to the current food legislation that they are required to enforce.

Conclusions

The training received on contaminants in food and assessment of procedures based on HACCP was not sufficient to allow the inspectors to undertake their duties competently, which is not in line with the requirements of Article 6 of Regulation (EC) No 882/2004. See also chapter 5.2.3.2.

5.2.3 Contaminants Control Programmes

5.2.3.1 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 noncompliance.

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.

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, presence, prevention and reduction of certain contaminants in foodstuffs.

Findings

Planning of official controls at central level

The central level of the SSI prepares annually the "Plan for sampling and testing of food, as part of official control and monitoring". Official controls are planned for food categories and contaminants whether or not limits are established in EU legislation. Monitoring concerns contaminants/foodstuffs for which there are no established limits or when monitoring is required by EU legislation. The audit team was informed that no sampling is planned in the primary production of plant products.

The 'Plan for sampling for testing food, in the framework of official control and monitoring for the SSI' is prepared every year in cooperation with research and development entities such as the NIPH-NIH and the NFNI, and also with other bodies cooperating with the CCAs. The Plan sets out the directions and scope of testing, the range of products (including FAO at retail level) and the number of samples to be taken by each Voivodship.

The central level of the SSI sends the annual reports to the relevant research institutes involved. The results of testing are analysed and serve as a basis for the preparation of monitoring plans for the following year. However, the audit team noted that 180 monitoring samples taken in 2009 and 2010 for mycotoxins were analysed in 2011 by the NIPH-NIH. This makes it doubtful that results from the monitoring exercise for 2009 and 2010 were used for planning for the following year.

The audit team was informed by the central level of the SSI that priorities are set on the basis of the results from the previous controls and monitoring, legislative requirements, information obtained from the European Commission and other MSs, Rapid Alert System for Food and Feed (RASFF) notifications, number of the population and risk assessments, drawn up by the NIPH-NIH. However, the audit team noted that the plans for contaminants for 2010, 2011 and 2012 were identical. The audit team was not provided with written evidence of risk assessments. The procedure for planning provided to the audit team did not include a description of the risk analysis carried out. The sampling plan includes instructions for sampling based on the relevant EU Regulations.

In the SSI laboratory visited, the audit team was informed that sampling at retail level is not co-ordinated and it could happen that the same product from the same lot could be sampled and analysed by several Voivodships.

The control of contaminants in FAO is carried out by the VI in co-operation with the State Veterinary Institute and the State Research Institute in Puławy under the "National plan of control testing for the presence of prohibited substances as well as of residues of chemical, biological or veterinary medicine products in animals and in food of animal origin" as well as the "National plan of control testing of dioxins, furans and dioxin-like Polychlorinated Biphenyls (PCBs), and non-dioxin-like PCBs in animals, and in products of animal origin". Under these programmes, products are tested for the presence of residues of toxic metals (lead, cadmium, mercury, arsenic - 1779 samples in 2011), of mycotoxins (ochratoxin A (OTA) – 128 samples in 2011, aflatoxin M1), as well as for the presence of dioxins (102 samples in 2011), furans and dioxin-like PCBs (939 samples in 2011) in FAO. However, no sampling for the testing of PAH is planned or taken at the FAO production level.

The plans of the SSI and VI are prepared separately and the audit team noted that there is no co-ordination between them.

Planning of official controls at regional and local level

In Podlaskie Voivodship, the audit team was informed by the SSI that at the end of the year the sampling plan for the following year is received. The plan is then broken down at Poviat level[3]. At Poviat level information is received about the number of samples to be taken for certain contaminants. On the basis of the plan received Poviat selects the premises, where and when the sampling will be carried out. If it is not possible to achieve the planned targets Voivoship can discuss a change of the plan with the central level.

The plan defines the minimum number of samples that should be taken. The Voivodships have the right to take an extra 30 percent of samples in case of food poisoning, complaints received or as the need arises during the inspections. The audit team noted that in Podlaskie Voivodship no such sample was taken in 2011 for contaminants. In Malopolskie Voivodship five such samples for heavy metals tests were taken in 2011.

On the basis of the SSI Poviats plans, the Voivodship official laboratories develop integrated testing plans[4].

Conclusions

The food contaminants sampling plans are designed to include all contaminants laid down in Regulation (EC) No 1881/2006 with the exception of PAH analysis in the production of FAO.

Monitoring of specific contaminants, in addition to the contaminants regulated under Regulation (EC) No 1881/2006, assist further in ensuring the safety of foodstuffs.

Primary producers of plant products are not subject to official controls before harvesting with regard to food contaminants and provisions of Annex I to Regulation (EC) No 852/2004, which is not in line with the requirements of Article 3(3) of Regulation (EC) No 882/2004.

The SSI planning of official controls on contaminants in food is not risk based. Covering the same products, the sampling plans are not co-ordinated between the SSI and the VI and between the SSI's Voivodship offices. In addition, during the planning process at Poviat level the FBO's past records are not taken into account to ensure effective and efficient sample planning.

5.2.3.2 Implementation 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. Union methods of sampling for the official control of contaminants in food are laid down in: Commission Regulation (EC) No 252/2012 (dioxins and dioxin-like PCBs); Commission Regulation (EC) No 333/2007 (certain chemical elements); Commission Regulation (EC) No 401/2006 (mycotoxins).

3 In their response the competent authorities noted that further detail is added to the plan at Voivodship level, prior to it being forwarded to individual Powiats for implementation. A set of samples to be taken by a specific Powiat is drawn up for each test, subdivided *inter alia* for quarters of the particular year.

4 In their response the competent authorities noted that the national plan for the Malopołskie Voivodship is developed at Voivodship level by indicating: the quantities, types and nature of tests for samples taken on the territory of a Powiat, the laboratory testing the sample and the month of testing. The plan is forwarded to the Powiats in that form. At Powiat level further detail is added to the plan indicating the location where the sampling is planned and the specific date of sampling.

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

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

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, GHP, good farming practices and HACCP, taking into account the use of guides established in accordance with EU legislation.

Findings

Inspections are not announced in advance. After each inspection a report is created and a copy is provided to the FBO. The results of the laboratory analysis are reported only if they are non-compliant.

The SSI planned frequency of controls in the food processing facilities is established by the central level and the required minimal frequency is once a year. At the cereals processor visited the actual frequency was twice a year due to the high volume of production. The CA did not take into account the good results of previous controls and internal controls carried out by the FBO. The Poviat staff in the Malopolskie Voivodship informed the audit team, that in food processing facilities the established frequency of controls represent minimum frequency. The frequency is at least once a year or once every two years depending on the type of facility and it could not be decreased.

The implementation of the sampling plan on contaminants in food starts at the beginning of each year and results are reported twice a year by the Voivodship level to the central level.

In both SSI Voivodship offices visited, the audit team was informed that planned targets for 2011 were met.

The inspections are carried out according to a general procedure for official control on foodstuffs and Food Contact Materials (FCM). However, the inspectors met by the audit team in Podlaskie Voivodship, reported that during the inspection of the primary producers they use checklists which they developed themselves specifically for each facility visited. They stated that the official procedure is not specific enough for the official inspection of those establishments.

The SSI has not developed procedures regarding compliance with the maximum limits for contaminants in the case of dried, diluted, processed or compound food products.

Under Article 63(2)(12) of the Act of 25 August 2006 on Food Safety and Nutrition, FBOs in primary production are subject to registration with a competent Poviat SSI. Registration is carried out on request at the FBO. Following registration the SSI issue an official confirmation letter. In Podlaski Voivodship 83 primary producers are registered. In Malopolski Voivodship approximately 100 primary producers are registered. The audit team noted that the registration started in 2010.

The MPPSI has developed several Guides to GAP, which include very limited information on prevention of mould contamination. The MPPSI supervise training courses organised on GAP for farmers, where basic information on *Fusarium* prevention is disseminated. However, the MPPSI supervises only the implementation of GAP regarding the use of PPPs.

Two guides to GHP have been developed in the context of this audit. One guide is dedicated to small establishments processing fruit and vegetables at farm level and one for establishments processing cereals. These guides were prepared by the Agricultural Advisory Centre and approved by the Ministry of Agriculture and Rural Development.

The audit team observed four inspections undertaken by inspectors from the Poviat offices of the SSI and one visit to a smoked meat producer carried out by VI officials.

Controls at visited premises

In Podlaskie Voivodship one cooperative of growers was visited. They produce mainly wheat, maize, rape, rye, triticale and oat on a cultivated area of 1600 ha in total, with temporary storage area during the harvesting period. The audit team noted that the representative of the grower met was aware of the possibility of mould growth and considered the quick drying of cereals as a critical step to reduce this risk. He has shown his own procedures based on the HACCP principles. The grower informed the audit team, that he received an order from the Poviat SSI office to develop and implement them.

The comprehensive inspection of the co-operative of growers carried out by two SSI inspectors covered only the processes after harvesting and focused mainly on hygiene requirements for equipment, storage and personal. The inspectors followed the requirements set out in Annex II to Regulation (EC) No 852/2004. The inspection did not cover any threat for the contamination of products with moulds.

The inspection in the cereal processing establishment focused on procedures based on the HACCP principles and sampling. The cereals processor had implemented an in-house developed HACCP plan and carried out random contaminants testing of raw materials and final product. He applied checks of moisture on reception of raw materials. However, the HACCP plan implemented did not include any assessment for mycotoxins[5]. The inspector checked the documentation at one critical control point (reception of raw material). However, the inspector failed to connect the monitoring data with the delivered product. The facility was checked by the same inspector two months earlier and no problems were noted with the HACCP plan.

The farmer visited in Malopolskie Voivodship cultivated cabbage (in an area of 4 to 6 ha) and potatoes. The facility also processed sauerkraut. The farmer has been registered as a food processor (since 2009) but not as a farmer growing plant products. The inspectors from the Poviat sanitary and epidemiological station considered that as he grows the raw material for his own food processing activities, there was no need to be registered for his farming activities[6]. However, there is a legal requirement according to the national legislation for the registration of all business operators producing plant products by the competent Powiat SSI authority. The Poviat SSI inspectors carried out official controls only of the processing of sauerkraut. The audit team noted that sampling for food contaminants analyses has never been carried out under the official controls or the farmer's own-checks. The farmer stated that he was aware of the GAP principles regarding the use of PPPs from publications which were available on the internet or specialised literature and from lectures he had attended. However, he was not aware of the controls required for contaminants such as heavy metals.

The processor of smoked meat visited had a system in place for approval of the suppliers, the required specifications for the incoming raw materials and for the wooden chips used in the smoking process. There was a crisis management plan which was verified twice a year. The food processor had developed a HACCP plan but the risks linked to the smoking process were not considered in the hazard analysis. The HACCP plan did not include the contamination of smoked

5 In their response the competent authorities noted that at the establishment assessed a critical control point was identified: reception of raw materials where moisture checks are constantly carried out. That parameter is taken as a starting point for assessment of the batch. Should any deviations be noted, the batch is not accepted onto the premises.

6 In their response the competent authorities noted that on 6 September 2012 a document (ref: NHŻ.1610.1.2012,) was sent to Powiat SSIs reiterating the requirement for producers of raw material to be registered, and should those producers also be processors, for their activities in the area of primary production to be registered as well.

meat products with PAHs as hazards. These shortcomings had not been detected during the VI official controls. Laboratory analysis of the finished smoked products had been carried out as part of the FBO's own-checks. However, official sampling for verifying compliance with the PAHs limits set out in the Regulation (EC) No 1881/2006 had never been carried out. The veterinary inspector met stated that this was due to the absence of a designated official laboratory for PAH analysis[7].

The inspector from Powiat sanitary and epidemiological station met during the visit to the nut processing company checked if aflatoxins had been included as a hazard in the HACCP plan. However, the inspector was unclear about how to verify the results provided in the laboratory analysis certificate. The audit team discussed food contaminants official controls with the inspector and noted that the inspector relied entirely on the information provided by the company as regards the control measures applied for contaminants controls.

However, all inspectors met failed to adequately assess the risks associated with the chemical contaminants in food during the controls of Hazard Analysis and Critical Control Points (HACCP) procedures.

All inspectors met had limited practical experience in controls of contaminants in food, in the food establishments and in most cases official sampling had not been carried out to verify compliance of the processed foodstuff with the limits set out in the EU legislation.

Conclusions

The SSI planning of official controls on contaminants in food is not risk based. Covering the same products, the sampling plans are not co-ordinated between the SSI and the VI and between the SSI's Voivodship offices. In addition, during the planning process at Poviat level the FBO’s past records are not taken into account to ensure effective and efficient sample planning.

Official controls of growers do not include assessment of GAP in the context of this audit, which is not in line with the requirement of Article 10(2)(d) of Regulation (EC) No 882/2004.

The requirement on establishing written procedures based on HACCP principles in primary production is not in line with the provisions of Article 5(3) of Regulation (EC) 852/2004.

Official controls are carried out without prior warning as required by Article 3(2) of Regulation (EC) No 882/2004.

Official controls on FBOs after primary production level include verification of food contaminants requirements. However, all inspection observed did not adequatelly assess the risk associated with chemical contamination, which is not in line with requirements of Article 10(2)(d) of Regulation (EC) No 882/2004.

5.2.4 Sampling

Legal requirements

Article 11 of Regulation (EC) No 882/2004 establishes general requirements for sampling. Article 8

7 In their response the competent authorities noted that the inspector supervising the establishment has knowledge, which he draws upon in the course of his supervision. The allegation that the processor had not included the risk of contamination of products with PAHs in the hazard analysis, and the fact that the shortcomings had not been identified by VI's services as non-compliance with existing legislation does not indicate lack of competence on the part of the inspector supervising production at the establishment. Nonetheless, following the comments by the FVO auditors, changes were made to the risk analysis and PAHs were included. The processor is currently preparing to change to a water based smoking process.

of Regulation (EC) No 1881/2006 requires that the sampling for the official 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 (EC) No 1883/2006 (dioxins and dioxin-like PCBs) and Regulation (EC) No 333/2007 (chemical elements, 3-monochloropropane-1,2-diol (3-MCPD), PAHs).

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

Findings

The general sampling standard operating procedure and provisions in the sampling plan are in place for the SSI inspectors.

In the Voivodship SSI laboratory visited the audit team noted two cases of sampling protocols, when the weight of aggregate samples from retail was one kg for lots of coffee with a weight 636 and 1260 kg. According the requirements of Annex I part G to Regulation (EC) No 401/2006 the weight of aggregate sample should be three and four kg.

Sampling observed in the cereal processing establishment was carried out in line with the requirements laid down in Regulation (EC) No 401/2006. The number of incremental samples was calculated based on the EU requirements and proper equipment was used. The requirements for the equipment are established by a standard operating procedure developed by the Voivodship level.

The audit team observed the sampling of peanuts for mycotoxins analysis. The SSI inspector took two aggregate samples, each approximately 20 kg from a 25 tons consignment. He did not use the appropriate equipment. The probe used was not long enough and the inspector was only able to take samples from a 20 cm layer under the surface of a big bag with a diameter of approximately 150 cm. The inspector took the correct number of incremental samples. The samples were put in transparent plastic bag, placed in a cardboard box, labelled and sealed.

Conclusions

The sampling demonstrations observed followed Regulation (EC) No 401/2006, however, there were some cases of sampling for mycotoxins which were not in line with Annex I part G of this Regulation.

The sampling equipment was not always sufficient to ensure that staff can perform their tasks efficiently and effectively by Article 4(d) of Regulation (EC) No 882/2004 (see also chapter 5.2.2.2).

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 Article 12(2) and (3) of Regulation (EC) No 882/2004. Requirements for designation 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 (nitrates), Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs) and Regulation (EC) No 333/2007 (chemical elements, 3-MCPD, PAHs).

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 audit team noted that for the majority of contaminants there are three designated NRLs, two under the SSI (the Food and Nutrition Institute's laboratory for acrylamide and the NIPH-NIH laboratory for PCB, 3-MPCD, nitrates and nitrites, PAH, mycotoxins, heavy metals, histamines and furans) and one under the VI. The audit team was informed, that all NRLs are part of the EURL network and attend the meetings organised by the EURLs. The audit team was informed that the last EURL meeting on mycotoxins was attended by only one NRL, the second NRL was not officially informed of the meeting. No evidence was provided to the audit team regarding the exchange of information between the appointed NRLs[8].

The NRLs of the SSI organise training courses for the SSI Voivodship laboratories. Participants pay a fee for such training courses[9]. These courses are used to communicate the information received from the EURLs and to provide information regarding the new legislation and methods. However, training planned for 2012 was cancelled due to budgetary constraints of the Voivodship official laboratories. In the official laboratory visited the audit team was informed, that with the exception of the paid training courses and the participation in Proficiency Tests (PTs), they did not receive any other information from the NRLs during the last two years.

All NRLs organise PTs for the official laboratories within their competence. The NRLs participate in the PTs organised by the EURLs.

The NIPH-NIH laboratory deals with different types of analysis in food matrixes and it is the NRL for heavy metals, mycotoxins and PCBs. The section involving analysis of contaminants in food employs 24 people, 21 members of staff have academic degree. The laboratory is equipped with three High Performance Liquid Chromatographies (HPLC), one Liquid chromatography with mass (GC/MS), Flame Atomic Absorption Spectroscopy (FAAS), Graphite Furnance Atomic Absorption Spectroscopy (GFAAS), Hydride Generation Atomic Absorption Spectroscopy (HGAAS) and spectrofluorimeter.

Most of the samples (foodstuffs/contaminants) analysed by the laboratory come from other laboratories for confirmatory purposes (part of the aggregate homogenised sample), private clients and as part of the monitoring plan. The laboratory does not analyse samples taken in the course of the official controls.

The NRL organised PTs for the SSI laboratories involved in contaminant analysis in foodstuffs (2010-2012: heavy metals in tomato concentrate (23 laboratories) and in freeze-dried herbs and apple purée (20 laboratories), aflatoxins in peanut butter (seven laboratories), Ochratoxin A (OTA) in powdered paprika (10 laboratories), Deoxynivalenol (DON) in wheat flour (eight laboratories)

8 In their response the competent authorities noted that the NIPH-NIH NRL representative attends meetings and all proficiency tests organised by the EURL every year (since 2006).

9 In their response the competent authorities noted that to date, all the information to be communicated by the NRL has been communicated at fee paying sessions for SSI workers. It was necessary to impose charges because the NRLs had no funding for this area.

and PAHs in vegetable oils (10 laboratories)).

The audit team was informed that laboratory representative took part in the EURL meeting concerning PAH in foodstuffs in April 2012.

The SSI laboratory in Bialystok has eight sections; one of these is the laboratory for food and FCM which is designated for the official controls and monitoring of acrylamide, mycotoxins, PAHs, heavy metals and nitrates in foodstuffs. The number of official samples analysed in 2011 was around 700 (approximately 50 samples for mycotoxins), 104 food-samples for acrylamide monitoring and samples for private clients. No non-compliances were found regarding official controls in 2010-2012. The laboratory has an adequate number of staff (technical/academic) and is well equipped for their scope of analyses carried out for official controls and monitoring with the exception of homogenisation equipment for large quantity samples. Staff responsible for contaminant analysis in foodstuffs mainly receives on the job training - personnel who start working on a new method are trained by analysts qualified for the particular method. Training is documented and tested by performing analysis using real samples. Laboratory representative took part in an external training course organised by the NIPH-NIH in Warsaw (analysis of metals (Al and Sn) in foodstuffs (13 and 14 December 2010)).

Sample handling and analytical methods

The laboratory at NIPH-NIH Warsaw was accredited according to EN ISO/IEC 17025:2005 by the Polish Centre for Accreditation (PCA) on 15 July 2004. According to the list of accredited methods (PCA, Nr AB 509) the laboratory has a flexible scope for the determination of heavy metals (Pb, Cd, Cu and Zn – FAAS; As - HGAAS), nitrates and nitrites (cadmium reduction and spectrometry), mycotoxins HPLC method (OTA, aflatoxin B1, Sum of aflatoxins B1, B2 ,G1,G2, M1, Zearalenon (ZEA), DON, Fumonisin B1, Fumonisin B2; T2 and HT-2), histamine (spectrometry), PAH (HPLC/FLD), 3-MCPD and furan (GC/MS).

The SSI Voivodship laboratory in Bialystok was accredited according to EN/ISO IEC 17025:2005 by PCA. According to the list of accredited methods (PCA, Nr AB 311) the laboratory has a fixed scope for the determination of mycotoxins (aflatoxin B1, Sum of aflatoxins, OTA, DON, ZEA, fumonisins B1 and B2 – HPLC, patulin – HPLC; matrix: peanuts, nuts, dried fruit, spices, cereal grains including corn and buckwheat and their products, wine and grape juice, apple juice, coffee and food for infants and young children), metals (Pb, Cd, Cu, Zn, As, Hg, Sn – FAAS, GFAAS, matrix: food products, fish and fish products, fruits, cruciferous and leafy vegetables, mushrooms, alcoholic drinks, other food products including foods for special nutritional uses, canned fruit and vegetables), PAH (benzo(a)pyrene, benzo(a)antracene, benzo(b)fluorantene, chrysene – HPLC; matrix: food products), nitrates and nitrites (spectrometry; matrix: fruits, vegetables and their products, food for infants and young children). The audit team was informed that accreditation for determination of acrylamide in foodstuffs is planed for 2013. The same goes for participation in PTs regarding acrylamide[10].

Both laboratories were audited by the PCA at the beginning of 2012 - only minor systemic inconsistencies were found, and no corrective measures were given regarding the methods for contaminant analysis in foodstuffs.

Both laboratories have Quality Managers and quality control procedures in place. The audit team was informed that all samples received by the laboratory are checked for correct handling, packaging and quantity. However, there were no written instructions on sampling and transport

10 In their response competent authorities noted that Under the Regulation dated 19 June 2012 (Journal of Laws, item 728), the Minister for Health designated the Food and Nutrition Institute as a reference laboratory for identifying the acrylamide contained in foodstuffs. On 21 January 2010 the Institute was accredited by the Polish Accreditation Centre under EN ISO/IEC 17025:2005 for the identification of acrylamide in foodstuffs by the liquid chromatography with tandem mass spectrometry method (LC-MS/MS).

requirements for particular contaminants and type of matrix. Samples are properly registered and all information is traceable back to sample documentation.

Procedures concerning sample handling, homogenisation and analysis in the case of determination of mycotoxins in foodstuffs were audited more closely by the audit team. The laboratory at NIPH-NIH deals mostly with confirmatory samples sent by other official laboratories – samples received by the NIPH-NIH already homogenised. They also have equipment for homogenisation of large sample quantities (homogenisation volume of 40 to 50 litres). Homogeneity of a sample is checked by performing duplicate analysis (two independent samples taken from different parts of homogenate).

The SSI Voivodship laboratory in Bialystok on the other hand has homogenisation apparatus (grinder) capable of handling up to maximum of five kg sample. The audit team was informed that samples originating from larger lots demanding bigger aggregate sample weights are analysed by other laboratories designated for the official controls of mycotoxins in foodstuffs. The audit team was informed by laboratory staff, that in the case of unshelled peanuts, the laboratory would use 100 g portions instead of 100 peanuts to calculate the edible-part weight which is not in compliance with Annex I part D of Regulation (EC) No 401/2006.

Regarding the accreditation scope, all methods are fully validated and include data for concentration range, limit of detection, limit of quantification, precision, linearity, accuracy and measurement uncertainty. All validation data checked was within the range set by the legislation. Calibration was done using a minimum of five points for each method checked (mycotoxins, metals). Each batch of samples analysed included a blank probe and recovery check. Both laboratories use matrix spiked samples with a known concentration of analyte for their recovery evaluation – concentration is chosen to be close to the maximum residue limit or close to the concentration of analyte in the real sample analysed in a particular batch. Values are monitored by means of control charts – the charts observed did not show any trends and significant deviation from the requirements of the legislation. Both laboratories use Certified Reference Material (CRM) for calibration and recovery checks. However, in the case of the NIPH-NIH, when checking the method for determination of OTA in foodstuffs, the audit team noticed that the expiry date for the CRM has expired (March 2011). There was also a lack of traceability between the CRM used and the batch of samples analysed. The audit team was informed that CRMs with an elapsed expiry date are used for research purpose only.

Analytical reports contain all the necessary data and are in compliance with legislation in both laboratories.

Both laboratories participate in the international PTs (EURL, IRMM, FAPAS) with satisfactory results for all contaminants in the scope of their designation.

Conclusions

The exchange of information between official control laboratories and the NRLs is limited.

All laboratories visited involved in contaminants monitoring are accredited to EN/ISO IEC 17025. Both laboratories visited have adequate resources to meet legal requirements concerning official controls of contaminants in food. All analytical methods are accredited and properly validated. Quality control is in place and is followed with every batch of samples. Both laboratories participate in PTs with satisfactory results. However, some inconsistencies were noted regarding the reception of samples in one laboratory visited and in calculation of edible part weight of the sample, which is not in line with the requirements of Annex I part D of Regulation (EC) No 401/2006.

5.2.6 Procedures for Performance and Reporting of Control Activities

Legal requirements

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

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

Findings

The central level of the SSI has developed Guidelines for official controls of foodstuffs and FCM and for sampling. The audit team noted that they do not include any specific provisions regarding contaminants in food. Guidelines for official control contain a number of checklists for different types of facilities. However, there is no checklist for primary production for plant products. See also chapter 5.2.3.2.

Regarding the implementation of the requirements of Article 2 of Regulation (EC) No 1881/2006, there are no written instructions for the inspectors to follow when determining compliance with the maximum levels in the case of dried, diluted and compound foodstuffs.

The results of the official controls on contaminants in food are reported twice a year from the Voivodship level to the central level of the SSI. Since 2011 results for the acrylamide controls are sent electronically.

Conclusions

There are procedures in place for the performance and reporting of control activities as required by Article 8(1) of Regulation (EC) No 882/2004. However, there is no procedure in place for the official controls of primary production of plant products and assessment of contamination of dried, diluted and compound foodstuffs.

5.2.7 Cooperation between and within Competent Authorities

Legal requirements

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

There are co-operation agreements in place between the SSI and the VI at all levels of official controls; central, Voivodship and Poviat.

A cooperation agreement is in place between the SSI and the MPPSI and the Inspectorate of Commercial Quality of Agri-Food Products regarding controls of food products of plant origin

exported to the Russian Federation for human consumption. The CA provided the audit team with a copy of the agreement on this matter reached by the central levels of the Inspectorates.

The audit team noted that control plans in the context of this audit are prepared separately by the SSI and the VI, however, they both cover FAO. See also chapter 5.2.3.1.

There are two NRLs designated for each of the EURLs for heavy metals, dioxins and PCBs and mycotoxins. The audit team was not provided with any evidence of co-operation between them. The audit team noted that co-operation between the NRLs and the other SSI official laboratories is limited. There is no co-operation between the SSI laboratories and the VI laboratories. See also chapter 5.2.1.

The co-ordination between the Voivodships offices of the SSI for sampling at retail level is not in place. See also chapter 5.2.3.1.

Conclusions

There is no co-operation in place between the SSI Voivodships for the implementation of the contaminants sampling plan, which is not in line with the requirements of Article 4(5) of Regulation (EC) No 882/2004.

Regarding the planning and monitoring of food contaminants controls, there was not sufficient co-operation in place between the different CAs involved, which is not in line with the requirements of Article 4(3) of Regulation (EC) No 882/2004.

The NRLs do not work closely together which is not in line with the requirements of Article 33(5) of Regulation (EC) No 882/2004.

5.2.8 Enforcement Measures

5.2.8.1 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

The Code of Administrative proceedings provides that the legal basis for measures in cases of non compliance and procedures are in place for all the CAs to take appropriate action.

In 2011, departments of the SSI issued 34 decisions prohibiting the marketing of products containing contaminants at a level which was unacceptable from a public health viewpoint.

In the case of four RASFF notifications studied by the audit team action had been taken to prevent the sale of a contaminated product and arrangements had been put in place to withdraw, recall and destroy the products.

Conclusions

Legal and administrative bases are in place in order to allow CAs to take action in case of noncompliance as required by Article 54 of Regulation (EC) No 882/2004.

5.2.8.2 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 Union 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

There are provisions on sanctions applicable to infringements on food law which include on the spot fines, confiscation of product and closure of an establishment.

The audit team was informed that specific provisions are established in Polish law to impose sanction on infringements in relation to Article 6(2) of Regulation (EC) No 852/2004 - registration of the facilities. The level of the sanctions in such cases defined by the law is from 1000 to 5000 PLN.

The audit team was informed in Podlaskie Voivodship that there were no fines for non-compliance with registration requirements. The CAs stated that since 2008 they focused on informing the primary producers of FNAO by letters and through information campaigns.

The farm visited in Podlaskie Voivodship was registered in April 2012, therefore, the official SSI control in 2011 did not recognize non-compliance and no sanction was imposed.

In Malopolski Voivodship the audit team was informed that in 2010 four sanctions were imposed on the primary producers for non-registration with CA[11].

Conclusions

The rules and sanctions applicable to infringements of food law exist. However, they are not implemented in case of nonregistered primary producers, which is not in line with the requirements of 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

The central level of the SSI reported that an internal audit procedure has been developed. The central level audits the Voivodships and this level in turn audits the Poviats. However, no audits were carried out in the context of the contaminants in food by the central level. The audit team was informed that such audits are planned for the second semester of 2012.

11 In their response the competent authorities noted that from June 2012 till September 2012, 10 sanctions have been imposed.

In both Voivodships visited the audit team was informed by the SSI that general audits are carried out in Poviats each year according to the plan and they cover, among others, controls of contaminants in food. Audits are carried by a team of two auditors. A report with recommendations for improvement is drafted after each audit. No non-compliances concerning contaminants were reported in the last three years.

In both Voivoships visited the SSI verification procedures involved the checking of an inspection report by a supervisor. In these Voivodships, a system of on-the-spot visits has been implemented whereby inspectors are observed by the head of department. In Malopolskie Voivodship the audit team was informed, that verification is carried out on the basis of the procedure developed by SSI Poviat inspectorate in Krakow.

The VI informed the audit team, that the current audit plan does not cover the monitoring of contaminants in foodstuffs.

Conclusions

There are verification procedures and audits in place to ensure supervision on the implementation of the contaminants monitoring plan. However, audits carried out by the central level of the SSI and within the VI do not cover official controls of contaminants in food which is not in line with the requirements of Article 4(6) of regulation (EC) No 882/2004.

6 Overall Conclusions

There is an operational system in place for controls of contaminants in food controls within the scope of this audit. However, it does not cover primary production of plant products before harvesting and all contaminants/foodstuffs under Regulation (EC) No 1881/2006. The control system is facilitated by a monitoring plan covering non regulated contaminants/foodstuffs. Shortcomings in the planning and a lack of co-ordination between and within Competent Authorities weaken the effectiveness of the control system. Inconsistencies in the sampling procedures applied and a lack of adequate training and instructions on sampling and official controls of contaminants in food and deficiencies in the assessment of the HACCP plans decrease quality and consistency of official controls.

7 Closing Meeting

A closing meeting was held on 12 June 2012 with the 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 offered some comments to the findings and preliminary conclusions.

8 Recommendations

N°.	Recommendation
1.	Ensure that a CA is designated for the official controls of primary production before

N°.	Recommendation
	harvesting as required by the Article 4(1) of Regulation (EC) No 882/2004.
2.	Ensure official controls of food contaminants across the whole food chain in order to monitor the compliance with the requirements of Regulation (EC) No 1881/2006 in primary production before harvesting, as required by Article 3 of Regulation (EC) No 882/2004.
3.	Ensure that the NRL for PAH analysis is designated as required by Article 33 of Regulation (EC) No 882/2004.
4.	Ensure that the NRLs designated for contaminants in food fulfill all tasks as described in Article 33 of Regulation (EC) No 882/2004.
5.	Ensure that staff performing official controls in the area of contaminants in food, including those taking samples under the contaminants monitoring programmes receive appropriate training on contaminants in food, HACCP and sampling for contaminants, as required by Article 6 and Annex II of Regulation (EC) No 882/2004 and taking into account of Commission Regulation (EC) No 401/2006, Commission Regulation (EC) No 1882/2006, Commission Regulation (EC) No 1883/2006 and Commission Regulations (EC) No 333/2007.
6.	Ensure that staff performing official controls in the area of contaminants in food, including those taking samples under the contaminants monitoring programmes have access to adequate sampling equipment as required by Article 4 (1) (d) of Regulation (EC) No 882/2004; so they can perform their tasks efficiently and effectively as required by Article 4 (1) (c) of Regulation (EC) No 882/2004.
7.	Ensure that food contaminants sampling plans include PAH in the production of FAO as required by Article 3(2) of Regulation (EC) No 882/2004.
8.	Ensure that the frequency of the SSI official controls on contaminants in food is fully in line with Article 3(1) of Regulation (EC) No 882/2004.
9.	Ensure that official controls in the area of contaminants in food include assessment of GAP in primary production as required by Article 10(2)(d) of Regulation (EC) No 882/2004.
10.	Ensure, that the CAs correctly apply the requirements of Article 5(3) of Regulation (EC) No 852/2004 regarding the implementation of procedures based on the HACCP principles in primary production.
11.	Ensure that sampling for the official controls of mycotoxins is carried out according to

N°.	Recommendation
	the requirements laid down in Regulation (EC) No 401/2006.
12.	Ensure that official controls of food contaminants are carried out in accordance with documented procedures as required by Article 8 of Regulation (EC) No 882/2004.
13.	Ensure there is adequate co-operation between CAs and within the SSI in the context of official controls of contaminants in food as required by Articles 4(5) and (3) of Regulation (EC) No 882/2004.
14.	Ensure that rules on sanctions are implemented as required by Article 55 of Regulation (EC) No 882/2004.
15.	Ensure that audits carried out cover contaminants in food as required by Article 4(6) 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=2012-6288

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. 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
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
Dec. 2002/657/EC	OJ L 221, 17.8.2002, p. 8-36	2002/657/EC: Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results

Annex 2 - Standards and EU Recommendations 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 foodCommission 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