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Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

POLAND

FROM 15 TO 26 APRIL 2013

IN ORDER TO EVALUATE THE OFFICIAL CONTROLS ON FOOD SAFETY AND PROCESS HYGIENE CRITERIA (COMMISSION REGULATION (EC) N° 2073/2005)

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

The report describes the outcome of a Food and Veterinary Office (FVO) audit to Poland which took place from 15 to 26 April 2013. The objective of the audit was to evaluate the official controls of food safety and process hygiene criteria (Commission Regulation (EC) No 2073/2005). Competent Authorities (CA – The Veterinary Inspection (VI) and the State Sanitary Inspection (SSI)) inspectors carry out official controls according to annual risk based plans. However, in some cases the established frequency was not proportionate to the risk, since in some cases repeated non-compliances concerning food safety criteria would only result in a slight increase in the inspection frequency. The FVO audit team verified that official sampling programmes and projects were carried out according to the plans by the two CAs (the VI and the SSI).

The inspectors met who are responsible for the controls over microbiological criteria had participated in training on this topic to varying degrees.

The nine establishments visited covered various ranges of food production including ready to eat (RTE) food (red meat, poultry meat, dairy, fishery products, sushi, sprouted seeds, salads, vegetables and sandwiches) and slaughter. The inspections carried out cover all the aspects included in the annual inspection plan. Standard format reports of the inspections were available but did not cover microbiological criteria in all cases. Documents and procedures for official controls concerning control for compliance with Regulation (EC) No 2073/2005 were in place, which were, in most cases adequate concerning the VI's procedures but inadequate or absent concerning the SSI's procedures.

The official laboratory network in Poland comprises two parallel systems of official accredited laboratories (one for the VI and one for the SSI). National Reference Laboratories (NRL) have been appointed for the most relevant microbiological parameters. The NRLs had participated in proficiency rounds with largely good results and evidence of a well co-ordinated official laboratory network was present except for the organisation of proficiency tests within the remit of SSI. The methods used by the CA were accredited. Only reference methods and a few alternative methods validated against the reference methods were used. The methods used by the FBOs were in the majority of cases reference methods.

The FBOs' procedures based on Hazard Analysis Critical Control Plan (HACCP) principles were in general well implemented. However, in a few cases the product characterisation was not taken into account when the risk of Listeria (L.) monocytogenes growth was assessed and the criteria of the Regulation were not always used for verification of the HACCP programmes. Evidence of the CA's audits over the food business operators' (FBOs) own control systems and HACCP was available. However, some shortcomings were not noted by the CA. Evidence of corrective actions taken by the FBOs was available in the case of unsatisfactory results as well as enforcement action taken by the CAs. Co-ordination of information flows in terms of timely forwarding of laboratory results within the VI and the SSI and between the VI and the SSI and of enforcement actions taken was largely adequate. However, the initial response to Rapid Alert System for Feed and Food (RASFF) notifications was not timely in all cases.

The FBOs had carried out shelf-life studies for RTE products to a varying degree. Some of the shelf-life studies seen had been carried out with very low temperatures therefore not taking consumer behaviour into account.

A number of recommendations have been made to the CA with a view to addressing the deficiencies identified during this audit.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
DG(SANCO)	Health and Consumers Directorate-General
E. coli	*Escherichia coli*
EC	European Community
EU	European Union
EURL	European Union Reference laboratory
FBO(s)	Food Business Operator(s)
FVO	Food and Veterinary Office
GVI	General Veterinary Inspectorate
Hygiene Package	Set of the following Regulations: Regulations (EC) No 852/2004, No 853/2004, No 854/2004, No 882/2004
HACCP	Hazard Analysis critical control points
ISO	International Standardisation Organisation
L. monocytogenes	*Listeria monocytogenes*
MSM	Mechanically Separated Meat
NHI	National Health Institute
NRL	National Reference laboratory
NVRI	National Veterinary Research Institute
PCA	Polish Centre of Accreditation
PSES	*Poviat* Sanitary and Epidemiological Station
PVI	*Poviat* Veterinary Inspectorate
RASFF	Rapid Alert System for Feed and Food
RTE	Ready-to-eat
Sp	Subspecies
SSI	State Sanitary Inspectorate
STEC	Shiga Toxin producing *E. coli*
VI	Veterinary Inspectorate
VSES	*Voivodship* Sanitary and Epidemiological Station
VTEC	Vero Toxin producing *E. coli*
VVI	*Voivodship* Veterinary Inspectorate

1 Introduction

The audit to evaluate the official controls on food safety and process hygiene criteria (Commission Regulation (EC) No 2073/2005) in Poland formed part of the FVO's planned audit programme. It took place from 15 to 26 April 2013. It is part of a series of audits to Member States in 2011 (Denmark, Germany and Ireland), 2012 (France, Finland, Hungary, Spain, Czech Republic) and 2013 (Belgium, Cyprus, Italy, Poland). The audit team comprised two auditors from the FVO. The FVO audit team was accompanied during the whole audit by a representative of the CCA, the General Veterinary Inspectorate (GVI) of the VI or the SSI. An opening meeting was held on 15 April 2013 with the CCA. At this meeting, the objectives of, and itinerary for the audit were confirmed by the FVO audit team and the control systems were described by the authorities.

2 Objectives and Scope

The objective of the audit was to evaluate the implementation of official controls on food safety and process hygiene criteria, mainly in products of animal origin, including in addition RTE foods, pre-cut RTE fruits and vegetables, and unpasteurised fruit and vegetable juices, in the framework of Regulations (EC) No 178/2002, No 852/2004, 853/2004, 854/2004, 882/2004 and 2073/2005.

The scope of the audit covered the chain involved in the production of the above foodstuffs (from the establishment receiving the primary products to retail). Special emphasis was given to the implementation of the official controls in relation to RTE foods and to the use of shelf-life (durability) studies or other scientific based demonstration of the implementation of the *Listeria* criteria in RTE foods and the application of the criteria in the absence of such studies.

The table below lists the activities of the establishments visited and meetings held in order to achieve the objectives of the audit:

Meetings/Visits		**Number**	**Comments**
Competent authorities	Central	2	
	Regional and local	9	1 regional office and districts where the food businesses are located.
Laboratories	Reference	2	The NRL of the VI and the SSI.
	Local/Regional	1	Official laboratory within the remit of the VI.
Food business operators (FBOs)		9	1 pig slaughterhouse producing RTE meat products, minced meat, meat preparations and mechanically separated meat, 1 slaughterhouse for bovines, pigs and poultry producing RTE meat products, minced meat, meat preparations and mechanically separated meat, 1 poultry slaughterhouse producing RTE meat products, 1 establishment producing RTE meat products and meat preparations, 1 dairy establishment producing fresh and ripened cheese (semi-hard), 1 fish processing establishment producing smoked products and cooked products, 1 establishment producing sushi, 1 establishment producing RTE pre-cut vegetables and sandwiches, 1 establishment producing sprouted seeds.
FBOs own control laboratories		2	Two on-site laboratories in 1 dairy establishment, 1 establishment producing pre-cut vegetables and

Meetings/Visits	Number	Comments
		sandwiches.

3 Legal Basis

The audit was carried out under the general provisions of the legislation of the European Union (EU) and, in particular 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.

References to relevant EU legislation are given in Annex I and refer, where applicable, to the last amended version.

In addition to the standards established by the EU legislation against which the evaluation was carried out, account was taken of the relevant international standards, in particular the standards, guidelines and recommendations developed by Codex Alimentarius and the International Organisation for Standardisation (EN/ISO).

4 Background

The Hygiene Package and Regulation (EC) No 2073/2005 provide specific rules on FBO's obligations in relation to food safety and process hygiene criteria and official controls over these criteria. FVO audits to Member States on official controls in relation to food safety and process hygiene criteria have been scheduled in 2011-2013. This is the first audit round in the Member States targeted at official controls solely on this area of activity.

Several FVO audits to Poland covering different sectors of food and feed production were carried out in 2010-2012. The reports of the individual audits can be found at:

http://ec.europa.eu/food/fvo/ir_search_en.cfm

In 2012 there have been 38 RASFF notifications in relation to other Member States and third countries and from Poland in relation to microbiological hazards concerning products of Polish origin.

5 Findings And Conclusions

5.1 National Legislation/criteria and guidelines

Legal requirements

Article 291.1 of the Treaty on the functioning of the EU requires that the Member States adopt all measures of national law necessary to implement legally binding Union acts.

Article 7 of Regulation (EC) No 852/2004 stipulates that Member States shall encourage the development of national guides to good practice for hygiene and for the application of HACCP in accordance with Article 8 of the Regulation and that Community Guides should be developed in accordance with Article 9 of the Regulation. Article 8.1 of the same Regulation stipulates that national guides to good practice shall be developed and disseminated by food business sectors in

consultation with the stakeholders. The guides should have regard to relevant codes of practice of the Codex Alimentarius. The Member States shall forward the national guides to the Commission. According to Article 3.2 of Regulation (EC) No 2073/2005 guidelines for conducting shelf-life studies may be included in the guides to good practice referred to in Article 7 of Regulation (EC) No 852/2004.

Findings

VI

The following national guides and instructions for the CA have been issued for the implementation of Regulation (EC) No 2073/2005:

- Instructions to the CA have been issued on how to organise official sampling in order to verify compliance of the FBOs' implementation of Regulation (EC) No 2073/2005 and on official recognition and control of FBOs' sampling programmes to ensure compliance with the Regulation. Detailed rules are laid down for exemption from the sampling rules in the Regulation (EC) No 2073/2005 that can be granted by the CA, taking into account volume of production and other risk related risk factors.
- An instruction on the design of FBOs' sampling programmes in fishery products establishment and on the official control thereof has been issued.

SSI

The service has not produced any guide or instructions to the CA or to the FBOs on the control and implementation of Regulation (EC) No 2073/2005. However, several guides have been issued based on Article 7 of Regulation (EC) No 852/2004: guides for the milling and juice industries, bakeries, guides on margarine and spreadable fats, good hygiene practices, frozen products and good warehousing. The SSI assesses the guides that are prepared by the industry and makes recommendations on a regular basis.

With regard to *Salmonella* a national programme for poultry is in place in line with the zoonosis legislation, however, there is no national programme in place for pigs.

Observations

- Concerning the SSI, very limited instruction or guidance is available for the CA and the FBOs on how the proper implementation of Regulation (EC) No 2073/2005 should be controlled. However, industry guides are used to support the official control.

Conclusions

The Polish authorities have prepared some official instructions and guidelines covering some aspects of Regulation (EC) No 2073/2005 in particular within the remit of the VI. Nevertheless, full coverage of the interpretation of Regulation (EC) No 2073/2005 is not yet in place and, in particular, within the remit of the SSI no such instructions and guidance have been issued.

Limited evidence of detailed documents for official control concerning checking for compliance with Regulation (EC) No 2073/2005 was noted within the remit of the SSI.

Detailed rules have been adopted for the sampling exemptions for low throughput meat establishments as provided for in Regulation (EC) No 2073/2005.

5.2 COMPETENT AUTHORITIES

5.2.1 Designation of the CAs

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires that the Member States shall designate CAs responsible for the purposes and official controls set out in the Regulation.

Findings

Detailed description of the CAs can be found in the country profile for Poland which is accessible at: http://ec.europa.eu/food/fvo/country_profiles_en.cfm.

The two main responsible authorities are the VI and the SSI.

The VI, under the Ministry of Agriculture and Rural Development is responsible for all controls in the meat, dairy, fishery products and egg products sectors.

The VI is operationally divided into the GVI, 16 *Voivodship* (Regional) Veterinary Inspectorates (VVI) and 305 *Poviat* (District) Veterinary Inspectorates (PVI).

The SSI under the Ministry of Health is responsible for the controls of the implementation of Regulation (EC) No 852/2004 in all producers of food of non-animal origin and retailers facilities, excluding retail facilities, where cutting and mincing of meat is undertaken, such as butchers' shops and butchers' counters in supermarkets. These establishments are under the control of the VI.

At regional level the controls are organised in 16 *Voivodship* Sanitary and Epidemiological Stations (VSES) and at district level in 318 *Poviat* Sanitary and Epidemiological Stations (PSES).

In accordance with Article 73 of the Act of 25 August 2006 on Food Safety and Nutrition the official food control authorities as regards food containing both food products of non-animal origin and processed products of animal origin referred to in Article 1 (2) of Regulation No 853/2004 is the SSI.

Nevertheless, in accordance with the Framework agreement of 21 September 2007, concluded between the SSI and the VI, supervision over establishments producing composite products may be exercised jointly by both Inspectorates - if regulations applicable in countries of destination of products or other regulations provide for the necessity that such an establishment possesses a veterinary identification number.

The PVIs and the PSESs are in charge of the implementation of official controls in establishments.

The number of staff has remained almost constant for the last three years in both services concerned.

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

Legal Requirements

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

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a CA, more than one unit

is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units.

Findings

Co-ordination at the level of the GVI, the VVI and the PVI is generally achieved through regular meetings, exchange of e-mails and faxes between the official services concerned at different levels and a clear delineation of responsibilities in the legislation.

Co-ordination at the level of the SSI, is generally achieved by the same means.

There are cooperation agreements in place between the SSI and VI at all levels of official controls; central-, *Voivodship*- (regional) and *Poviat* (district) level.

Observations

- Reporting of laboratory results from the PVI to the VVI includes the parameters used and the result and the context (verification of compliance with Regulation (EC) No 2073/2005) in which the sample was taken. The VVI evaluates the reports from the PVI, compiles the results into a final report of the regions and forwards the compiled data to the GVI on a yearly basis.
- Concerning control results the reporting includes figures on controls on hygiene and food safety including the number of infringements without any further specifications.[1]
- Reporting to the SSI goes via the PSES to the VVES from the official laboratories and includes the reporting of sampling activities such as the parameters tested and the results, and the context in which the samples have been taken. Positive results are reported immediately by the laboratory to the PSES and the FBO and also to the VVES in order to ensure that adequate supervision of the actions can be carried out. A similar system is in place within the remit of the VI.
- In the case of positive results for food pathogens detected within the SSI monitoring programme, a procedure is in place based on the framework agreement, where the PSES informs the responsible PVI in the case of positive results including the result and the establishment of origin. If the PVI is located in another VVI the information is passed via this particular VVI. The FVO audit team was informed that this was decided in order to ensure co-ordination of the actions taken. In two cases reviewed, one where an unclear indication of shelf-life of a RTE meat product of beef was noted and another where *Salmonella* in a chicken meat preparation intended to be eaten cooked was noted, the responsible PVI was contacted by the PSE responsible for the control at retail level and timely and adequate actions were taken that were reported by the two PVIs to the PSE. In the third case, where *Salmonella was* also detected in a chicken meat preparation intended to be eaten cooked the responsible PVI and the VVI (as the establishment was located in another region) were contacted in due course. However in such a case no reporting of actions taken by the PVI is sent back. It was explained that the system foresees that the VVI will supervise that adequate actions will be taken by the PVI.
- Eight RASFF notification cases were reviewed by the FVO audit team. In these cases actions were not taken before, on average four to six days, after the notification. However, the action taken on the spot thereafter was timely and adequate (for more details see Chapter 5.2.4).

1 In their response to the draft report the CCA noted that new reporting forms for highly detailed information on the laboratory results have been designed, and their use will become compulsory in 2014.

5.2.3 Staffing provisions and facilities

Legal Requirements

Article 4 (2) of Regulation (EC) No 882/2004 requires the CA to ensure that they have access to 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 of any conflict of interest.

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

Findings

The staffing provisions were provided to the FVO audit team with detailed staff numbers. No evidence of staff shortages was noted by the FVO audit team and facilities and equipment for official use seen were appropriate.

The staff met at the different offices and premises and at the official laboratories were suitably qualified and experienced.

According to both services a few specific training courses for microbiological criteria and official microbiological control had been implemented. Nevertheless, different aspects of the controls have been included in several training courses, in particular concerning courses on official controls on HACCP implementation. In the VI, the National Veterinary Research Institute (NVRI) has organised specific training on microbiological risks in food, on microbiological criteria and on the testing methods of Regulation (EC) No 2073/2005 and on shelf-life studies, however, only for a limited number of staff. In the SSI, some limited training on the control of the implementation of Regulation (EC) No 2073/2005 was implemented in 2012. Based on the cascade principle, where officials had participated in Better Training for Safer Food on microbiological criteria, other officials were then trained in both services.

5.2.4 Enforcement requirements

Legal requirements

Article 54 of Regulation (EC) No 882/2004 requires a CA that identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation. Article 55 of Regulation (EC) No 882/2004 states that a Member State shall lay down rules on sanction applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare and shall take measures necessary to ensure that they are implemented. The sanctions provided must be effective, proportionate and dissuasive.

Findings

Cases were reviewed of non-compliances detected for the two services involved in official control.

VI

In a case reviewed in one establishment slaughtering pigs in which the FBO sampling programme for *Salmonella* was not fully implemented regularly, the FBO was requested to rectify the situation. Adequate and timely CA follow-up was carried out.

In a case reviewed in one establishment slaughtering poultry in which the FBO had not implemented the sampling for *Salmonella* of fresh poultry meat as a food safety criteria, the FBO was requested to rectify the situation. Adequate and timely CA follow-up was carried out.

In one establishment producing poultry meat preparations intended to be eaten cooked, in which the FBO had detected (before dispatch) *Salmonella* in poultry meat preparations intended to be eaten cooked, and *Salmonella* was detected in an official sample of Mechanically Separated Meat (MSM), the CA requested the FBO to destroy the products in both situations. However, it was not noted that the FBO for a period of approximately two months continued to apply the reduced sampling frequency that previously had been granted due to satisfactory results for more than 30 weeks. Moreover, the FBO was not requested to review the own-check programme taking into account the non-compliant results. Three RASFF notifications of poultry meat preparations contaminated with *Salmonella* were issued related to this establishment three to five months later. However, in respect of the latter, the actions taken by the CA and the FBO were timely and adequate, including adjustments to the HACCP programme.

Eight cases of RASSF notifications were reviewed. Actions were not taken before on average four to six days after the notification. However, the actions taken on the spot thereafter were timely and adequate.

SSI

Limited evidence of enforcement actions were noted in the three establishments visited controlled by the PSE, due to very few non-compliances detected although non-compliances were present.

Conclusions

The CAs are largely well organised. Evidence of co-ordination in line with the requirements of Articles 4(3) and (5) of Regulation (EC) No 882/2004 was noted.

The training system established by the CCA and the CAs is well developed and provides largely adequate training to staff.

The flow of information concerning laboratory results is generally adequate.

Evidence of adequate enforcement measures taken was seen by the FVO audit team. However, lack of enforcement in one case by the VI was noted and in some cases by the SSI which is not in line with Article 4 (2.a) and Article 54 (1) of Regulation (EC) No 882/2004. Moreover, the initial response to RASFF notifications was not timely in all cases.

5.3 Laboratory network

Legal requirements

Article 12 of Regulation (EC) No 882/2004 requires that the CA designates laboratories that may carry out the analyses of samples taken during official controls. Point 2 (c) of Article 4 of Regulation (EC) No 882/2004 stipulates that the CAs must ensure that they have or have access to an adequate laboratory capacity for testing.

Article 33 of Regulation (EC) No 882/2004 stipulates that the Member States shall arrange for the designation of one or more NRLs for each EU reference laboratory (EURL) referred to in Article 32. Article 33(5) of the same Regulation requires that Member States that have more than one NRL for a EURL must ensure that these laboratories work closely together, so as to ensure effective

co-ordination. The tasks of the NRLs are laid down in Article 33(2).

5.3.1 National reference laboratories

Findings

Poland has appointed a NRL for each relevant microbiological parameter. The NRL functions within the remit of the VI is managed by the National Veterinary Research Institute (NVRI) and cover *Salmonella, Campylobacter, E. coli* including Vero Toxin producing-/Shiga Toxin producing *E. coli* (VTEC/STEC), anti-microbiological resistance, *L. monocytogenes* and Coagulase Positive *Staphylococci* including *Staphylococcus aureus, Staphylococcus* enterotoxins, and also the monitoring of viruses and bacteria in bivalve molluscs.

The National Health Institute (NHI) within the remit of the SSI is NRL for products placed on the market and covers *L. monocytogenes,* Coagulase Positive *Staphylococci* including *Staphylococcus aureus, Staphylococcus* enterotoxins, *E. coli* 0157:H7, *Yersinia enterocolitica, Cronobacter.*

Thirty seven private laboratories are approved by the VI to carry out microbiological testing. Preconditions for approval are a favourable opinion by the NRL concerning facilities and testing performance and that the laboratory is accredited according to ISO 17 025. Approved laboratories can be appointed by the VI to carry out official tests. Currently no such appointments have been issued.

The NRLs for food pathogens participate in proficiency rounds organised by the EURL or another NRL.

The FVO audit team visited the NRLs of the VI and the SSI and one official regional laboratory accredited according to ISO 17 025 through the Polish Centre of Accreditation (PCA).

Observations

- The official laboratories were accredited for all parameters listed in Regulation (EC) No 2073/2005 except for the method of detection of STEC managed by the NHI. There was very limited use of alternative methods used for testing against the criteria in Regulation (EC) No 2073/2005.
- There are only three official laboratories accredited in Poland for STEC to be detected. It was explained that as necessary such samples would be forwarded to one of those laboratories or to the NRL.
- Evidence of regular meetings (on a yearly basis) between the staff of the NRLs and the official laboratories was available. Several issues concerning the testing of the parameters of Regulation (EC) No 2073/2005 have been included.
- The NVRI and the NHI visited participated in proficiency tests provided by the EURLs and tests given by providers accredited according to ISO 17 043.
- The outcome of the participation in proficiency tests by the laboratories visited was satisfactory.
- The NRLs for *E. coli* carry out method development for VTEC and STEC in co-operation with the EURL. The NHI had analytical capacity for VTEC and STEC.
- The NVRI and the NHI were all accredited to test fields according to ISO 17 025. Moreover, the NHI applied a flexible scope of accreditation, which implied a higher frequency of accreditation visits from the PCA.
- In general, there was a good flow of information from the NRLs of the VI and of the SSI to

staff concerning EURL initiatives and projects that had been communicated to the NRL by the EURL. Although the NVRI had organised a wide range of proficiency tests for its official laboratory network, limited activities were noted concerning proficiency tests for dairy products. In general, the NHI activity in this area was limited and irregular. For instance no proficiency tests had been organised in 2011 and 2012. For 2013 proficiency tests have been scheduled.

5.3.2 Laboratory accreditation and quality controls

Legal requirements

Point 2 of Article 12 of Regulation (EC) No 882/2004 requires that the designated laboratories have to be accredited in accordance with the following European standards:

(a) EN/ISO/IEC 17025 on "General requirements for the competence of testing and calibrating laboratories".

(b) EN/ISO/IEC 17011 on "General requirements for accreditation bodies accrediting conformity assessment bodies", taking into account criteria for different testing methods laid down in the feed and food law of the EU.

The accreditation and assessment of testing laboratories referred to above may relate to individual tests or groups of tests.

Findings

The official laboratory network in Poland consists of two parallel systems managed by the VI and the SSI respectively. Each of the 16 regions in Poland has its own regional laboratory including some branch divisions, one system within the framework of the VI and one system within the framework of the SSI. All laboratories are accredited according to ISO 17 025 by the PCA.

Observations

- The accreditation certificates were available for the official laboratories visited. Evidence of successful participation of the official laboratory visited in the relevant proficiency testing schemes for food pathogens was available (for example, for *Salmonella*, *L. monocytogenes* and *E. coli*). However, limited participation in proficiency tests covering dairy products was noted.

The reference methods as given in the Annex to the Regulation (EC) No 2073/2005 or alternative methods validated against the reference methods using ISO 16 140 were used.

Conclusions

The laboratory network is well organised. In relation to the distribution of EURL information and the organisation of proficiency tests, the laboratory network and NRL functions were adequate except for the function with regard to the organisation of proficiency tests by the NHI.

All methods used for official controls were accredited except for the method for STEC .

5.4 METHODS OF SAMPLING AND ANALYSIS

Legal requirements

Article 11 of Regulation (EC) No 882/2004 requires that sampling and analysis methods used in the context of official controls shall comply with relevant rules of the EU or, if such rules do not exist, with internationally recognised rules and protocols or those agreed in national legislation. In the absence of above, other methods fit for the intended purpose or developed with a scientific protocol may be used. Whenever possible, the methods of analysis should be characterised by the criteria set out in Annex III to Regulation (EC) No 882/2004.

Article 5 of Regulation (EC) No 2073/2005 stipulates that the analytical methods and sampling plans and methods laid down in Annex I to this Regulation have to be applied as reference methods.

Findings

5.4.1 Methods used for official sampling and testing

Official samples include only regulatory samples.

VI

When official sampling takes place one sample is taken initially and the FBO has the opportunity to take a contradictory sample if he so wishes. The VI informed the FVO audit team that this opportunity is used very seldom. However, in one dairy establishment visited the CA informed the FVO audit team that this opportunity was used in cases of official sampling of large quantities destined for export.

SSI

National rules are in place for the taking of official samples stating that the FBO can request the CA to take a contradictory sample, that, if negative after an initial official sample has tested positive, will require the testing of a third official confirmatory sample.

The NVRI and the PHI stated that the reference methods included in the Regulation (EC) No 2073/2005 are mainly used and only a few alternative methods validated against the reference methods using ISO 16 140 are used.

Observations

- During the official testing seen only accredited reference methods or alternative methods validated against the reference methods were used and for all official samples seen five sample units were taken.
- National legislation within the remit of the VI do not describe the FBOs right to have a contradictory sample taken during official sampling sessions. However, the VI informed the FVO audit team that such legislation is going to be adopted in future legislation.

5.4.2 Methods used in the framework of FBOs own controls

The use of alternative methods if validated against reference methods is allowed.

The two in-house FBO laboratories visited were not accredited. However, evidence was provided of successful participation in a proficiency test by a certified provider for *E. coli* and

Enterobacteriaceae for one FBO and parallel testing with an accredited laboratory for *E. coli* and *Stahpylococcus aureus* for the other one.

Observations

- Instructions on FBOs' testing and sampling in the framework of own controls were seen in the establishments controlled by the VI. In particular, the FBO sampling plans are recommended to be forwarded on a yearly basis to the PVI for recognition and eventual comments. In all establishments visited controlled by the VI, this option was used. In addition, for establishments producing fishery products a minimum sampling frequency for verification of food safety criteria has been laid down. However, in the establishments controlled by the SSI no instructions or guidelines on how to ensure compliance with Regulation (EC) No 2073/2005 were in place.
- In one establishment it could not be documented that the use of alternative methods were validated against the reference methods provided for in Regulation (EC) No 2073/2005. Nevertheless, the FBOs visited in the remaining eight establishments could document the use of only accredited laboratories for testing of samples for food safety and process hygiene criteria using exclusively accredited reference methods or methods validated against the reference methods.
- Eight FBOs producing RTE food defined as supporting the growth of *L. monocytogenes* used the "absence in 25g" criteria for *L. monocytogenes* for microbiological own control of their final products as they had data to demonstrate that the level of *L. monocytogenes* present in the RTE products would remain below the limit stipulated in Regulation (EC) No 2073/2005 during shelf-life. Only one FBO visited had data to demonstrate that the level of *L. monocytogenes* present in the RTE products would remain below the limit stipulated in Regulation (EC) No 2073/2005 during shelf-life.
- In the two slaughterhouses visited slaughtering pigs the sampling for *Enterobacteriaceae* and Aerobic Colony Count was carried out using the destructive sampling method and the swab technique was used for testing of *Salmonella*.

Conclusions

The methods used by the CA in the framework of official controls on microbiological criteria were accredited and reference methods were used in the majority of cases. The use of alternative validated methods was limited

The methods used by the FBO were in the majority of cases reference methods. However, in a few cases it could not be demonstrated that alternative methods had been validated against reference methods according to ISO 16 140 or other internationally accepted protocols.

5.5 Official controls

Legal requirements

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. Controls shall be carried out at any of the stages of the production and processing chain and, in general, are to be carried out without prior warning. Controls shall be applied with the same care to exports from the EU, imports into the EU and to products placed on the EU market.

Article 10(1) of Regulation (EC) No 882/2004 stipulates that tasks related to official controls shall, in general, be carried out using appropriate control methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis.

Point (2) (d) of Article 10 of Regulation (EC) No 882/2004 requires that official controls on food shall include, inter alia, the assessment of procedures on good manufacturing practices(GMP), good hygiene practices (GHP) and HACCP, taking into account the use of guides drawn up in accordance with EU legislation.

Article 4(2) of Regulation (EC) No 854/2004 specifies that the CA shall carry out official controls in respect of products of animal origin to verify FBO compliance with these requirements.

Point 5 (a) of Article 4 of Regulation (EC) No 854/2004 stipulates that the CA's audits of HACCP-based procedures shall determine whether the procedures guarantee, to the extent that it is possible, that products of animal origin comply with microbiological criteria laid down in the legislation of the EU. Point 8 (c) of the same Article requires the CA to take special care to take samples for laboratory analysis when necessary. The second paragraph of Point 5 of Article 4 of the same Regulation stipulates that if the FBO uses procedures set out in guides to the application of HACCP principles rather than establishing its own specific procedures, the audit should cover the correct use of these guides.

Preamble (15) of Regulation (EC) No 852/2204 states that HACCP requirements should provide sufficient flexibility to be applicable in all situations, including in small businesses. Point 4(a) of Article 5 of the said Regulation stipulates that the FBO has to provide the CA with evidence of their compliance with the implementation of procedures based on HACCP principles in a manner that the CA requires, taking account of the nature and size of the food business.

Point 1(f) of Article 5 of Regulation (EC) No 854/2004 requires that the inspection tasks of the official veterinarian in a slaughterhouse, game handling establishment and cutting plant placing fresh meat on the market, should include inspections on laboratory testing.

Point F 1 (a) of Chapter II, Section I of Annex I to Regulation (EC) No 854/2004 requires that the official veterinarian has to ensure that sampling takes place and that samples are appropriately identified and handled and sent to the appropriate laboratory within the framework of the monitoring and control of zoonosis and zoonotic agents.

Article 1 of Regulation (EC) No 2073/2005 requires that the CAs verify compliance with the rules and criteria laid down in Regulation (EC) No 2073/2005 in accordance with Regulation (EC) No 882/2004.

Findings

5.5.1 Organisation of official controls

The district authorities of both the VI and the SSI have to verify compliance of FBOs with Regulation (EC) No 2073/2005 and HACCP provisions as part of the official control.

VI

Establishments are categorised into three risk classes based on the different risk rated factors. The assessment included the type of products, product type and variety, compliance history, reliability of HACCP programmes, and production volume. The frequency can be increased by a decision of the inspector, if the risk is considered to be higher based on the compliance history and laboratory results.

SSI

For production establishments a fixed frequency of one visit per year has been established. The frequency can be increased by the local inspector based on compliance history. A draft guidance document for risk assessment of all types of establishments is due to be completed soon, which will provide for a more diversified approach for establishing the frequency taking into account the provisions of Article 3 of Regulation (EC) No 882/2004.

Observations

VI

- A distribution of the rating of risk factors was applied, which led to cases where non-compliant results with regard to food safety criteria or RASFF notifications only led to a slight increase in the audit frequency. As a consequence, in several cases the VI increased the frequency further than the system provided for.
- Procedures and check-lists for the control of Regulation (EC) No 2073/2005 were used. In general they were adequately elaborated. However, the general instruction on control of Regulation (EC) No 2073/2005 and the instruction on the design of FBOs' sampling programmes in fishery products establishment and on the official control only refer to volume of production and compliance history and does not take into account inherent risk factors such as pH and water activity of the products when assessing the sampling programme.
- The performance of the laboratory used by the FBO was not taken into account when official controls were carried out.

SSI

- Guidelines issued by the SSI are used to implement controls on own-checks. In addition, a check-list which is common for all types of establishments has to be followed, when controlling the FBOs' implementation of controls.
- The check-lists included an adequate level of detail concerning the implementation of HACCP, whereas no specific element concerning Regulation (EC) No 2073/2005 had been included. Therefore specific control measures concerning compliance with Regulation (EC) No 2073/2005 were inadequately implemented by the FBO and controlled by the CA. Moreover, in one establishment visited producing sushi, there was limited awareness by the FBO of the requirements of the Regulation. However, the available HACCP programme was implemented and documented.
- The sprouted seeds establishment visited had not been controlled from 2008 to 2011. Moreover, official sampling had only taken place in 2011 and 2013 right before the audit despite the lack of a FBO sampling programme.

Overall VI/SSI

- Shortcomings with regard to HACCP validation (three cases), shelf-life studies (five cases), trend analysis (two cases), use of non-validated methods (one case), established sampling frequencies for testing for food safety criteria decided within the framework of the HACCP programme (four), appropriate sampling programme and number of sampling units (two cases), lack of environmental sampling and testing for *L. monocytogenes* (two cases) were not noted by the CA.

Conclusions

The system of official control of the VI largely takes into account Article 3 (1) of Regulation (EC) No 882/2004 as regards applying the relevant criteria. However, the system does not ensure that the frequency in all cases is proportionate to the risk.

As regards the VI the elaborated documented control procedures in relation to Regulation (EC) No 2073/2005 were adequate.

The system of applied official control of the SSI was only partly taking into account Article 3 (1) of Regulation (EC) No 882/2004. However, a draft guidance document is due to be implemented soon taking into account Article 3 (1) of Regulation (EC) No 882/2004.

As regards the SSI the elaborated documented control procedures in relation to Regulation (EC) No 2073/2005 were inadequate to ensure that all relevant aspects of Regulation (EC) No 2073/2005 were controlled.

The system implementation of audits of HACCP based procedures in order to determine to the best extent possible that the procedures guarantee compliance with microbiological criteria in EU legislation as required by Point 5 (a) of Article 4 Regulation (EC) No 854/2004 was not adequate in all cases.

5.5.2 Official sampling and testing

VI

The sampling is based on a general instruction from the GVI.

In practice the following aspects are taken into account:

- Sampling and analysis is carried out to verify FBOs' compliance with Regulation (EC) No 2073/2005.
- Sampling and analysis is based on FBO sampling programmes already officially recognised.
- The sampling frequency should be proportionate to the risk. Moreover, it should cover up to 10% of the total number of samples taken by the FBO under the recognised programme and should be carried out during 3 sessions during the year.
- In addition zoonosis monitoring based on the zoonosis Regulation (EC) No 2160/2003 is carried out in the poultry sector.

Sampling of imported products of animal origin is risk based and based on plans from the VI.

Summary results on the microbiological sampling plans for 2012 were received and are given in the table below:

Official Microbiological Samples

Types of samples	Total number	Total positive	Salmonella positive	Listeria positive	Other microbes
Total number	57 685	2 362	469	753	1 140
Red meat and offal	4 834	49	14	13	22
Meat products	13 595	466	12	439	15
Poultry meat and offal	3 340	297	273	1	23
Poultry meat products	1 041	39	18	6	15

Types of samples	Total number	Total positive	Salmonella positive	Listeria positive	Other microbes
Fresh fish products	251	11	0	11	0
Processed fish products	1 909	94	0	72	22
Molluscs and Crustaceans	166	4	0	3	1
Raw milk	2 466	153	0	0	153
Dairy products	5 144	137	1	1	135
Honey	0	0	0	0	0
Table Eggs	193	0	0	0	0
Egg products	239	97	2	0	95
Animal fats	470	3	0	1	2
Minced meat and meat preparations	5 279	397	43	46	308
RTE products	1 933	58	0	41	17
Samples for health inspection testing	15 888	500	68	114	318
Other Foodstuffs	518	57	38	5	14
Urine, blood, fatty tissues	419	0	0	0	0

SSI

In 2012 the microbiological sampling programme of the SSI comprised 33 356 samples taken mainly from the retail level. The samples analysed were for the relevant food safety criteria or other microbiological contaminants. 3.2 % of the samples were either non-compliant with regard to food safety criteria or had an unsatisfactory result with regard to other microbiological contaminants.

A survey carried out by the SSI in 2010 and 2011 on *Campylobacter* Sp. showed a high prevalence in retail products based on fresh poultry meat of approximately 50%, whereas the prevalence in retail products based on fresh pork and beef meat was approximately 10 %.

For both services data generated from the laboratory is forwarded to the district level and the FBO and includes all the relevant details. The number of official controls executed within the framework of the Hygiene Package is reported together with the total number of non-compliances detected however, without specifying for instance, how many were caused due to non-compliance with regard to food safety and process hygiene criteria laid down in Regulation (EC) No 2073/2005.

Regarding the sampling programmes the following was noted:

VI

- The allocation of samples for the establishments is decided by the PVI based on the above mentioned instruction.
- The verification programmes are risk based and cover all processing establishments:
    - The programmes were followed in the establishments visited. The files checked in the establishments included testing in the majority of cases for the relevant food safety and process hygiene criteria. The results seen were in the majority of cases satisfactory. Evidence of adequate follow-up actions taken was available in most

cases where there were unsatisfactory results (for more details see below and under 5.2.4).

- In addition to the verification programme the CA can take extra samples when relevant.

SSI

The plans are based on the principles laid down in the MANCP. In practice the following aspects are taken into account:

- Sampling and analysis is carried out as a monitoring programme taking into account RASFF statistics, results from previous years, food consumption patterns and sensitive populations, associated risk and emerging risks.
- Basically 5.5 samples per 100 000 inhabitants have to be taken and the distribution of the number of samples is based on the above risk considerations. The number of samples of each group of foodstuffs is distributed by the SSI to each individual VSES. The VSES in turn will distribute the number of grouped samples to the PSES. The PSES will in turn distribute the number and type of samples to individual food businesses based on the group of foodstuffs, type of establishment, volume and distribution of production, assessment of hygiene conditions and compliance history.
- No official sampling activity for sprouted seeds took place in 2010. However, in 2011 and 2012 spouted seeds were sampled and tested and sampling is planned for 2013 as well.
- In case of positive results corrective actions are taken by the PSE.
- In addition, targeted samples can be taken based on official control findings.

The sampling frequency should be proportionate to the risk and should include the risk assessment provided for in the sampling plans established.

Import control of products of non animal origin is based on EU legislation in place and the SSI stated that the imports of products of non-animal origin is limited. Such products will mainly be sampled based on an ad-hoc basis (suspicion, RASFF alerts).

Conclusions

Comprehensive risk based official sampling and microbiological testing programmes for different types of foodstuffs are implemented in both the food of animal origin sector and in the food of non-animal origin sector.

The information flows are well organised within both CAs.

5.5.3 Controls over HACCP based procedures

Findings

Controls over FBOs' HACCP based procedures are carried out both by the VI and the SSI during the comprehensive inspections using dedicated check-lists which take into consideration the principles of Article 5 of Regulation (EC) No 852/2004.

Separate dedicated check-lists for each type of establishment are used by the VI for checking compliance with Regulation (EC) No 2073/2005 during the comprehensive inspection. No such check-list or guidelines are available for SSI control staff.

All establishments visited had HACCP based procedures in place. These procedures have been subject to CAs' controls with the frequency established to a minimum once per year in accordance with the instructions in place in all cases except for the sprouted seeds establishment.

Observations

The FVO audit team noted a few shortcomings not identified by the CA (in relation to hazard analysis, specification and validation of CCP, determining the frequency of sampling, verification of HACCP, taking action in the case of non-compliant test results):

General, VI/SSI

- In four of the nine establishments visited producing RTE products, the hazard analysis did not take into consideration the product characteristics in particular in relation to the ability to support the growth of *L. monocytogenes* and in three of the cases it did not identify the relevant microbiological hazards for the specific product. Similarly, the established frequency of sampling was not decided within the HACCP based procedures.
- Verification of the correct functioning of the FBOs' HACCP based procedures was carried out using microbiological testing only in three of the establishments visited.
- The procedure for action to be taken in case of non-compliant test results did not include all applicable food safety criteria in five of the nine establishments visited. Moreover, in one case such a procedure did not exist (the sprouted seeds establishment).

VI

- In one integrated slaughterhouse-meat products and meat preparations establishment validation of CCPs was not carried out.
- In the stand-alone meat preparations establishment the CA did not note that the FBO had failed to take appropriate action after a detection of *Salmonella* in a poultry meat preparation within the FBO sampling programme, and only after a series of RASFF alerts was a review of HACCP based procedures carried out and new preventive measures were put in place (see also chapter 5.2.4).

SSI

- In the sushi producing establishment the CA identified, during a control carried out one year after granting full approval to the establishment, that no HACCP based procedures were in place. Although this has been rectified to the date of the FVO audit, numerous shortcomings had not been identified by the CA: the hazard analysis did not take into consideration all relevant ingredients, the CCPs were describing products which according to the FBO were not in use and the provisions of Regulation (EC) No 2073/2005 had not been adequately integrated in the HACCP based procedures.
- In the small sprouted seeds establishment disinfection procedures were applied to the seeds prior to germination.

Conclusions

The CAs' controls over HACCP-based procedures were carried out within the planned inspection frequencies and in most cases covered the relevant parts of the programmes in line with the legal requirements. Nevertheless, some issues were not identified such as to establish the sampling

frequencies within the framework of the HACCP programme, inadequate hazard analysis in some cases, lack of verification and validation of the programmes using the criteria in Regulation (EC) No 2073/2005 and lack of a specific recall procedure in the case of non-compliant results with regard to the applicable food safety criteria.

5.5.4 Controls over FBOs' compliance with food safety criteria

Findings

Controls over FBOs' compliance with food safety criteria are carried out by the VI three times a year in all establishments under their supervision in accordance with the instruction in place. The dedicated check-lists for checking compliance with Regulation (EC) No 2073/2005 in the different types of food producing establishments cover compliance with the food safety criteria.

The SSI has no instruction available for such controls. In the reports seen very limited evidence was available that such controls were carried out.

All but one of the establishments visited had sampling plans in place for the food safety criteria. In most cases all the relevant parameters were included. The test results seen were in most cases satisfactory.

Verification sampling was carried out by the CA for the relevant food safety parameters in all establishments visited.

Observations

The FVO audit team noted some shortcomings not identified by the CA (in relation to sampling frequency, sampling units, parameters to be tested and the limit of acceptance):

VI

- In one large establishment producing RTE products (50 tonnes/week) able to support the growth of *L. monocytogenes,* the HACCP based procedures required a minimum of five samples per year. Although the number of samples taken was higher due to some unfavourable test results, two of the five product categories were not tested at all for this parameter in 2012. This had been approved by the CA supervising the establishment.
- In one of the establishments visited only one of the meat products and one of the meat preparations categories produced were tested for food safety criteria. No testing was carried out in the RTE meat products which were not subject to thermal processing. In the same establishment a limit of 10 colony forming units/g was used in the previous year for *L. monocytogenes,* although the FBO was unable to demonstrate that the product could not support the growth of the pathogen. Nevertheless, this issue was in the process of being rectified by the FBO.

SSI

- In the small sprouted seeds establishment no testing was carried out by the FBO. Only official samples were available. The FBO was sampled once in 2011 and tested for *E. coli* and in 2013 for *E. coli* and *L. monocytogenes* with a negative result. However, the FBO applied a disinfection procedure to seeds before germination (see also chapter 5.5.3).
- In one large establishment producing pre-cut vegetables, salads and sandwiches and in the sushi establishment visited, the sampling plans and the test results showed that sampling and

testing for food safety criteria was carried out once a year and only by testing one sample unit.

- In the sushi establishment, no testing was in place for Histamine although species of fish were handled that should be subject to such testing according to Regulation (EC) No 2073/2005. In the fishery products establishment visited, testing for Histamine was carried out only in one of the three product categories produced in the plant for which the criteria applies.

Conclusions

The official controls over FBOs' compliance with food safety requirements were considered to be adequate within the remit of the VI in the majority of cases and inadequate within the remit of the SSI due to lack of official control procedures on this issue.

5.5.5 Controls over FBOs' compliance with process hygiene criteria

Findings

Controls over FBOs' compliance with process hygiene criteria are carried out by the VI three times a year in all establishments under their supervision in accordance with the instruction in place. The dedicated check-list for checking compliance with Regulation (EC) No 2073/2005 covers compliance with the process hygiene criteria in the different types of establishments.

The SSI has no instruction or check-list available for such controls. In the reports seen, very limited evidence was available that such controls were carried out.

All the establishments visited had sampling plans in place for the process hygiene criteria, in most cases for all the relevant parameters. The test results seen were in most cases satisfactory.

Verification sampling was carried out by the CA for most of the relevant process hygiene parameters in all establishments visited.

Observations

The FVO audit team noted some shortcomings not identified by the CA (in relation to sampling frequency, sampling units, sampling procedure, parameters to be tested, limits of acceptance):

VI

- In the stand-alone meat preparation establishment and one of the integrated slaughterhouse-meat preparations establishments visited, the day of sampling was not alternated in order to ensure that all production days of the week were covered. In the latter establishment only one of the categories of meat preparations was tested for process hygiene criteria. In addition, the pig and beef carcasses were tested once per month per species despite CA authorising testing once every two weeks. The test results seen showed that in all cases five consecutive carcasses were sampled per sampling session.[2]

SSI

- In the pre-cut vegetables establishment and the sushi establishment, sampling and testing for

2 In their comments to the draft report the CCA stated that the DVI had requested an increase of the sampling frequency for carcasses to the correct one, to take account of all days when sampling and extend the sampling to all categories of meat preparations.

process hygiene criteria was carried out by testing only one sampling unit.

- In the sushi producing establishment no testing for Coagulase-positive *staphylococci* was carried out although shrimps were used as an ingredient. In addition, test results indicating *E. coli* less than forty/g were considered compliant in sushi samples with cooked shrimps.

Conclusions

The official controls over FBOs' compliance with the process hygiene requirements were considered to be adequate within the remit of the VI in the majority of cases and inadequate within the remit of the SSI due to lack of official control procedures on this issue.

5.5.6 Controls over sampling and testing of processing areas and equipment (especially for Listeria monocytogenes when manufacturing ready-to-eat foods)

Findings

Controls over sampling and testing of processing areas and equipment (in particular for *L monocytogenes* when manufacturing RTE foods) are carried out by the VI in accordance with the dedicated check-lists, which also cover this aspect. Such controls were not documented to have been carried out by the SSI.

The Polish translation of the Commission guidelines document for *L. monocytogenes* environmental sampling was available to the official control staff met.

Observations

VI

- All FBOs visited, had sampling programmes in place for the verification of cleaning and disinfection. Five of the six FBOs visited which produced RTE foods had sampling and testing plans in place for *L. monocytogenes* on processing areas and equipment
- The VI was also taking official environmental samples in the majority of the establishments visited, including for *L. monocytogenes* in FBOs producing RTE foods.

SSI

- The FBO producing sprouted seeds did not have a sampling programme in place for the verification of cleaning and disinfection.
- Two out of three establishments visited did not have sampling and testing plans in place for *L. monocytogenes* on processing areas and equipment but only for the verification of cleaning and disinfection.

Conclusions

The official controls over sampling and testing of processing areas and equipment including for *L. monocytogenes* when manufacturing RTE foods was adequate within the remit of the VI and inadequate within the remit of the SSI.

5.5.7 Controls over alternative sampling and testing procedures

Findings

Controls over sampling and testing procedures are included in the VI dedicated check-list for checking compliance with Regulation (EC) No 2073/2005 in the different types of establishment. No such check-list or instructions for such checks are in place for the SSI.

In most of the cases, the test results seen by the FVO audit team indicated that the methods used were the ISO methods prescribed by Regulation (EC) No 2073/2005.

Observations

- The method used for *E. coli* testing was not the reference method in the pre-cut vegetables establishment visited. No information was available to ascertain if the method used was an alternative method validated against ISO 16 140.

Conclusions

The official controls over alternative sampling and testing procedures sampling and testing procedures were adequate.

5.5.8 Controls over shelf-life studies and over analyses of trends

Findings

Controls over shelf-life studies and over analysis of trends are included in the VI dedicated check-list for checking compliance with Regulation (EC) No 2073/2005. No such requirement is mentioned in the SSI's instruction, guidelines and check-list.

Shelf-life studies are understood by the CA and the FBOs visited as tests at the end of the shelf-life. Except for the FBO producing sprouted seeds, the FBOs visited carried out tests at the end of the shelf-life. None of them had used the other options as provided for by Annex II to Regulation (EC) No 2073/2005.

Observations

- Trend analysis was carried out by the FBOs visited under VI supervision, while no such information was available in the FBOs visited which were under the supervision of the SSI.
- In five of the establishments visited, the tests seen at the end of the shelf-life did not take into consideration the conditions foreseen for storage, distribution and use of the foodstuffs as required by Article 3 of this Regulation. This aspect was not checked by the CAs.

Conclusions

The findings indicated that shelf-life studies in the majority of cases take place. Nevertheless, the temperature in some cases did not reflect common customer behaviour by applying too low a temperature for the studies. CA controls with regard to this aspect of Regulation (EC) No 2073/2005 (trend analyses and shelf-life study) were only documented in a few cases.

5.5.9 Supervision of in-house and other private laboratories used by the FBOs for microbiological analyses of foodstuffs

Findings

No rules are in place for the supervision of the private laboratories used by the FBOs for microbiological analysis of foodstuffs.

Observations

- All FBOs visited used accredited laboratories for own testing for food safety and process hygiene criteria. Two of the FBOs visited used also their own laboratory for testing for process hygiene criteria in both cases using the ISO methods.

Conclusions

The official controls applied on the use of in-house and other private laboratories were adequate. All FBOs used accredited laboratories for testing for food safety and process hygiene criteria

5.6 Labelling requirements for minced meat, meat preparations and meat products intended to be eaten cooked

Legal requirements

Article 6 of Regulation (EC) No 2073/2005 sets out labelling requirements for batches of minced meat, meat preparations and meat products of all species, intended to be eaten cooked, which fulfil the requirements for *Salmonella* as set down in Annex I. Such batches must be clearly labelled by the manufacturer in order to inform the consumer of the need for thorough cooking prior to consumption.

Findings

CA checks over compliance with the provisions of Article 6 of Regulation (EC) No 2073/2005 are not included in the check-lists for inspection at production level and were not documented to have been carried out in the establishments visited.

Observations

- The FBOs visited labelled the meat preparations as intended for thermal processing prior to consumption, in accordance with the Polish official version of Regulation (EC) No 2073/2005.

Conclusions

The labelling requirements for minced meat, meat preparations and meat products intended to be eaten cooked, as applied, were in line with the requirements of Article 6 of Regulation (EC) No 2073/2005 in the two meat processing establishments visited.

6 Overall Conclusion

The Polish authorities have implemented controls of food safety and process hygiene criteria as

required by Regulation (EC) No 2073/2005. The system of official control of the VI largely takes into account Article 3 (1) of Regulation (EC) No 882/2004 as regards applying the relevant criteria. However, the system does not ensure that the frequency in all cases is proportionate to the risk. As regards the SSI the provision of Article 3 of Regulation (EC) No 882/2004 is not yet fully implemented.

Enforcement actions were in the majority of cases adequate within the remit of the VI. However examples of inadequate enforcement were noted within the remit of the SSI due to lack of detection of some shortcomings. The controls were in most cases adequately documented.

The official laboratory network was largely well co-ordinated by the NRLs. However, the organisation of proficiency tests within the remit of the NHI was limited.

The FBOs visited used the tools stipulated in Regulation (EC) No 2073/2005 to establish the shelf-life of the products only to varying degrees. The FBOs' procedures based on HACCP principles were in general well implemented. However, adequate validation of the programmes were only implemented in a limited number of cases. Shortcomings were noted in relation to audits over the HACCP-based principles and over the implementation of this Regulation.

7 Closing Meeting

A closing meeting was held on 26 April 2013 with representatives of the CCA. At this meeting, the FVO audit team presented the main findings and preliminary conclusions of the audit. The authorities clarified some of the issues raised during the presentation and provided documentation of actions already taken in relation to some of the issues that referred to the specific findings in the establishments visited.

8 Recommendations

The competent authorities 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 this specific audit report.

N°.	Recommendation
1.	To further develop national official interpretations of the requirements of Regulation (EC) No 2073/2005.
2.	To further develop appropriate documented procedures for official controls of Regulation (EC) No 2073/2005 as required by Article 8 (1) of Regulation (EC) No 882/2004 in particular within the remit of the State Sanitary Inspectorate, in order to ensure that all relevant aspects of Regulation (EC) No 2073/2005 are controlled.
3.	To ensure that efficient actions are taken in all cases when official samples are non-compliant with regard to food safety criteria as required by Article 54 of Regulation (EC) No 882/2004.

N°.	Recommendation
4.	To ensure appropriate co-ordination by the National Reference Laboratories of the participation of official laboratories in relevant proficiency tests as required by Article 33 of Regulation (EC) No 882/2005.
5.	To ensure that the system of official controls for both services is organised in a way that ensure that the applied frequency is appropriate in all cases taking into account the relevant risk criteria as required by Article 3 (1) of Regulation (EC) No 882/2004.
6.	To ensure that the systems of audits of Hazard Analysis Critical Control Point procedures verify compliance with microbiological criteria as required by Article 4.5 (a) of Regulation (EC) No 854/2004 in all cases.
7.	To ensure that reasonably foreseeable storage conditions are taken into account when shelf-life studies are carried out as required by Annex II to Regulation (EC) No 2073/2005 and compliance with the labelling requirements laid down in Article 6 of Regulation (EC) No 2073/2005.

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=2013-6870

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. 2160/2003	OJ L 325, 12.12.2003, p. 1-15	Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents
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. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
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. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs