EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

Ares(2013)3543888

DG(SANCO) 2013-6878 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

FINLAND

FROM 10 TO 20 JUNE 2013

IN ORDER TO EVALUATE THE FOLLOW-UP ACTION TAKEN BY THE COMPETENT AUTHORITIES WITH REGARD TO OFFICIAL CONTROLS RELATED TO THE SAFETY OF FOOD OF ANIMAL ORIGIN, IN PARTICULAR MEAT, MILK AND THEIR PRODUCTS

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 an audit carried out by the Food and Veterinary Office (FVO) in Finland from 10 to 20 June 2013. The main objective of the audit was to evaluate the official controls related to production and storage of food of animal origin and the follow-up action taken by the competent authorities (CAs) with regard to official controls related to the safety of food of animal origin, in particular meat, milk and their products.

The Finnish Central Competent Authority (CCA), the Finnish Food Safety Authority (Evira) provided satisfactory guarantees in response to all the recommendations in the report DG(SANCO)/2009-8229. Since 1 September 2011 the Evira has been directly responsible for the official control of all plants attached to slaughterhouses (SH)s and taking over the official controls of low-throughput SHs. The Municipal Food Control Authorities (MFCA)s are now only responsible for the control of independent meat plants and for the control in the dairy sector.

In general the co-ordination between the Evira and regional and local authorities was adequate apart from the coordination of the official controls of the low-throughput SHs. Several national measures for small establishments have been put in place in line with Article 10 of Regulation (EC) No 853/2004 and notified to the Commission.

A risk based approach in line with Article 3 of Regulation (EC) No 882/2004 was taken by the Evira and implemented by the MFCAs. However, the system does not ensure that the frequency in all cases is proportionate to the risk. The flow of information from local levels to the Evira level regarding certain types of non-compliances in relation to the Hygiene Package detected and outcome of official sampling did not include relevant details about non-compliances.

Enforcement was not adequate either within the remit of the Evira or within the remit of the MFCA due to the fact that some deficiencies were not noted by the CA or in several cases, although results of non-compliances were registered, deadlines were either not set or not adhered to. Consequently the necessary follow-up actions were not always taken to verify the rectification of the non-compliances detected. The Evira has established an auditing system and, in addition, some limited internal auditing takes place in the milk sector by the RSAAs. Nevertheless, the system cannot be considered as adequate.

Five of the eight establishments visited were generally considered to meet the general and specific hygiene requirements in Annex III to Regulation (EC) No 853/2004 with shortcomings identified in two low-throughput slaughterhouses and a stand-alone meat processing plant. The microbiological sampling in relation to the requirements of Regulation (EC) No 2073/2005 was organised in line with the requirements with some shortcomings noted. HACCP based systems were in place in all the establishments visited. Nevertheless, they were only fully adequate in six of the establishments visited. Traceability, identification marking and labelling were in general satisfactory except for labelling of Mechanically Separated Meat (MSM), which was not labelled as such and in relation to animal by-products. The ante-mortem inspections were not carried out in compliance with EU requirements, as sometimes official auxiliaries carried out this task. Areas such as post-mortem inspections, identification marking, traceability, food chain information, animal welfare controls in slaughterhouses and of raw milk upon collection were in compliance with Community requirements and satisfactorily controlled by the CA.

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

Table of Contents

Abbreviations and definitions used in this report

Abbreviation	Explanation
ABP	Animal By-Product
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
CCP(s)	Critical Control Point(s)
CP	Cutting Plant(s)
DG(SANCO)	Health & Consumers Directorate General
EC	European Commission
EU	European Union
FBO(s)	Food Business Operator(s)
FCI	Food Chain Information
FTE	Full time equivalent
FVO	Food and Veterinary Office
GHE	Game Handling Establishment
HACCP	Hazard Analysis of Critical Control Points
Hygiene Package	Regulations (EC) No 852/2004, No 853/2004 and No 854/2004
ISO	International standard Organisation
L. monotygenes	*Listeria monocytogenes*
MANCP	Multi-Annual National Control Plan
MFCA	Municipal Food Control Authority(ies)
MP	Meat Processing Plant(s)
MSM	Mechanically Separated Meat
NRL	National Reference Laboratory
OV	Official Veterinarian
RSAA	Regional State Administrative Agency(ies)
SCC	Somatic Cell Count
SH	Slaughterhouse(s)
TBC	Total Bacterial Count (Plate count at 30 °C)

1 Introduction

The audit took place in Finland from 10 to 20 June 2013 as part of the planned audit programme of the FVO. The FVO audit team comprised two auditors from the FVO.

The FVO audit team was accompanied throughout the audit by representatives from the Central Competent Authority (CCA), the Finnish Food Safety Authority (Evira).

The opening meeting was held on 10 June 2013 with the CCA in Helsinki. At this meeting the FVO audit team confirmed the objectives of, and itinerary for the audit, and additional information required for the satisfactory completion of the audit was requested.

2 Objectives

The main objective of the audit was to evaluate the official controls related to production and storage of food of animal origin and the follow-up action taken by the competent authorities (CAs) in response to the recommendations made in report DG(SANCO)/2009-8229 – MR Final with regard to:

- CA organisation and operation;
- official controls over food business operators' (FBOs') compliance with general and specific rules on the hygiene of food of animal origin.

In particular, controls over meat of domestic ungulates, farmed game, wild game, minced meat, meat preparations, mechanically separated meat, meat products, raw milk and dairy products in the framework of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 were subject to this evaluation.

In pursuit of these objectives, the audit itinerary included the following meetings and visits:

Table 1

COMPETENT AUTHORITIES			**Comments**
Competent authorities	Central	2	Opening and closing meeting
	Regional	2	The Regional State Administrative Agency of Western and Inner Finland
	Local	4	The Municipal Food Control Authorities (MFCAs) of Tampere and Sastamala and local authorities during on-the-spot visits.
FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES			
Slaughterhouses		3	1 full-throughput, 2 low-throughput
Cutting premises		4	3 co-located
Minced meat / meat preparation establishments		4	3 co-located
Mechanical Separated Meat		1	1 co-located

Meat products establishments	3	2 co-located
Game handling establishments	2	Establishments with other activities
Cold stores	1	
Laboratories	1	The National Reference Laboratory for *Trichinella* examination
Milk processing plants	3	1 large, 1 medium-sized, 1 small
Dairy holdings	1	Milking cows

3 Legal Basis

The audit was carried out under the general provisions of EU legislation and, in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

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

4 Background

The previous audit concerning the safety of food of animal origin in Finland was carried out from 8 to 18 September 2009, the results of which are described in report DG(SANCO)/2009-8229. This report is accessible at:

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

The action plan received from the Finnish authorities provided satisfactory guarantees in response to all of the report's recommendations.

5 Findings And Conclusions

5.1 Competent Authorities

5.1.1 Designation of Competent Authorities

The Evira, under the Ministry of Agriculture and Forestry (MAF), is the CCA for controls on meat and milk. In addition, the Evira is since 1 September 2011 directly responsible for the official control of all full-throughput as well of low-throughput slaughterhouses (SH - less than 1 000 units per year) and for all attached plants. The meat inspection is carried out by the staff of the Evira Meat Inspection Unit. The Evira Meat Inspection Unit is internally divided into five groups according to geographic areas, so-called regional units.

Seven Regional State Administrative Agencies (RSAA) in Finland have since 1 January 2010 been responsible for coordination and supervision of the Municipal Food Control Authorities (MFCAs). In addition, they carry out training of staff in the MFCAs in the respective regions. The RSAAs are responsible for the official control of reindeer SH (including attached CP and MP). The FVO audit team visited the RSAA of Western and inner Finland and met a representative of the RSAA of Northern Finland.

Finland is divided into Municipalities with either individually or joint MFCAs. The MFCAs are responsible for official control of independent CPs and MPs and for the official control of raw milk and milk processing establishments within their respective geographic areas. The FVO audit team visited two MFCA offices.

Observations

- Based on the Veterinary Act of November 2009 the authorities are obliged to describe how the resources can ensure that controls will be established with regard to animal health and animal welfare. Through this background performance agreements between the Evira and the RSAAs are drawn up including assessments of how resources are needed to ensure the implementation of the MFCA control plan taking into account the risk points.

- In line with the Veterinary Act, the Finnish State pays for official controls from the MFCAs on animal health and animal welfare. In this way 42 full time equivalent (FTE) posts at the level of the MFCAs as control veterinarians are in operation. Through these posts 9 FTE is spent on food control and meat inspection. The majority of food control tests are undertaken by other officials of the MFCA.

- According to the Act of 15 June 2009 on cooperation within the Environmental and Health sectors, the MFCA are required to have at least 10 FTEs as of first January 2013. By the end of 2011 the number of MFCA was reduced to 88 and is expected to be 63 at the end of 2013.

- The two MFCAs visited had already merged to ensure a level of more than 10 FTEs.

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the CAs responsible for the purposes and official controls set out in the Regulation. It also lays down operational criteria for the CAs.

Audit findings

5.1.2 Co-operation and co-ordination 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 the Regulation 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.

Audit findings

The Evira annually negotiates service level contracts with each RSAA for official controls including the meat and milk sector. The performance agreements between the Evira and the RSAAs specifies the human resources used by the RSAAs for the tasks in the Evira's sector of activity (food control and supervision of animal health and welfare). On the other hand, the Evira does not have the legal power to order the MFCAs to carry out specific official tasks.

Each MFCA draws up and implements an annual control plan based on the National Food Control Plan. According to Food Act, the RSAA is responsible for evaluating the control plan and for

checking its implementation by the MFCAs. The RSAA has no authority over the MFCAs and can only issue recommendations on improvements to the plan and its implementation. However, the RSSA has power to take actions against non-compliant FBOs.

Similarly, Evira, RSSA, the RSAA employed officials performing reindeer meat inspection and the Evira employed Official Veterinarians (OV) in SHs are also obliged to draw up and implement an annual control plan.

The Food Act provides that the Evira only can take action at MFCA level in cases where the issue concerns more than one municipality and where the MFCA has not taken sufficient action to prevent a health hazard. Moreover, actions can be taken against FBOs if it is considered that actions taken by the MFCA are considered as inadequate. Such actions have not been taken since 2008.

A new information system KUTI is implemented in stages. KUTI 1a allows monitoring of FBOs' and establishments. This part is used by more than 90% of the MFCUs. KUTI 2a allows monitoring the control data of approved establishments and notified premises (KUTI 2a enables monitoring e.g. specific data on inspections, non-compliances identified as well as administrative enforcement measures used). This part is used by 10% of the Units. However, this system will be fully implemented during 2014. By KUTI 3 Evira has been able to make reports from KUTI since 2012. The Evira's control data is added to KUTI in 2013-14 (includes also the control measures performed by the Evira). An official samples section KUTI 2b is planned to start 2013. Until now MFCAs not using KUTI are using the old so-called ELTU system for reporting control data to the Evira.

Observations

- The RSAA visited organised working meetings and training for MFCA officials. Certain issues to be covered during these meetings were defined in the service contracts with the Evira.
- The Food Hygiene Unit and the Meat Inspection unit belonging to the Evira's Control Department draw up the food control plan (EVO, *elintarvikevalvontaohjelma*) for the municipalities.
- The RSAA visited had three offices in different locations and the responsibilities for official tasks were divided between the regional state officers.
- According to the revised guideline of 2012 for the RSAAs on the review of the municipal food control, the RSAA has to verify if the relevant points of the national food control plan have been included in the control plan of the MFCA, and how this has been implemented based on a desk-based evaluation. In addition audits are carried out.
- The control plans in both MFCAs visited were evaluated by the RSAAs each year, which includes establishments review as well.
- The organisation of the official control varied between the two low-throughput SHs visited. In one of the SHs an Evira official was responsible for audits according to Article 4 of Regulation (EC) No 854/2004 and for meat inspection. In the other SH visited an Evira official was responsible for the Article 4 audits and a contracted Evira official was in charge of the meat inspection. Nevertheless, due to the lack of implicit instructions a gap and a lack of coordination of official control was noted in both establishments visited e.g. official controls in line with Article 4 of Regulation (EC) No 854/2004 were inadequate (incomplete

checks of general and specific hygiene requirements). Moreover, contracted staff was not informed by Evira about outcomes of inspections.

- In the MFCAs visited it was noted that reporting to the Evira of outcome of official controls and official microbiological sampling showed a lack of relevant details, such as specific information about the nature of non-compliances detected and the results of the microbiological sampling from locally designed projects, which could be used for the future organisation and development of the official control. No data was available as regards reporting from the SHs and meat establishments of control results to Evira. The Evira explained that the implementation of KUTI 2b will rectify this issue.
- In the dairy sector a reporting system was in place, where the MFCAs reported annually outcomes of official controls including specification of non-compliances detected for official controls and for official sampling which is used for supervisory purposes.

5.1.3 Registration/approval of Food Business establishments

Legal requirements

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration/approval of food and feed business establishments, for reviewing compliance with conditions of approval and for the withdrawal of approvals.

Audit findings

All establishments in the meat and dairy sector have been re-approved as required by the Food Act since the previous audit.

National measures and derogations have been adopted with effect from 1 January 2012 by Decree 1369/2011:

Allowing waiting pens instead of lairage areas in low-throughput SHs (including reindeer SHs); no requirement for a separate lockable detention chiller in low-throughput SHs (including reindeer SHs); cutting in a non-separate cutting place under temperature control; de-skinning of wild bears and seals before entering the Game Handling Establishments (GHEs); a separate located facility for cleaning and disinfection of transport vehicles of animals.

In addition a risk based approach is applied for: separation in time of different processes with different levels of associated risks; location of changing facilities and toilets for workers in a different building; conditions for surface materials; common chillers for carcasses and offals; production in the same facility of cut meat, minced meat and meat preparations under certain conditions. Food Chain Information (FCI), for slaughter animals originating from the farm where a low throughput SH is located may be kept in the animal shed where ante-mortem inspection takes place.

From 1 September 2013 meat inspection of wild game must be carried out in GHE only and not in premises approved by the MFCAs for handling of wild game as previously allowed. However, hunters direct sale to the final consumer and to retail of small amounts of wild game is exempted. Nevertheless, all *Trichinella* suspect species have to be examined before being handed over to the final consumer.[1]

1 In their response to the draft report the CCA noted that since 1 September 2011, when the amended Food Act came into force it has been possible for a hunter to sell un-inspected wild game of birds, rabbits, hares and cervids also to retail.

No specific derogations have been granted to the dairy sector.

With regard to establishment approvals, the FBOs own-check programmes do not need a formal approval any longer, only an official recognition.

Observations

- In the two low-throughput SHs visited, the FBOs were in practice availing of several of the above derogations. Nevertheless, neither the FBO nor the OV were aware of this, creating confusion for the CA about the establishments' compliance with the different requirements of the general and specific hygiene requirements as laid down in Regulation (EC) No 852/2004 and 853/2004.
- The two low-throughput SHs visited were approved without fulfilling all infrastructure requirements (more details in Chapter 5.2.1). Moreover, in one of the establishments activities were carried out for which the establishment was not approved for.
- A review of the compliance of low-throughput SHs with the approval conditions is being carried out by Evira. Nevertheless, in one of the low-throughput SHs visited, the review had not detected the non-compliances with regard to infrastructural requirements.
- In one full-throughput SH visited, the approval did not specify for which animal species the SH was approved for (this was only specified in the application from the FBO). Moreover, in a small dairy establishment visited it was not mentioned in the approval document that the processing of fresh cheese was based on raw milk.[2]

5.1.4 Prioritisation of 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 product placed on the EU market.

Audit findings

Risk based criteria has been described in the National Food Control Programme. A fixed frequency has been established based on criteria such as type and volume of production and their associated risks, production facilities and hygiene of production. The frequency can be reduced or increased by up to 50% based on the reliability of own-check programmes of the establishments and the FBOs' past records.

Observations

- A risk assessment, in order to establish the inspection frequency, was carried out in all Evira and MFCAs controlled establishments visited. In the two MFCAs visited the systems were

2 In their response to the draft report the CCA noted that, where approval was granted a number of years ago, the original approval documents cannot be changed. However, the publically available list of approved establishments contains all the necessary data (including the animal species for which a slaughterhouse is approved). They further state that more recent approval documents contain all the necessary data.

inconsistently applied. The weighting of the risk based criteria was organised differently. In addition, in both establishments very little emphasis was put on the reliability of own-check programmes of the establishments and the FBOs' past records and consequently the risks associated with those factors would have very little impact on the established inspection frequency. An example was provided from a third MFCA which confirmed this finding.

- The established frequencies in the establishments visited were deemed to be appropriate in light of the objectives to be achieved. No examples were seen of the established frequency increasing or decreasing. Nevertheless, in one case reviewed of a MP controlled by the MFCA, despite the fact that the FBOs Hazard Analysis Critical Control Points (HACCP) programme was considered to be inadequate for a long period (one and a half years), this had not caused an increase in the established inspection frequency.[3]

- The established inspection frequency was followed in most cases. Only in a few cases seen was it lower due to a lack of staff resources within the MFCA.

5.1.5 Official sampling and laboratory analysis

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires CAs to have, or to have access to, adequate laboratory capacity. Article 11 of the Regulation establishes requirements for sampling and analysis and Article 12 requires the CA to designate laboratories that may carry out analysis of samples taken during official controls. It also lays down accreditation criteria for the laboratories so designated.

Audit findings

The Evira's laboratory is designated as National Reference Laboratory (NRL) for the relevant tests to be carried out. Forty-six laboratories for official control samples (including eleven laboratories carrying out T*richinellea* examinations*)* and six laboratories analysing own- check samples have been approved by the Evira according to the Food Act. All laboratories examining official samples have been accredited to ISO 17 025 apart from six *Trichinella* laboratories located in SHs.

The Evira has registered all methods accredited, ring-test participation and the organisation responsible for organising the ring-tests in order to monitor the approved laboratories. Annual data gathering will continue and the laboratories are guided in the choice of proficiency tests rounds.

In the Evira, an electronic data collection system (patogenix) is used where all laboratories have to feed in all relevant information in relation to *Salmonella,* EHEC bacteria, *Campylobacter, Listeria* and pathogenic Y*ersinia* examinations at least once per year by the end of March.

According to the CCA, there are currently 17 laboratories carrying out *Trichinella* examinations in the country of which 11 are accredited and the others are pursuing accreditation. The non-accredited laboratories are subject to a regular evaluation by the Evira. In addition, ring tests are organised by the NRL (the Evira's laboratory in Oulu). Successful results in the ring tests are needed to maintain the approval. Only accredited laboratories will be approved from 1 January

3 In their response to the draft report the CCA noted that different MFCAs apply different formulae when calculating a risk based frequency for controls. In some cases, other activities such as maintenance, cleaning, hygiene and sampling results are included under own-checks in addition to the evaluation of the HACCP programme. This would change the weighting in the risk assessment calculation.

2014. Evidence of successful participation of the laboratory network was provided. In case of unsatisfactory results the laboratory is offered training at the NRL. The activities of one laboratory failing the proficiency test was suspended until the laboratory participates in such training and demonstrates to be able to produce reliable results.

5.1.6 Procedures for performance 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.

Audit findings

Documented procedures and report forms are available for all staff performing official control of MP, SHs and milk processing establishments. Special report forms for follow-up of non-compliances are available.

Observations

- Reports drawn up for official controls and copies were available in all establishments visited. Requests for corrective actions to be taken were not always specified in the reports concerning those issued by the Evira and by the MFCAs. Reports were signed by the competent authorities and the FBO.
- The purpose and the method of control were indicated. Some examples of the lack of established deadlines were noted.
- Some verbal requests for corrective action were also noted

5.1.7 Enforcement measures

Legal requirements

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

Audit findings

Chapter 7 of the Food Act includes the enforcement measures of Article 54 of Regulation (EC) No 882/2004. The administrative procedures to be followed are laid down in the Administrative Procedures Act (434/2003). The Evira has given a guide on how to use administrative coercive measures according to the Food Act (100011/2). Three model documents have been adopted concerning decisions, FBO hearing and an internal code of conduct.

A model document 10110/2 is available for decision making when using administrative coercive measures.

The further development of the KUTI database will enable enforcement data and audit data to be available for follow–up by the Evira and RSAAs.

The MFCAs use of enforcement measures are covered by the RSAAs' audits of the MFCAs.

Observations

- Non-compliances detected that required corrective action were reviewed by the FVO audit team. In some cases, deadlines were not set, neither at the MFCA nor at OV (Evira) level. Generally, only some follow-up actions were taken on the basis of non-compliances detected and the deadlines established were not always adhered to.
- In two establishments controlled by the MFCAs (large dairy and a MP) despite deadlines set for some deficiencies noted, no follow-up was taken and therefore no sanctions imposed.
- In one low-throughput SH with attached CP and MP despite deficiencies detected, no deadlines for corrective measures were established and consequently no follow-up action was taken and no sanctions had been imposed.
- In one of the MFCAs visited, it was verified through a documentary review that a MP controlled by the MFCA, deadlines were not adhered to, despite the fact that the FBOs HACCP programme was considered to be inadequate for a long period (one and a half years), and consequently no follow-up action was taken and no sanctions had been imposed (for more details see chapter 5.2.2).

5.1.8 Verification and review of official controls and procedures

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. Under Article 4 of the Regulation CAs are required to carry out internal audits or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Audit findings

Control and verification procedures and the Evira guidelines are available at the Evira web-site for all control personnel.

The Evira has laid down an Audit Strategy for 2011-15, established by the Evira's Audit Coordinating Group, which sets the priorities for the audits. Evira audits its own control activities and RSAAs audit the MFCAs. Specific guidelines are issued for the audits carried out by the RSAA.

General Audit guidelines and an Auditors' Manual have been drafted and training of auditors has been carried out. The Auditors' Manual describes how effectiveness should be evaluated by a comparison of the annual audit report with the strategic objectives. It also includes guidance on how to carry out audits and the evaluation.

In 2014 it is foreseen to change the audit approach from isolated thematic audits to fewer types of audits (two comprehensive audits covering the whole food chain for some well-defined topics). In addition, the auditor should carry out audits in sectors different from where they have their primary

official control responsibility.

Observations

- So far audits are the main tool used for verification of the effectiveness of official controls:
    - The Evira is carrying out an audit of the application of approval conditions of the low-throughput SHs including also associated meat cutting and processing activities as appropriate by a review exercise which has not been completed yet (for more details see Chapter 5.1.3).
    - During 2010-11 an audit was carried out on the performance of OVs in all full-throughput SHs. In addition, an audit has been carried out of the RSSAs control of reindeer slaughter.
    - For 2013 a risk based audit including the control of associated cutting and processing activities have been organised covering five full through-put SHs and three low-throughput SHs.
    - In the guideline for RSAAs of the review of the official controls of the MFCAs it is stated that evaluation shall take place based on a review and a comparison of documented control results based on the control plan and the yearly control report carried out as a desk-based exercise and two audits on-the-spot.
    - The RSAA audits of the official controls in the milk and meat sectors are agreed between the Evira and the RSAA. Results of the previous audits of the MFCAs are not taken into account when planning such audits.
    - The RSAA audit of two MFCAs was verified by the FVO audit team and was carried out according to the audit guideline.
    - Generally, the RSAAs are required to audit the MFCA at least every three years. This was confirmed for the RSAA concerned during this audit. Nevertheless**,** although the target is that the RSAA should audit each MFCA every three years only 12 to 16% have been audited during the last years. However, with the continuing reduction in MFCA number the target will be met later.
    - Only a few examples were seen of verifications by the RSAAs of effectiveness of official controls in the framework of the review of the official controls of the MFCAs based on their control plans.
    - Despite the extensive availability of guidelines, instructions and checklists and the fact that some audit activities were carried out in particular within the remit of the Evira, the FVO audit team found some non-compliances, with regard to specific Community requirements (structure, maintenance, and hygiene of operations, own-check controls, water testing, controls for microbiological contamination, validation of critical control points (CCP)) that were not detected by the CA.

Conclusions on Competent Authorities

The Evira has, since 1 September 2011, been directly responsible for the official control of all types of SHs and connected plants and the MFCAs are responsible for control of independent meat plants and for the control in the dairy sector in line with the requirements of Article 4 (1) of Regulation (EC) No 882/2004.

The coordination and cooperation between the CA at the Evira and the regional level and between the RSAAs and the MFCAs is in general adequate.

The coordination within the Evira was satisfactory as regards the controls in the part of the meat sector that has been under its responsibility so far, but inadequate as regards the official controls of the low-throughput SHs for which the responsibilities of the official controls have been taken over from the MFCAs, despite the introduction of a new regionalised system for organisation of the controls. This is mainly due to the lack of specific guidance and instruction on the organisation controls of such establishments, which is contrary to the requirements of Article 4 (5) of Regulation (EC) No 882/2004.

Several national measures have been put in place in line with Article 10 of Regulation (EC) No 853/2004 and notified to the Commission. From 1 September 2013 meat inspection of wild game must be carried out in GHE only and not in dedicated MFCA approved premises as previously allowed. However, hunters direct sale to the final consumer of small amounts of wild game is exempted.[4]

According to the CCA, all establishments have been re-approved in line with Article 31 of Regulation (EC) No 882/2004as required by the Food Act. Nevertheless, in the meat sector, full compliance with Article 31 (2)(c+d) of Regulation (EC) No 882/2004 was not ensured, as establishments were approved without fulfilling all relevant requirements of the Food Law or approvals did not specify all activities that was carried out.

A risk based approach in line with Article 3 of Regulation (EC) No 882/2004 was taken by the Evira and implemented by the MFCAs establishing the control frequency of independent meat plants and milk processing establishments. However, the system does not ensure that the frequency in all cases is proportionate to the risk.

The lack of information at the Evira level about certain types of non-compliances in relation to the Hygiene Package detected at local level limits the possibility of making a proper risk assessment as required by Article 3 (1) of Regulation (EC) No 882/2004.

Documented procedures and inspection forms are in place for the majority of the controls to be carried out in the milk and meat sectors, which were adhered to in line with Article 8 of Regulation (EC) No 882/2004.

All laboratories (apart from some *Trichinella* laboratories) for official controls in the meat and milk sectors are designated and approved by the Evira and accredited according to ISO 17025 as required by Article 12 of Regulation (EC) No 882/2004.

In several cases, although results of non-compliances were registered during the official control , deadlines were either not set or not adhered to. The necessary follow-up actions were not always taken to verify the rectification of the non-compliances detected, which resulted in some cases that detected problems remained for long periods of time without any proper action taken by the CA contrary to the requirements of Article 54 of Regulation (EC) No 882/2004.

Despite extensive availability of guidelines and instructions some non-compliances were detected by the FVO audit team that were not detected or not reacted upon or followed-up in a consistent manner by the CA contrary to the requirements of Articles 4 and 8 of Regulation (EC) No 882/2004.

Evira has established an auditing system and internal audits are carried out by the Evira in the meat sector and is in the process of further development. In addition, some limited internal auditing takes

4 In their response to the draft report the CCA noted that in addition to retail, it is allowed to deliver small amounts of un-inspected wild game meat of birds, rabbits, hares and cervids. Hunters sale of un-inspected wild game meat is allowed according to Article 1 (3.e) of Regulation (EC) No 853/2004. Small amounts of game meat can also be inspected in reindeer SHs, which are approved for slaughtering of wild game.

place in the milk sector by the RSAAs. Nevertheless, the requirements of Article 4 (6) of Regulation (EC) No 882/2004 cannot be considered to be fully implemented.

5.2 Official controls over food Business Operators' compliance with hygiene rules at establishment level

5.2.1 General and specific hygiene requirements

Legal requirements

Article 4(2) of Regulation (EC) No 852/2004 establish that the FBO carrying out any stage of production, processing and distribution of food after the stage of primary production/associated operations shall comply with general hygiene requirements as set out in Annex II to Regulation (EC) No 852/2004. These provisions relate to cleaning and maintenance, layout, design, construction, siting and size of food premises.

Article 3 of Regulation (EC) No 853/2004 sets out that the FBO shall comply with the specific requirements of Annexes II and III to this Regulation. Article 4(3) of Regulation (EC) No 852/2004 states that FBOs shall adopt specific hygiene measures regarding compliance with microbiological criteria for foodstuffs, compliance with temperature control requirements and sampling and analyses.

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 the FBO's compliance with these requirements.

Audit findings

A specific guideline has been issued on this topic (16001/1).

Observations

- Compliance with the general hygiene requirements varied between the establishments visited. Generally, the three dairy establishments visited were of an acceptable standard.

- Despite actions in response to recommendation Nos 2 and 3 of report DG(SANCO)/2009-8229 regarding measures to ensure that deficiencies with regard to general and specific hygiene requirements had been identified by the CA and corrective actions taken, and the first element of recommendation No 4 regarding ensuring FBOs compliance with good hygiene practices being considered satisfactory, the following non-compliances were noted by the FVO audit team, however, the majority of them were not noted by the CA:

    - In a full-throughput SH visited major deficiencies were noted regarding cleanliness and housekeeping in a storage room for spices and many spices had passed best before dates. The microbiological quality for ice used for cooling purposes of products was not verified.

    - In one low-throughput SH with attached CP and MP no major deficiencies were noted. However, in a second low-throughput SH visited with attached CP and MP significant deficiencies were noted as regards cleanliness and housekeeping of changing rooms, neglected maintenance, unhygienic storage of knives and inadequate cleanliness of equipment. The date on many spices to be used as

ingredients had expired. The microbiological quality for ice used for cooling purposes of products was not verified.

- In a small stand-alone MP visited, deficiencies were noted as regards condensation over exposed products and neglected maintenance. No attention was paid to prevent contamination through contact between exposed and packaged raw meat during thawing. Many spices to be used as ingredients were expired.
- In five establishments visited there were no results available from water testing for contaminants and pesticides (four establishments having municipal water supply and one having its own bore-hole).
- Documented pest control programmes were available in the establishments visited. However, in one SH visited could not be regarded as sufficiently protected against the entry of pests as insects were seen inside.
- One low-throughput SH had been approved without meeting all the infrastructure and equipment requirements (no restraining facilities available, when stunning bovines). Another low-throughput SH had been approved without having a proper separation between changing room facilities and toilet facilities.

Conclusion

Five out of the eight establishments visited were generally considered to meet the general and specific hygiene requirements in Annex III of Regulation (EC) No 853/2004. However, deficiencies were identified in two low-throughput SHs and one small standalone meat product plant.

The official controls on potable water did not cover all the requirements of Council Directive 98/83/EC.

Although some measures have been taken, recommendation Nos two, three and first element of No 4 cannot be considered to have been addressed as regards low-throughput SHs. Furthermore, the CAs were in some cases not able to detect deficiencies noted by the FVO audit team.

5.2.2 HACCP-based systems

Legal requirements

On the basis of Article 5 of Regulation (EC) No 852/2004 the FBO shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. Section II of Annex II to Regulation (EC) No 853/2004 lays down the specific requirements for HACCP-based procedures in slaughterhouses. Official controls in respect of all products of animal origin in the scope of Regulation (EC) No 854/2004 shall include audits of HACCP-based procedures (Article 4 (3)(a) and (5) of Regulation (EC) No 854/2004).

Audit findings

The official controls of red meat and dairy establishments include an annual check on procedures based on HACCP principles. The CCA had developed a checklist for such controls and it could verified that the annual controls had been carried out and that the checklist had been used by the CAs met.

All visited FBOs had put in place procedures based on HACCP principles and the procedures were

in general well documented.

Observations

Despite actions in response to the second element of recommendation No 4 regarding ensuring FBOs compliance with HACCP based procedures being considered satisfactory, the following non-compliances were noted by the FVO audit team, however, they were not noted by the CA:

- In the stand alone meat plant and one low-throughput (SH, CP, MP) the validation of the heat treatment was insufficient (time component not described in both plants, no description available of location of the probes, a guidance document for canning of vegetables and fruits was used for canned meat to establish heat treatment in the combined plant). In addition, the test results for checking the seals lacked interpretation for the values outside the permitted range in the combined plant.
- In another low-throughput SH and CP, the HACCP plan for the SH covered only ostriches but not the red meat slaughter.
- In another small dairy, heat-treatment was not classified as a CCP (the FBO stated that if the product was not properly heat-treated, the product's quality would be unacceptable).
- The FVO audit team checked the file over controls in another red meat establishment in a MFCA visited. In this file, no follow–up in relation to shortcomings noted in relation to HACCP was documented for one and a half years.

Conclusion

Although the CA carry out regular controls on HACCP-based procedures, these controls have not been effective, in particular in the small-scale red meat establishments (small scale MP and low-throughput SH).

Although some measures have been taken, the second element of recommendation No 4 as regards small scale meat establishments cannot be considered to have been addressed. Furthermore, in some cases the CAs were not able to detect deficiencies noted by the FVO audit team.

5.2.3 Microbiological criteria for foodstuffs

Legal requirements

Details on which the microbiological criteria for foodstuffs shall comply with are set out in Regulation (EC) No 2073/2005. Article 1 of Regulation (EC) No 2073/2005 specifies that the CA shall verify compliance with the rules and criteria laid down in that Regulation. These cover a range of items with regard to requirements for slaughterhouses, cutting plants, emergency slaughter, game handling, raw milk and dairy products and other products of animal origin.

Audit findings

The Evira collects information on both own controls and official sampling and analysis in relation to *Listeria monocytogenes* (*L. monocytogenes*) and *salmonella* in products and the production environment as part of the information gathered on official controls carried out in dairy establishments. The FVO audit team received the summary statistics for 2011 and 2012. In general, the results were satisfactory. For the meat sector, such annual statistics are not yet compiled.

In the establishments visited, microbiological criteria were included in the own control plans of the

FBOs and the testing was in general implemented according to the plans. The results seen were in general satisfactory and evidence of corrective actions and resampling taken was available in most cases seen where the limits had been exceeded.

Observations

Despite actions in response to recommendation No 5 regarding ensuring sampling and analysis in compliance with Regulation (EC) No 2073/2005 being considered satisfactory, the following non-compliances were noted by the FVO audit team, however, the majority of them were not noted by the CA:

- The specific requirements in relation to the sampling numbers as given in Chapter 1 of Annex I to Regulation (EC) No 2073/2005 were not always followed. For example, the sampling requirement for five sample aliquots for *salmonella* was not respected for minced meat or for milk products.
- In one low-throughput SH visited, the carcasses were not sampled for process hygiene criteria as required in Annex I to the above Regulation and in one case the laboratory had analysed the samples for a wrong parameter and no resampling had been carried out by the FBO.
- In several establishments visited, environmental samples were taken for *L. monocytogenes* but these were taken after cleaning and disinfection and not during processing as recommended in the EU guidelines for environmental sampling for *L. monocytogenes*.
- One of the CAs met was not aware that monitoring for *L. monocytogenes* in the environment should be carried out during the process and not after cleaning and disinfection.
- In one low-throughput combined red meat establishment visited, no sampling was carried out to verify the effectiveness of the cleaning and disinfection procedures in place.
- In the stand-alone meat plant, the product characterisation (of approximately 60 different products) did not specify whether the products were supporting the growth of *L. monocytogenes* or not (however, the products were analysed for absence of this pathogen).
- In some cases the consumer behaviour was not taken into account in the shelf-life studies carried out by the FBOs.

Conclusion

Although FBOs visited were aware of the requirements of the Regulation (EC) No 2073/2005 and had included the requirements in their own control plan, the implementation of the rules had some deficiencies, especially in the small-scale establishments.

Although some measures have been taken, the second element of recommendation No 5 as regards small scale meat establishments cannot be considered to have been addressed. Furthermore, in some cases the CAs were not able to detect deficiencies noted by the FVO audit team.

5.2.4 Traceability, labelling and identification marking

Legal requirements

According to Article 18 of Regulation (EC) No 178/2002 the traceability of food and food-producing animals and any other substance intended to be incorporated into a food shall be established at all stages of production, processing and distribution. The FBO shall have in place systems and procedures to identify from whom they have been supplied and the other businesses to which their products have been supplied. Article 4(6) of Regulation (EC) No 854/2004 requires that

the verification of compliance with traceability requirements takes place in all approved establishments.

Provisions for the identification marking of a product of animal origin are made in Article 5 and Annex II, Section I to Regulation (EC) No 853/2004 and verification of compliance with these requirements is foreseen by Article 4(6) of Regulation (EC) No 854/2004. Article 3 of Directive 2000/13/EC sets out the particulars on the labelling of foodstuffs to be delivered as such to the ultimate consumer. Regulations (EC) No 1760/2000 and 1825/2000 set out specific labelling requirements for beef meat.

Audit findings

- The requirements regarding identification marks and labelling were generally complied with. However, in one full-throughput SH, an initial mechanical recovering of fresh meat was not labelled as such but labelled as "assortment of meat" and sent to other establishments with that description. A second mechanical recovery of the bone part from the initial recovery was labelled as "pressed meat".
- In one low-throughput SH with integrated MP visited, meat products were labelled with old rectangular identification marks referring to the previous approval, when the establishment was approved only for the national market. The CA responsible for the supervision had not reacted on this.
- Traceability systems were in place in all the establishments visited and when verified by the FVO audit team the systems provided for backwards traceability.

Conclusion

The requirements in general regarding labelling and identification marking were, with one exception, complied with.

The practices in one full-throughput SH, as regards the labelling of MSM were not in compliance with the provisions of Article 3 (1) of Directive 2000/13 (the labelling shall indicate the ingredients and their quantities in compliance with the relevant provisions of the same Directive) and Article 2 of Directive 2000/13 and Article 16 of Regulation (EC) No 178/2002 9 (the labelling shall not mislead the consumer).

The traceability systems implemented in accordance with Article 18 of Regulation (EC) No 178/2002 were in place in the establishments visited and could be regarded as reliable.

5.2.5 Food Chain Information

Legal requirements

According to Article 3 of Regulation (EC) No 853/2004, the FBO shall comply with the relevant provisions of Annex II and III to this Regulation. In particular the FBOs operating slaughterhouses must as appropriate, request, receive, check and act upon food chain information (FCI) in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouse. According to Article 5(1) of Regulation (EC) No 854/2004 the OV shall carry out inspection tasks in

slaughterhouses also as regards FCI.

Audit findings

- A system for FCI is in place based on a comprehensive guideline including national implementing provisions.
- The system as demonstrated in the SHs visited was found to be in compliance with Community requirements in two of the SHs visited. In the third SH (low-throughput), some documentation was missing and some documentation was inaccurate.
- The FCI was verified by the OVs but the above shortcomings had not been noted by the OV.

Conclusion

A system for FCI is in place and despite some shortcomings noted generally in compliance with the Community requirements.

5.2.6 Ante-mortem and post-mortem inspection

Legal requirements

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including ante-mortem inspection of all animals before slaughter in accordance with the general requirements of Section I, Chapter II of Annex I to Regulation (EC) No 854/2004 and post-mortem inspection in accordance with the general requirements of Section I, Chapter II of Annex I and the specific requirements of Section IV, Regulation (EC) No 854/2004.

Specific rules on official controls for *Trichinella* are laid down in Regulation (EC) No 2075/2005.

Audit findings

- The ante-mortem inspections including controls of animal identification at slaughter were carried out as planned according to the CA and generally in compliance with Community requirements. Records on ante-mortem inspections were in place in the SHs visited.
- In one approved SH, it was documented that some ante-mortem examinations were normally carried out by an Official Auxiliary without any presence of the OV and despite satisfactory guarantees being provided in response to recommendation No 6 of report DG(SANCO)/2009-8229 concerning the same issue.
- The records from post-mortem examinations were available in all SHs visited. The post-mortem inspection was only observed in one SH visited and was in general carried out as foreseen in legislation.
- The organisation of *Trichinella* examination in the three SHs visited followed the requirements of Regulation (EC) No 2075/2005.

Conclusion

The results of the ante-mortem examinations were documented. However, in one establishment the ante-mortem examinations were sometimes carried out by an Official Auxiliary which is not in accordance with the requirements of Article 5(1) of Regulation (EC) No 854/2004.

Despite satisfactory guarantees being provided, recommendation No 6 of report DG(SANCO)/2009-8229 concerning the same issue has not been addressed.

Post-mortem inspection was carried out in accordance with the general requirements of Section I, Chapter II and the specific requirements of Section IV of Annex I to Regulation (EC) No 854/2004 and the examination for *Trichinella* was carried out in accordance with Regulation (EC) No 2075/2005.

5.2.7 Health marking

Legal requirements

Article 5(2) of Regulation (EC) No 854/2004 requires that health marking of carcasses of domestic ungulates, farmed game mammals other than lagomorphs and large wild game as well as half-carcasses, quarters and wholesale cuts shall be carried out in slaughterhouses and game-handling establishments by, or under the responsibility of, the OV when official controls have not identified any deficiencies that would make the meat unfit for human consumption.

Audit findings

Health marking was carried out under the control of the OV in two of the SHs visited. In the third SH (low-throughput), the health marking was carried out by the FBO and the health mark was not kept under control by the OV out of normal working hours. The CA stated that this would be rectified immediately.

Conclusion

The overall situation as regards compliance with Article 5 (2) of Regulation (EC) No 854/2004 was satisfactory despite some shortcomings noted in one SH visited.

5.2.8 Animal welfare at the time of slaughter or killing

Legal requirements

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including animal welfare. Regulation (EC) No 1099/2009 sets out EU rules with regard to the protection of animals at the time of killing.

Audit findings

In the draft Animal Welfare Act and Ordinance the RSAA has been designated as the CA delivering certificates of compliance. In addition, the OVs can deliver temporary certificates.[5] Furthermore, the Finnish Centre for Animal welfare has published guides to good practice concerning slaughter and killing of production animals to good and is designated to provide scientific support.

The CCA has not yet finalised the organisation of training for the achievement of the certificate of compliance and Finland is availing of the transitional period given in Article 29 of the Regulation

5 In their response to the draft report the CCA noted that the Animal Welfare Act came into force on 1 September 2013 and according to it the RSAAs can deliver certificates that remain in force until further notice or certificates that are temporary.

(EC) No 1099/2009. The requirements in relation to animal welfare in SHs are already included in the curriculum for persons carrying out the slaughter.[6]

The CCA has organised training on the requirements of the Regulation both to the OVs and Official Auxiliaries working at SH and FBOs. Evidence of such training was available.

All CAs met responsible for controls in the meat sector were aware of the requirements of the Regulation (EC) No 1099/2009.

The FVO audit team verified the animal welfare controls in relation to killing in two SHs visited. In the full-throughput pig SH, documentation was available on the controls on animal welfare carried out by the OVs. The own control plan of the FBO included controls on the stunning and the controls were documented adequately. Both FBOs had a second stunning device available. The observed stunning on-the-spot was adequate. The full-throughput SH had nominated an animal welfare officer.

Observations

- The OV responsible for the welfare controls in both the low-throughput SHs stated that the animal welfare at stunning was checked but it was not documented. Nevertheless, the last inspection report by the OV from one of the SHs visited included shortcomings in relation to the documentation of the FBO in relation to animal welfare checks at slaughter.
- In the low-throughput SH visited that was slaughtering during the visit the reserve stunning equipment was operational but poorly maintained.

Conclusion

The animal welfare requirements of the Council Regulation (EC) No 1099/2009 are currently being transposed into the national legislation. The rules were implemented adequately in the full-throughput SH visited. In the two low-throughput SHs the documentation of the own checks was inadequate.[7]

5.2.9 Control of milk production holdings and of raw milk upon collection

Legal requirements

Article 8 of Regulation (EC) No 854/2004 requires that Member States shall ensure that official controls with respect to raw milk and dairy products take place in accordance with Annex IV to Regulation (EC) No 854/2004. The CA shall carry out official controls to verify that health requirements and hygiene requirements for raw milk and colostrum are complied with and monitor the checks carried out for plate count, somatic cell count and residues of antibiotic substances.

Audit findings

Controls on dairy holdings

The official controls at milk production holdings are carried out by the OVs employed by the MFCAs. Previously, the target was to inspect every holding within a 3 year cycle. Since 2013, the

6 In their response to the draft report the CCA noted that it is possible to get the competency according to Regulation (EC) No 1099/2009 in a training system that already exists. The amended Welfare Act prescribes the organizer of the training. The Ministry of Education and Culture is responsible for the training. According to Article 29 of Regulation (EC) No 1099/2009 the personnel with several years of experience are presumed to have a certain level of expertise and therefore the requirements for the certificate of competence for this personnel are moderate.

7 In their response to the draft report the CCA noted that the amended Animal Welfare Act came into force on 1 September 2013.

inspection frequency should be risk-based and described in the annual control plan of the MFCA. However, in the regions visited, the target in practice was still to inspect all holdings in 3 years. For example, in the region of Northern Finland 408 dairy holdings of 1543 holdings in total had been inspected in 2012.

The controls on the animal health requirements of Section IX, Chapter I of Annex III to Regulation (EC) No 853/2004 are part of the inspections carried out by the OVs.

Evira has developed a checklist and aide memoire to carry out the holding inspections. The checklist was updated recently (approved 2 May 2013) to include recent changes in legislation in relation to raw milk and colostrum sale. Evidence of the use of the checklists was available in the regions visited and reports of holding inspections were available. The reports seen covered all relevant aspects.

The FVO audit team visited one dairy holding and did not note any deficiencies in relation to the dairy hygiene of this holding. A register of medical treatments was available, including identification of the treated animals and withdrawal period.

Observations

- In one local control area the municipal OV had visited only 5 of the 16 holdings to be visited. The remaining 10 holdings had not been inspected for five years. The CA had not carried out a risk assessment that would justify such a low frequency of inspections.

Controls on raw milk quality

After the previous FVO audit in 2009, the CCA had sent a reminder to the MFCAs to include checks on raw milk quality in their routine controls.

The collection of raw bovine milk collection is, for the majority of the milk production, carried out by co-operatives that purchase the milk. The FBO has to organise the testing of raw milk and to carry out corrective actions in case of failures and to inform the CA.

The system for bovine raw milk control is centralised and all samples are analysed for Somatic Cell Counts (SCC), Total Bacterial Count (TBC) and inhibitory substances in an industry-owned laboratory. The Bactoscan method is used for TBC. The correlation table for the number of impulses with Bactoscan and the reference method for TBC was received. The results of SCC and TBC were available in the dairies and on the holding visited. The results were in general in compliance with the requirements of Annex III, Chapter I to Regulation (EC) No 853/2004. The goat raw milk used by one cheese plant visited was analysed in an accredited laboratory and TBC results were available and satisfactory.

The Finnish Association of Milk Hygiene (*Maitohygienialiitto*) publishes national statistics on raw milk quality. The raw milk quality was in general good. In 2012, the annual geometrical average for SCC was 131 000/ ml and for TPC 5300. In 2011, 8960 dairy holdings were sampled for inhibitory substances in raw milk. Of the 18 096 analyses carried out, 32 were positive for inhibitory substances (0.16 %).

In the large scale dairy establishment visited, raw milk was tested at the tanker level with a rapid test. The milk could only be dispatched into the raw milk reception tank if the test result was negative. The result was further verified by testing the same sample with another test before start of the production. In the two small scale dairies visited the milk was received from only five holdings in one dairy and from own farm animals in the second dairy and the testing for inhibitory substances was not done routinely. However, the five holdings delivered most of their milk to another dairy and the FBO visited stated that it was tested there. According to the procedure in place, in case the geometrical averages for SCC and TBC and inhibitory substances exceed the legal

requirements, the FBO is required to send the results to the RSAA. The RSAA will then notify the local municipal OV to carry out an inspection on the holding with poor results. Evidence of the correct implementation of the procedure was available in the MFCA and RSAA offices visited.

Conclusion

The CAs had monitored the checks on TBC, SCC and residues of antibiotic substances in line with Chapter II of Annex IV to Regulation (EC) No 854/2004 in the regions visited. Although evidence was available in the regions visited that dairy holdings are checked to verify the health status of the animals and that the hygiene requirements are met, evidence was available that the planned inspection frequency is not reached by MFCAs.

5.2.10 Documentation of official controls

Legal requirements

Article 9 of Regulation (EC) No 882/2004 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.

Audit findings

- The inspection activities of the officials were satisfactorily documented both in establishments controlled by the Evira and in establishments controlled by the MFCAs.
- Evidence was seen of the detection and, in a number of cases, requests for correction of shortcomings concerning FBOs' operations and records as well as of deficiencies detected in establishments (for additional information see points 5.1.6, 5.1.7 and 5.1.8). However, some deficiencies had not been noted by the CAs:
    - Structures, lack of restraining facilities for stunning of bovines, maintenance, cleaning, or operational hygiene issues that were not in compliance with Community requirements in three of the eight establishments visited (two low-throughput SHs controlled by the Evira and one stand-alone meat product plant controlled by the MFCA).
    - The FBOs lack of compliance with regard to the obligation of organisation of HACCP checks in line with Article 5 of Regulation (EC) No 852/2004 in three establishments (two establishments controlled by the Evira and one controlled by the MFCA). Microbiological sampling was not carried out according to Community requirements in two of the eight establishments visited (two establishments controlled by the Evira). Likewise, water sampling results were not available for heavy metals and pesticides in five out of eight establishments (three establishments controlled by the Evira and two controlled by the MFCA).
    - The organisation of ante-mortem inspection reflected by the documentation of the inspection was not in compliance with community requirements in one of the three SHs visited (controlled by the Evira).

Conclusion

Standardised report forms were used and copies of these were provided to FBOs. However, some shortcomings were not noted by the CA, thereby making it difficult to set up corrective actions,

deadlines, follow-up actions and eventual sanctions contrary to the requirements of Article 9 of Regulation (EC) No 882/2004.

5.2.11 Animal by-products

Legal requirements

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including animal by-products (ABP). Regulation (EC) No 1069/2009 sets out amongst others the requirements for the collection and transport of ABP, including requirements for identification, records and the use of commercial documents.

Audit findings

- The CA informed the FVO audit team that the legal situation concerning milk which has tested positive in a screening test for antibiotics is still the same. The dairy industry still do not use this milk for feed purposes but is sending it for destruction (bio gas or other means). The FVO audit team noted that the plants visited complied with this decision.
- In the establishments visited ABP were properly labelled in five out of eight establishments visited. However, in the full-throughput SH visited, several products were not labelled as ABP although the FBO had decided to disposed of the products as an ABP. Acknowledgement of reception was available of disposed products.

Conclusion

The overall situation regarding compliance with Regulation (EC) No 1069/2009 was not satisfactory as regards the identification of the products.

6 Overall Conclusions

The Competent authorities (CA) are well-organised and cover all aspects of food safety controls in the meat and milk sectors. Coordination of official controls between CAs was adequate. However, the coordination within the Evira was inadequate as regards the low-through-put SHs.

A risk based approach is followed. However, the system does not ensure that the frequency in all cases is proportionate to the risk.

Although a comprehensive system of procedures and checklists is in place, enforcement was in some cases weak due to a lack of follow-up or lack of deadlines set or adhered to.

The situation as regards compliance with general and specific hygiene requirements and good hygiene practices was not satisfactory in the sector of low-throughput SHs and standalone meat processing plants. Moreover, shortcomings were noted as regards compliance with HACCP based procedures, microbiological sampling programmes in line with Regulation (EC) No 2073/2005 and the organisation of ante-mortem inspection.

Some labelling issues were identified as regards MSM.

Areas such as identification, traceability, FCI, animal welfare controls in establishments and of raw milk upon collection were in compliance with Community requirements and satisfactorily controlled by the CA.

7 Closing Meeting

A closing meeting was held on 20 June 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 provided clarification to some of the issues raised during the presentation.

8 Recommendations

An action plan describing the action taken or planned in response to the recommendations of this report and setting out a time table to correct the deficiencies found should be presented to the Commission within 25 working days of receipt of the report.

N°.	Recommendation
1.	To ensure appropriate coordination of the official controls of low-throughput slaughterhouses as required by Article 4(5) of Regulations (EC) No 882/2004 with a view to ensure compliance with general and specific hygiene requirements as laid down in Regulation (EC) Nos 852/2004 and 853/2004.
2.	To ensure during the approval process that all establishments when approved comply with Article 31 (2) (c+d) of Regulation (EC) No 882/2004.
3.	To ensure that the system of official controls is organised in a way that ensures that the applied frequency is appropriate in all cases taking into account the relevant risks as required by Article 3 (1) of Regulation (EC) No 882/2004.
4.	To ensure that appropriate action is taken when non-compliances have been identified ensuring that the operator remedies the situation as required by Article 54 of Regulation (EC) No 882/2004.
5.	To ensure that the official control is effective as required by Article 4(2) of Regulation (EC) No 882/2004 and that the effectiveness of the controls is verified as required by Article 8 (3) of Regulation (EC) No 882/2004 in particular in order to ensure that relevant deficiencies are detected by the CA and followed-up upon.
6.	To ensure that products of MSM as a raw material are labelled as such in order to ensure that products containing MSM intended for supply to the end consumer are correctly labelled in accordance with EU requirements (Chapter IV, Section V, Annex III of Regulation (EC) No 853/2004 and Ddirective 2000/13/EC).
7.	To ensure that the procedures implemented for ante-mortem examination in all slaughterhouses comply with Article 5 (1) of Regulation (EC) No 854/2004.
8.	To improve the awareness of the requirements of the Regulation (EC) No 2073/2005

N°.	Recommendation
	amongst Food Business Operators in particular in small-scale establishments.
9.	To ensure that the official controls on potable water cover the requirements of Council Directive 98/83/EC.

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=2013-6878

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Reg. 1760/2000	OJ L 204, 11.8.2000, p. 1-10	Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97
Reg. 1825/2000	OJ L 216, 26.8.2000, p. 8-12	Commission Regulation (EC) No 1825/2000 of 25 August 2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products
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. 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

Legal Reference	Official Journal	Title
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
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Reg. 2075/2005	OJ L 338, 22.12.2005, p. 60-82	Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for Trichinella in meat
Reg. 1162/2009	OJ L 314, 1.12.2009, p. 10–12	Commission Regulation (EC) No 1162/2009 of 30 November 2009 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council
Reg. 1069/2009	OJ L 300, 14.11.2009, p. 1-33	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
Dir. 93/119/EC	OJ L 340, 31.12.1993, p. 21-34	Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products

Legal Reference	Official Journal	Title
Dir. 98/83/EC	OJ L 330, 5.12.1998, p. 32-54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
Dir. 2000/13/EC	OJ L 109, 6.5.2000, p. 29-42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs