

Finland's comments on the draft report, ref. no. DG(SANCO)/2013-6878

The comments are **bolded** and *in italics*.

Executive summary

Since 1 September 2011 the Evira has been directly responsible for the official control of all types of slaughterhouses (SH)s and connected meat plants taking over the official controls of low-throughput SHs.

Since 1.9.2011 Evira has been responsible for control of all plants connected to SHs, not just meat plants.

1. Introduction

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

The Finnish Food Safety Authority (Evira) is the Central Competent Authority (CCA).

2. Objectives

Table 1

The mission team did not visit the The Regional State Administrative Agency in Oulu and therefore it should be deleted in the table1. Besides, the Agency in Oulu is called The Regional Administrative Agency of Northern Finland.

In the table the official veterinarians should be mentioned as local authorities.

In food production/processing/distribution – activities it is stated that cutting premises and minced meat/meat preparation establishments with other activities were visited. We think the idea in the report was to point out that establishments that were not connected to slaughterhouse were visited.

5. Findings and conclusions

5.1 Competent authorities

5.1.1 Designation of competent authorities

...In addition, the Evira is since 1 September 2011 directly responsible for the official control of full-throughput as well of low-throughput slaughterhouses (SH - less than 1 000 units per year) and for attached cutting plants (CP) and meat processing plants (MP).

Evira is responsible for the control of all plants attached to SH.

...The official control is organised in five regional meat inspection units under the Evira Meat Inspection Unit.

These five regional units are not independent (like e.g. The Regional State Administrative Agencies). It's better to say e.g. that the meat inspection is carried out by the staff of Evira Meat Inspection Unit. The Evira Meat Inspection Unit is internally divided into five groups according to geographic areas which are called 'regional units' and the 'unit' has a 'regional director' to help the head of (Meat Inspection) unit in practical matters.

Six Regional State Administrative Agencies (RSAA) in Finland have since 1 September 2011 been responsible for coordination and supervision of the Municipal Food Control Authorities (MFCAs).

The re-organisation of regional government took place on the 1st of January 2010. That date the Regional State Administrative Agencies (RSAAs) replaced the Provincial State Offices, which already had the responsibility of planning, steering and monitoring the compliance with the food regulations within their respective regions. The number of RSAAs is in fact seven; the Aland Islands is the seventh RSAA.

The FVO audit team met representatives of RSAAs of the provinces of Western and Inner Finland and Oulu.

The team visited Regional State Administrative Agency of Western and Inner Finland and met a representative of Regional State Administrative Agency of Northern Finland.

Observations

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

The Veterinary Act prescribes the RSAA and municipality to make a plan how to arrange the animal health and animal welfare issues. The Veterinary Act does not cover food safety, it is in the Food Act. The plans are to be risk based and they are not made according to available resources but what is the actual need for veterinary services.

- In line with the Act on Veterinary Care, the Finnish State pays for official controls from the MFCAs. In this way 30 full time equivalent (FTE) new posts at the level of the MFCAs have been created for which only an unknown proportion is dedicated for official controls on foodstuffs.

The name of the act is the Veterinary Act. The Finnish State does not pay for food control as food control is the responsibility of MFCA. Instead, the Finnish State pays for animal health and animal welfare to municipalities. At present there are 57 posts for 'control veterinarians' which perform 42 FTE in animal health and welfare. In these posts they perform about 9 FTE food control and meat inspection, but this is not paid for by the State. Thus, most of the food control is done by other officials than these 'control veterinarians'.

5.1.2 Co-operation and co-ordination between and within competent authorities

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

Similarly, Evira, RSAA, 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.

...

A new information system KUTI is implemented in stages. KUTI 1a allows monitoring of control activities e.g activities of high risk areas.

KUTI 1a allows monitoring of FBO's and establishments and KUTI 2a allows monitoring the control data of approved establishments and notified food premises (KUTI 2 a enables monitoring e.g. specific data on inspections, non-compliances identified as well as administrative enforcement measures used).

KUTI 3 for monitoring of control data was completed by Spring of 2012 and provides for control-data including also enforcement measures

By KUTI3 Evira has been able to make BO-reports from the KUTI since 2012. Evira's control data is added to KUTI in 2013-2014 (includes also the control measures performed by Evira).

Observations

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The Control Department of food control hygiene and the Meat Inspection Unit of the Evira are jointly responsible in drawing up Evira's control programme.

Food Hygiene Unit and Meat Inspection Unit belong to Evira's Control Department. The units of Evira's Control Department responsible for food control jointly draw up food control programme (or plan) (EVO, elintarvikevalvontaohjelma) for the municipalities.

...

The control plans in both MFCAs visited were evaluated by the MFCAs each year. However, in the 2 MFCAs visited, only two establishments were visited per review.

The RSAAs are to evaluate the MFCAs' food control plans. The MFCAs draw up a plan, but they don't evaluate their own plans.

The meaning of the second sentence remains cryptic to us: Do the auditors mean, that in both MFCAs only two establishments were inspected (the MFCAs inspect the establishments according their annual plan, they don't do any 'reviews'). Or do the auditors mean the RSAAs auditing system when the RSAAs audit the MFCAs? In these audits the RSAAs visit fish and egg establishments and retail businesses besides meat and milk establishments (because they audit the whole food control in place), but they don't visit all the establishments controlled by the MFCA.

The organisation of the official control varied between the two low-throughput SHs visited. In one of the SHs a contracted 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 from the regional meat inspection unit was responsible for the Article 4 audits and a contracted Evira official was in charge of the meat inspection.

In the first case it was an Evira official who was in charge of everything. In the second case it's unnecessary to say "Evira official from the regional meat inspection unit" because in that sense they (the OVs in SHs) all are from the regional meat inspection unit (=not from Helsinki unit) but they still belong to the same Meat Inspection Unit and their duties are the same in every 'region'.

5.1.3 Registration/approval of Food Business establishments

Audit findings

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no de-skinning of wild bears and boars before entering the Game Handling Establishments (GHEs);

Bears and seals are allowed to be skinned prior to bringing them into the game handling establishment according to national legislation which has been notified to the Commission and the Member States.

...

no need for accompanying Food Chain Information (FCI) for slaughter animals originating from adjacent farms supplied to low-throughput SHs.

FCI must always be available to OV, but in the situations where the low-throughput SH is located in the farm, FCI concerning this farm's animals can be kept in the animal shed where the ante mortem inspection takes place.

...

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.

Since the 1st of September 2011 when the amended Food Act came into force, it's been possible for a hunter to sell uninspected wild game meat of birds, rabbits, hares and cervids also to retail (Reg. 853/2004 art. 1 point 3 e).

Observations

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.

For what animal species the SH was approved for was, however, specified in the public list of approved establishments held by Evira.

The process of approval has evolved in Evira during the past years. At present, the approval documents meet the requirements. The approval documents the mission team was presented were the original documents (made about seven years ago) that cannot be changed however incomplete they are. On the other hand, the mission team was provided with some recent approval documents from this year, before the team arrived in Finland, and those documents show the more precise way how they are written today.

5.1.4 Prioritisation of official controls

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 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.

All the MFCAs visited had a risk based approach, but they didn't have exactly the same formula according to which they made the decisions. There was what we think a misreading of the risk assessment procedure: when the MFCAs gave 'points' to certain activities, the FVO interpreted e.g. that the only points given to company's own-check were the points

under the headline 'own-check', when in fact one should count also the lines like 'maintenance', 'cleaning', 'hygiene' and 'sampling results'. Thus in these three MFCA the proportion of points that could be given to own-check system was 41 %, 25 % and 57,5 %. If there is risk assessment guidance e.g. by FVO to clarify what would be the accepted proportion of different components, we would be open to that kind of information.

5.1.5 Official sampling and laboratory analysis

The Evira's laboratory is designated as National Reference Laboratory (NRL) for the relevant tests to be carried out. 46 laboratories for official control samples and six laboratories analysing owncheck samples have been approved by Evira according to the Food Act.

17 laboratories have been approved by Evira to carry out trichinella examinations; 11 of these are included in the above-mentioned 46 laboratories.

All laboratories examining official samples have been accredited to ISO 17 025 **apart from six trichinella laboratories located in slaughterhouses.**

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Until the information system KUTI 2b is implemented (see also Chapter 5.1.2), an electronic data collection system is used where all laboratories have to feed in all relevant information at least once per year by the end of April. Currently the data gathered is used for monitoring purposes.

In Evira an electronic data collection system (patogenix) is used where the laboratories have to feed information in relation to salmonella, EHEC-bacteria, campylobacter, listeria and pathogenic yersinia 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 nonaccredited laboratories are subject to an annual approval process by the Evira. In addition, ring tests are organised by the National Reference Laboratories (NRL) (the Evira's laboratory in Oulu). **an annual approval=a regular evaluation**

Successful results in the ring tests are needed to maintain the approval. Only accredited laboratories will be approved from 1 January 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 due to lack of participation in such training.

The activities of one laboratory failing the proficiency test were suspended until the laboratory participates in such training and demonstrates to be able to produce reliable results.

5.1.7 Enforcement measures

Audit findings

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An instruction has been adopted (100011/2) for verification controls of on enforcement measures imposed. Three model documents have been adopted concerning decisions, FBO hearing and an internal code of conduct.

An Evira instruction (10110/1) on administrative sanctions was adopted 9 August 2010.

Evira has given a guide how to use administrative coercive measures according to Food Act in food control (100011/2).

Model documents, 16 all together, can be found here

<http://www.evira.fi/portal/fi/tietoa+evirasta/lomakkeet+ja+ohjeet/elintarvikkeet/malliasiakirjat/>

...

An Evira instruction (10110/1) on administrative sanctions was adopted 9 August 2010.

A model document for making a decision of using administrative coercive measures is number 10110/2, 1.6.2012.

5.1.8 Verification and review of official controls and procedures

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 meat plants and the MFCA's 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.

Evira is responsible of the control of all plants connected to SHs.

...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.

In addition, to retail it is allowed to deliver small amounts of uninspected wild game meat of birds, rabbits, hares and cervids. Hunters sale of uninspected wild game meat is allowed according to Reg. 853/2004 art. 1, point 3e. Small amounts of game meat can also be inspected in reindeer SHs, which are approved for slaughtering of wild game.

5.2 Official controls over food business operators' compliance with hygiene rules at establishment level

5.2.1 General and specific hygiene requirements

Observations

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In one low-throughput EU approved SH with attached CP and MP no major deficiencies were noted.

and

5.2.6 Ante mortem and post mortem inspection

Audit findings

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In one EU approved SH, it was documented that some ante-mortem examinations were...

All the establishments are EU approved since re-approval.

5.2.8 Animal welfare at the time of slaughter or killing

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In the draft Animal Welfare Act and Ordinance the Evira has been designated as the CA delivering certificates of compliance. However, the plan is to delegate this responsibility to the RSAA.

In the draft Act Evira is not designated as a CA delivering certificates of competence, but the RSAA. In addition, the OVs could deliver temporary certificates. The Animal Welfare Act came into force on the 1st of September and according to it the RSAAs can deliver certificates that remain in force until further notice or certificates that are temporary, and the OVs can deliver certificates that are temporary.

Furthermore, the Finnish Centre for Animal welfare has been designated for developing guides to good practice and providing scientific support.

The Finnish Centre for Animal Welfare has published guides to good practice concerning slaughter and killing of production animals.

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 (EC) No 1099/2009.

In Finland it is possible to get the competency according to the Regulation (EC) No 1099/2009 in training system that already exists. The amended Animal Welfare Act (1.9.2013) prescribes the organizer of the training. The Ministry of Education and Culture is responsible for the organizing the training.

According to Reg. 1099/2009 art. 29 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.

Conclusions

The animal welfare requirements of the Council Regulation (EC) No 1099/2009 are currently being transposed into the national legislation.

The amended Animal Welfare Act came into force on the 1st of September 2013.