



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

Ares(2014)3099871

DG(SANCO) 2014-7132 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ESTONIA

FROM 10 TO 20 JUNE 2014

IN ORDER TO EVALUATE THE FOOD SAFETY CONTROL SYSTEMS IN PLACE  
GOVERNING THE PRODUCTION AND PLACING ON THE MARKET OF FISHERY  
PRODUCTS

## ***Executive Summary***

*This report describes the outcome of a Food and Veterinary Office audit in Estonia carried out from 10 to 20 June 2014, as part of its programme of audits in Member States.*

*The objectives of the audit were to verify that official controls of fishery products are organised and carried out in accordance with the relevant provisions of Regulation (EC) No 882/2004 and to evaluate whether the control system in place for the production and placing on the market of fishery products is in compliance with EU requirements.*

*The report concludes that there is an organised and documented official control system in place which is in accordance with the relevant provisions of Regulation (EC) No 882/2004. In general, this control system is consistently and adequately implemented and covers the fishery products production chain. Some shortcomings were identified in the establishment approval process.*

*Official controls are generally implemented in accordance with EU requirements. Nonetheless, certain weaknesses were identified in the control of fishing vessels and landing conditions (including organoleptic checks), HACCP evaluation and verification of food business operators' own-checks for some microbiological criteria.*

*Furthermore, although steps have been taken by the competent authority to strengthen the system of controls over Baltic Sea fish which may contain dioxins and PCBs above the EU maximum limits, some gaps remain in measures put in place and their implementation by some food business operators.*

*In the laboratory visited, methods used for official analyses are included in the scope of accreditation. However, deficiencies in validation and internal quality controls were noted in method for histamine analysis.*

*The report addresses to the Estonia competent authority a number of recommendations aimed at rectifying identified shortcomings and enhancing the control system in place.*

# Table of Contents

|          |  |           |
|----------|--|-----------|
| <b>1</b> | <b><u>INTRODUCTION</u></b> .....   | <b>1</b>  |
| <b>2</b> | <b><u>OBJECTIVES AND SCOPE OF THE AUDIT</u></b> .....                        | <b>1</b>  |
| <b>3</b> | <b><u>LEGAL BASIS FOR THE AUDIT</u></b> .....                                | <b>2</b>  |
| <b>4</b> | <b><u>BACKGROUND</u></b> .....   | <b>2</b>  |
| 4.1      | <u>GENERAL BACKGROUND</u> .....  | 2         |
| 4.2      | <u>PRODUCTION AND TRADE INFORMATION</u> .....                                | 2         |
| 4.3      | <u>RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) NOTIFICATIONS</u> .....      | 3         |
| <b>5</b> | <b><u>FINDINGS AND CONCLUSIONS</u></b> .....                                 | <b>3</b>  |
| 5.1      | <u>COMPETENT AUTHORITY</u> .....   | 3         |
| 5.2      | <u>REGISTRATION/APPROVAL OF FOOD BUSINESS OPERATORS ESTABLISHMENTS</u> ..... | 5         |
| 5.3      | <u>OFFICIAL CONTROLS</u> .....   | 7         |
| 5.3.1    | <i><u>OFFICIAL CONTROL OF PRODUCTION AND PLACING ON THE MARKET</u></i> ..... | 7         |
| 5.3.2    | <i><u>OFFICIAL CONTROLS OF FISHERY PRODUCTS</u></i> .....                    | 13        |
| 5.4      | <u>FOLLOW-UP OF RASFF NOTIFICATIONS</u> .....                                | 15        |
| 5.5      | <u>LABORATORIES</u> .....  | 16        |
| <b>6</b> | <b><u>OVERALL CONCLUSIONS</u></b> .....                                      | <b>18</b> |
| <b>7</b> | <b><u>CLOSING MEETING</u></b> .....  | <b>18</b> |
| <b>8</b> | <b><u>RECOMMENDATIONS</u></b> .....  | <b>18</b> |
|          | <b><u>ANNEX 1 - LEGAL REFERENCES</u></b> .....                               | <b>20</b> |

**ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT**

| <b>Abbreviation</b> | <b>Explanation</b>  |
|---------------------|---|
| As                  | Arsenic   |
| BIP                 | Border Inspection Post  |
| CA                  | Competent Authority   |
| Cd                  | Cadmium   |
| CVC                 | County Veterinary Centre  |
| DG SANCO            | Health and Consumers Directorate General of the European Commission |
| EAK                 | Estonian Accreditation Centre ( <i>Eesti Akrediteerimiskeskus</i> ) |
| EC                  | European Community  |
| EERC                | Estonian Environmental Research Centre                              |
| EI                  | Environmental Inspectorate  |
| EURL                | EU Reference Laboratory   |
| FVO                 | Food and Veterinary Office of the European Commission               |
| HACCP               | Hazard Analysis Critical Control Points                             |
| Hg                  | Mercury   |
| HPLC                | High Performance Liquid Chromatography                              |
| ISO                 | International Organisation for Standardisation                      |
| KIS                 | Fisheries Information System ( <i>Kalanduse Infosüsteemist</i> )    |
| MA                  | Ministry of Agriculture   |
| NRL                 | National Reference Laboratory                                       |
| OJ                  | Official Journal of the European Union                              |
| PAH                 | Polycyclic Aromatic Hydrocarbons                                    |
| Pb                  | Lead  |
| PCBs                | Polychlorinated Biphenyls   |
| PT                  | Proficiency Testing   |
| RASFF               | Rapid Alert System for Food and Feed                                |

|       |                                |
|-------|--------------------------------|
| TVB-N | Total volatile basic nitrogen  |
| VFB   | Veterinary and Food Board      |
| VFL   | Veterinary and Food Laboratory |

## 1 INTRODUCTION

The audit took place in Estonia from 10 to 20 June 2014 and was undertaken as part of the Food and Veterinary Office's (FVO) audit programme.

The audit team comprised two auditors from the FVO. An opening meeting was held in Tallinn on 10 June 2014 with the Competent Authority (CA) - Veterinary and Food Board (VFB). At this meeting the audit team confirmed the objectives of, and itinerary for the audit, and requested additional information required for the satisfactory completion of the audit. Representatives from the CA accompanied the FVO team during the whole audit.

## 2 OBJECTIVES AND SCOPE OF THE AUDIT

The objectives of the audit were:-

- to verify that official controls of fishery products are organised and carried out in accordance with the relevant provisions of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;
- to evaluate whether the control system in place for the production and placing on the market of fishery products is in compliance with EU requirements.

In terms of scope the audit focused on the organisation and performance of the CA, the official control system in place covering production, processing and distribution stages applicable to fishery products placed on the market. Accordingly, relevant aspects of the EU legislation referred to in Annex 1 were used as technical basis for the audit.

In pursuit of these objectives, the audit team visited the following sites:

| <b>COMPETENT AUTHORITY</b>                      |   |  |
|---|---|--|
| Central level                                   | 2 | Veterinary and Food Board                      |
| District level                                  | 3 | County Veterinary Centres                      |
| <b>LABORATORY</b>                               |   |  |
| National Reference Laboratory (NRL)             | 1 | Veterinary and Food Laboratory (VFL) in Tartu  |
| <b>PRIMARY PRODUCTION</b>                       |   |  |
| Hatcheries                                      | 1 |  |
| Aquaculture farms                               | 1 |  |
| Fishing vessels                                 | 1 |  |
| <b>LANDING AND FIRST SALE</b>                   |   |  |
| Landing sites/ auction halls/ wholesale markets | 4 | Two sites were private quays at establishments |
| <b>FACILITIES HANDLING FISHERY PRODUCTS</b>     |   |  |
| Processing Plants                               | 6 |  |
| Cold stores                                     | 1 |  |

### 3 LEGAL BASIS FOR THE AUDIT

The audit was carried out under the general provisions of EU legislation and, in particular, Article 45 of Regulation (EC) No 882/2004.

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

### 4 BACKGROUND

#### 4.1 GENERAL BACKGROUND

A previous audit on fishery products took place in 2008 (ref. DG(SANCO)/2008-7640; hereafter: 2008 FVO audit) and highlighted deficiencies in relation to official controls over certain parts of production chain (including primary production), follow-up actions in case of non-conformities and sampling requirements for contaminants and histamine; the report – published on the Health and Consumers Directorate-General (DG SANCO) internet site at [http://ec.europa.eu/food/fvo/ir\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm) – made a number of recommendations in respect of the action required by the CA. Written guarantees were received from the CA in relation to the implementation of actions aimed at addressing those recommendations.

In addition to the above mentioned audit, there have been more recently two related FVO audits dealing with smoking techniques for certain fishery products (ref. DG(SANCO)/2011-8879; hereafter: 2011 FVO audit) and the monitoring and control of dioxins, furans and PCBs in fish from the Baltic region (ref. DG(SANCO)/2012-6531; hereafter: 2012 FVO audit). The 2011 FVO audit report concluded that smoking techniques and official control system in place were able to ensure compliance with established maximum levels for Polycyclic Aromatic Hydrocarbons (PAHs; benzo(a)pyrene). The 2012 FVO audit highlighted deficiencies in the control system in place aimed at ensuring that potentially contaminated Baltic Sea fish were not being placed on the market, and the report made a recommendation in this regard. Both reports are published on the above cited DG SANCO website.

The follow-up of recommendations made in 2008 and 2012 FVO audit reports is reported under the relevant parts of this report.

#### 4.2 PRODUCTION AND TRADE INFORMATION

According to information provided by the VFB, approximately 65 000 tonnes of fresh fishery products were landed in Estonia in 2013. The main species were sprat (*Sprattus sprattus*) and Baltic herring (*Clupea harengus membras*) - approximately 30 000 and 15 000 tons, respectively, were landed by domestic trawlers in 2013. Approximately 8500 tons were landed by fishing vessels from other Member States. The main catch from coastal sea fishing is Baltic herring (approximately 7000 tons landed in 2013, representing 74% of overall coastal sea catch). Other significant wild-caught species include perch (*Perca fluviatilis*; approximately 2100 tons in 2013 - from coastal sea and inland waters) while the main aquaculture species is rainbow trout (*Oncorhynchus mykiss*; 465 tons were produced in 2013). All Estonian factory vessels are currently operating in the Atlantic Ocean and do not land fishery products in Estonia.

According to the lists set up by the VFB and available on its website, there are a total of 93 fish processing establishments, 41 cold stores (most of which handle fishery and other food products) and seven factory vessels approved to operate and place fishery products on the market. Approval

decisions for three processing establishments and one factory vessel are currently suspended and one establishment has been recently granted a conditional approval.

#### **4.3 RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) NOTIFICATIONS**

There were 14 RASFF notifications registered with regard to fishery products originating from Estonia since the 2008 FVO audit, of which:-

- Six notifications were linked to detection of *Listeria monocytogenes* (*L. monocytogenes*) in smoked fishery products (five) and in a pickled product (one).
- Three notifications were linked to the presence of benzo(a)pyrene/(PAHs) in smoked fish (two) and in smoked fish in oil (one).

The other five notifications were linked to undeclared presence of eggs (breaded product), altered organoleptic characteristics (frozen fillets) and presence of histamine (canned product), of metal pieces (canned product) and of plastic fragments (frozen cubes).

### **5 FINDINGS AND CONCLUSIONS**

#### **5.1 COMPETENT AUTHORITY**

##### **Legal requirements**

Articles 3 to 10, 54 and 55 of Regulation (EC) No 882/2004.

##### **Findings**

Details on the structure and organisation, designation of responsibilities, co-ordination between authorities and the role of CAs within the scope of this audit are described in the Country Profile of Estonia (available on the DG SANCO website here: [http://ec.europa.eu/food/fvo/country\\_profiles\\_en.cfm](http://ec.europa.eu/food/fvo/country_profiles_en.cfm)). A description of CAs involved in the control system for fishery products is also provided in the 2012 FVO audit report.

In brief, the VFB (a governmental agency under the aegis of the Ministry of Agriculture - MA) is responsible for official controls of fishery products. These are generally carried out by local fish inspectors (fish hygiene specialists) from County Veterinary Centres (CVCs). Official controls on aquaculture farms are mostly carried out by CVCs' animal health specialists.

The Environmental Inspectorate (EI; an administrative unit under the Ministry of Environment) is responsible for all areas of environmental protection including controls on fishing activities in order to ensure compliance with the EU Common Fisheries Policy. A co-operation agreement (dated 12.04.2012) between VFB and EI provides for exchange of information, joint actions and training involving the two authorities. Documented examples of meetings, joint inspections and notifications from EI to VFB on potential non-conformities related to handling and marketing of fishery products were presented to the audit team.

The audit team visited three CVCs and noted that conditions concerning number of staff, facilities, equipment and access to laboratories were adequate. VFB has an electronic document management system in place providing for, inter alia, exchange of information and co-ordination of activities between central and local level.

As far as fishery products are concerned, there is no delegation of official tasks from VFB to control bodies.

Regarding training of staff performing official controls, the audit team noted that:-

- Training is provided to official staff by VFB specialists from central level in accordance with annual training plans. This includes joint inspections of establishments. In addition, inspectors attend other training courses e.g. organised by universities and the Better Training for Safer Food sessions.
- Official staff has the obligation to attend training and this is evaluated during annual appraisal exercise including the identification of individual training needs.
- Inspectors interviewed at CVCs had received training on a regular basis and relevant for their tasks e.g. on food/fish hygiene, Hazard Analysis Critical Control Points system (HACCP), veterinary medicinal products etc.

Regarding verification procedures, the audit team noted that supervision of the performance of official controls is carried out at different levels according to specific procedures:-

- Comprehensive individual job descriptions are in place for official staff. Inspectors are assessed by their immediate superiors during an annual appraisal exercise carried out in accordance with VFB Director's Decree (hereafter: Decree) 201 of 18.12.2008. In addition, inspectors are audited by specialists from VFB central level every three years in accordance with Decree 6 of 11.01.2012. These audits include an assessment of their competence on-the-spot (observed inspection).
- Annual reports on control activities carried out by official staff have to be submitted to the VFB central by 15 January for the previous year, using a prescribed Excel format. The central level compiles these data and produces overall annual reports. Compiled tables and overall reports on official controls of fishery products in 2013 and 2012 were available to the audit team.
- The VFB informed the audit team that the Food Control Information System will be operational from 01.07.2014 (according to amendment of relevant Acts, the system is foreseen to operate as State Food and Feed Business Operator Register). The inspection data module (including database for supervision analyses - DSA) of this system will be operational from January 2015.

With regard to freedom from conflict of interest, the audit team noted that official staff had signed a declaration of independence and impartiality where reference is made to Act on Public Service and Act on Anticorruption.

With regard to documented control procedures, the audit team noted that:-

- A number of VFB Decrees are in place with comprehensive instructions and check-lists covering several areas of official controls such as approval of food establishments, planning and reporting on official controls, risk assessment of food business operators and related frequency of controls, audit of food business operators (HACCP), sampling procedures, verification of official controls, drafting of inspection reports, procedures for sanctions and management of RASFF notifications. These procedures, which are generally in line with EU requirements, are available to (via e-mails and VFB document management system) and used by official staff.
- At the beginning of every year, inspectors prepare risk-based inspection and sampling plans for the establishments assigned to them, in accordance with relevant Decrees setting the minimum frequency of official controls (see also Section 5.3.1.1). These plans are approved by Heads of CVCs before their submission to the VFB central level. Decree 105 of 04.06.2013 describes the procedures for planning and reporting on official controls.

- Reports on official controls are always drawn up using standardised formats and copies are provided to food business operators.
- The MA has issued several guidance documents intended for use by various stakeholders – food business operators (including aquaculture farmers, fishermen and retailers), consumers and CAs (VFB and EI) e.g. handbook “From catch to sale”, guidelines on registration of establishments, self-controls plans, fish freshness categorisation, drinking water supply, labelling requirements at retail and information on PAHs and dioxins. These documents are available at MA websites or/and have been distributed to CVCs and in turn to food business operators.

Regarding control activities, methods and techniques, the audit team noted that tasks related to official controls are, in general, satisfactorily carried out by inspectors, using appropriate control methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis.

With regard to enforcement measures, the audit team noted that:-

- CA has an extensive range of enforcement instruments at its disposal to perform its tasks, such as drawing up official reports, issuing warnings, imposing fines or penalties, suspension of activities, restricting or prohibiting of placing products on the market and withdrawal of approval authorisations. These powers are based upon provisions of the Estonian Food Act, Substitutive Enforcement and Penalty Payment Act and the Code of Enforcement Procedure.
- In addition to above Acts, Decree 17 of 22.01.2014 provides guidelines on penalty payment procedures and Decree 62 of 01.03.2013 provides instructions on drawing up inspections reports (in a prescribed format), including provisions on sanctions.
- In case of non-conformities, the inspection reports contain “precepts” for the food business operators including deadlines for implementation of corrective measures and, where applicable, penalty warnings. In general (i.e. applied in most cases), if non-conformities are not corrected by the set deadline, a penalty would be issued.
- In one CVC visited, the audit team was informed about the case of illegal handling of fishery products. A penalty (fine) was issued to the operator and all products were destroyed.

## **Conclusions**

Competent authorities responsible for the official control of fishery products are clearly designated as required by Article 4 of Regulation (EC) No 882/2004.

Official controls are carried out on a risk basis, according to documented procedures, and comply with most of the requirements laid down in Articles 3 to 10, 54 and 55 of Regulation (EC) No 882/2004.

## **5.2 REGISTRATION/APPROVAL OF FOOD BUSINESS OPERATORS ESTABLISHMENTS**

### **Legal requirements**

Article 6 of Regulation (EC) No 852/2004, Article 4 of Regulation (EC) No 853/2004, Article 3 of Regulation (EC) No 854/2004 and Article 31 of Regulation (EC) No 882/2004.

### **Findings**

The Food Act (in force since 2000, last amended in 2013) contains general requirements regarding registration and approval of food business operators in line with relevant EU regulations, including

provisions on suspension and withdrawal of approval decisions. Detailed procedures for approval of establishments are provided in national Regulation 84 of 30.05.2007 and in Decree 100 of 22.08.2012. Registration and approval procedures for aquaculture farms are provided in national Regulation 88 of 18.12.2002.

In order to be registered or approved, the food business operators have to send applications with relevant information to a CVC. For approval, the local inspector carries out assessment of compliance including an on-the-spot visit with HACCP evaluation. The approval application and opinion of the local inspector are forwarded to the VFB central level where the final decision is taken. Approved establishments receive a unique approval number and are included in the list which is available on the VFB website.

According to the VFB, farms which supply live fish to other farms and those which place on the market more than “small quantities” of fish to final consumer/local retail level are subject to approval while for other farms registration is sufficient; this is in accordance with national Regulation 88 of 18.12.2002. A list of approved aquaculture farms is available on the VFB website. The audit team was informed that Estonian Agricultural Registers and Information Board keeps a public register of aquaculture businesses in line with Commission Decision 2008/392/EU.

Small quantities of primary products which may be supplied to the final consumer or local retail establishments are defined in national Regulation 72 of 15.06.2006. For fishery products, this quantity is 100 kg per day.

The MA Fishery Economics Department is responsible for management of commercial fishing including issuing fishing permits, catch accounting and managing a national registry of fishing vessels - Fisheries Information System (*Kalanduse Infosüsteemist* - KIS). All vessels used for professional fishing have to be registered (see figures in Section 5.3.1.2). The same registry also contains updated information on landing sites and landings. Access to the registry is granted to the VFB staff and other external users upon request.

According to the Food Act, independent enterprises engaged in transport of food are subject to registration by the VFB. In case of transport means belonging to registered or approved establishments, the latter have the obligation to notify them to the VFB. The list of registered transport means is available on the VFB website and was provided to the audit team.

Guidelines and forms for food business operators having the obligation to register their activities are available on the VFB website.

The audit team noted that:-

- Processing establishments and the cold store visited were approved by the VFB. Approval documentation checked by the audit team showed that approval procedures have been carried out in accordance with the EU requirements, albeit the final approval and official control can be based on a documentary check, rather than an on-the-spot visit (see Section 5.3.1.4).
- A list of 14 registered primary producers is available on the VFB website, some of which also engaged in processing activities which included smoking of fishery products. A clear explanation why these operators had not been approved rather than registered could not be provided and the VFB undertook to investigate the matter and revise this list.

## **Conclusions**

The procedures in place for registration and approval of food business operators are compliant with the EU regulations and generally well implemented by the CA. However, some establishments requiring approval in line with Article 6(3)(b) of Regulation (EC) No 852/2004 have not been approved.

## 5.3 OFFICIAL CONTROLS

### 5.3.1 Official control of production and placing on the market

#### Legal requirements

Article 4 and 5 of Regulation (EC) No 852/2004, Article 3 and Section VIII of Annex III to Regulation (EC) No 853/2004 and Article 4 of Regulation (EC) No 854/2004 and Chapter I of Annex III to Regulation (EC) No 854/2004. Regulation (EC) No 2073/2005.

#### Findings

##### 5.3.1.1 Official control system in place

At central level, VFB is responsible for the official coordination and supervision of the fish sector, drafting procedures, work instructions and standardised check-lists to facilitate the performance and consistency of official controls. Official controls of factory vessels shall be performed by the chief hygiene specialist from the central level (in exceptional cases they could be carried out by CVC inspectors).

The CVCs are responsible for controlling the whole chain of production of fishery products, including aquaculture farms, fishing vessels, landing sites, processing establishments, cold stores and retail market. Control activities include, inter alia, evaluation of sampling results, assessment of HACCP plans and follow-up in case of identified non-conformities.

Check-lists are available for official controls at different stages of production chain i.e. aquaculture farms, fishing vessels, landing sites and (processing) establishments.

Decree 9 of 15.01.2014 (superseding the previous Decree 14 of 2012) provides instructions for official controls of fishing vessels, landing sites and establishments handling fishery products, including the minimum frequencies:-

- fishing vessels i.e. trawlers longer than 12 m and their landing sites (including sites used by trawlers from other counties) - an inspection once every two years (before 2014 the requirement was once per year),
- factory vessels – an inspection once in three years,
- establishments – a comprehensive audit once a year plus one to three inspection visits (which can be regular checks, follow-up visits, visits due to complaints etc.) depending on the risk categorisation: high risk – three times per year, medium risk – two times per year and low risk – once per year.

Procedures for auditing of establishments (at least once a year) are laid down in Decree 168 of 31.12.2013. The risk category of establishments is determined every year by CVC inspectors, taking into account criteria provided in Decree 9 of 15.01.2014 i.e. type of the product, production volumes, level of compliance with hygiene requirements and own-checks systems in place. This Decree also stipulates the minimum frequencies of sampling for each risk category and of some other checks:-

- traceability of raw materials and final products - twice per year,
- food business operator's measures to prevent fish from the Baltic Sea (Baltic herring and sprat) which is likely to contain dioxins and PCBs above the EU permitted limits from being placed on the market – once per year (see also Section 5.3.1.4),
- fish freshness assessment (categorisation) carried out by food business operators – every visit.

Except for comprehensive audits, official controls should be generally carried out without prior

warning to the food business operator.

According to one CVC inspector interviewed, there is no specific requirement for regular visits of registered establishments but these would be typically triggered by complaints and tip-offs; if a certain level of processing is carried out in such establishments (e.g. home production), inspections take place once per year. Transport means belonging to approved establishments are checked at establishment's level; this would apply also to independent transport means for which controls are generally initiated by complaints and tip-offs.

#### *5.3.1.2 Primary production*

##### Aquaculture farms

According to the VFB, there are 29 and 18 approved fish and crayfish farms, respectively, and a number of small-scale fish farmers.

Aquaculture farms have been inspected at least once per year in accordance with instructions and the comprehensive check-list from Decree 34 of 07.02.2014 (superseding the previous Decree 134 of 2011). These inspections cover, inter alia, hygiene requirements for primary production and the use of veterinary medicinal products. In the CVC responsible for the farm visited by the audit team, reports of regular inspections of farms including identified non-conformities, deadlines for corrective actions and follow-up checks were available.

According to the CVC inspector interviewed, the same control frequencies apply to both approved and registered farms, with some differences in the approach (e.g. samples for fish diseases tests are not taken from registered farms which only sell small quantities as defined by national rules). Since 2014, farms should be visited at least twice per year including one comprehensive inspection.

The audit team visited one hatchery/aquaculture farm (rainbow trout and arctic char) and noted that:

- Records in relation to the origin of feed, use of veterinary medicinal products (including veterinary prescriptions), mortality, water quality, harvesting and destination of harvested fish were kept by the food business operator.
- The farm was undergoing reconstruction of concrete ponds but natural ponds were operational. The facilities visited (hatchery, store rooms etc.) have been recently reconstructed and were in good condition.

##### Fishing vessels

There are four types of vessels engaged in primary production: trawler vessels longer than 12 metres (38); coastal sea fishing vessels less than 12 metres long (1403); inland vessels (469) and factory vessels (seven). In 2013, domestic trawlers landed approximately 67% of total fish landings in Estonia, coastal sea and inland fishing vessels together accounted for approximately 20% and fishing vessels from other Member States landed approximately 13% of fish.

Decree 9 of 15.01.2014 provides for official controls of trawlers longer than 12 m and their landing sites (see Section 5.3.1.1); information about trawlers and landing sites should be obtained from KIS (see also Section 5.2). The control system does not foresee regular inspections of fishing vessels other than trawlers.

The audit team noted that:

- According to the VFB, 27 (out of 42) and five (out of 39) trawlers were inspected in 2012 and 2013, respectively. The overall report for 2013 on controls of food business operators in fish sector links the lower control frequency than planned mainly with vessels being under repair or decommissioned. The same report indicates that in most cases vessels are inspected before going fishing.

- Inspection records for trawlers were available and generally kept in good order by inspectors interviewed. In one county visited, six to ten trawlers were checked annually between 2009 and 2012. However, apart from one case (in 2009), trawlers were always inspected before the start of fishing season (after maintenance works). As they were not in operation, inspections covered structural and equipment requirements but correct handling of fishery products could not be verified in line with the relevant check-list.
- In another county visited, the inspector carried out several controls of inland fishing vessels and landing sites, generally during landing operations, when inspecting four establishments with private quays. Another inspector met at one establishments stated that he would occasionally check the coastal sea vessels belonging to that establishment but these checks are not being recorded (as only controls of trawlers are compulsory).
- CVCs shall keep updated lists of vessels subject to official controls in respective counties. While 38 trawlers are currently listed in KIS, the data provided by CVCs include 26 trawlers one of which is not listed in KIS. In one county visited (where landings by a trawler took place in 2013), CVC staff did not have access to KIS.
- The fish inspectors interviewed stated they would generally gather information on availability (location) of vessels for inspection from food business operators (i.e. vessels' owners or establishments receiving fish from these vessels).
- The trawler visited by the audit team was not in operation but nevertheless presented generally adequate hygiene conditions. The intake of sea water (used for cleaning) was not positioned to avoid contamination by waste-water discharges. The owner stated to apply a time lag between these two operations. Annual inspection documents (2010-2012) were available on-the-spot.

#### *5.3.1.3 Landing operations, landing sites and first sale*

According to data provided by the VFB, there are no auction halls or wholesale markets for fishery products in Estonia. Currently there are 1047 active landing sites located in 13 counties. National rules provide for official controls of landing sites used by trawlers (see Section 5.3.1.1) and relevant information should be obtained from KIS. In 2013, trawlers were landing fish in 24 landing sites.

According to the VFB, during official controls of establishments with (private) quays, landing operation would be checked if landing takes place at the time of inspection.

The audit team noted that:-

- According to annual tables compiled by the VFB (see Section 5.1), 18 landing sites - five of which were inland - were inspected (during 21 visits) in 2012 and one (during two visits) in 2013.
- In one (trawlers') landing site visited, inspection records for this and two other landing sites frequently used by trawlers were available. Similarly to the situation with trawlers (see Section 5.3.1.2), these sites were inspected when landing operations were not taking place.
- All four landing sites visited (two were private quays belonging to establishments) presented generally adequate conditions in terms of structure. According to CVC inspectors and food business operators, ice used in fishing vessels is provided by establishments (which is generally not deemed necessary in winter months).
- Landing sites in two counties visited with no registered trawlers but used by trawlers from other counties are not being inspected by CVC inspectors.

#### 5.3.1.4 *Facilities, including vessels, handling fishery products*

##### Factory vessels

According to the VFB, Estonian factory vessels operate in Atlantic Ocean, mainly catching and processing shrimp (five vessels) or deep-sea fish (two vessels). Official controls take place in ports outside Estonia and relevant documentation was available at the VFB central level. These vessels were not available for a visit by the audit team.

The audit team reviewed two files of factory vessels. One of them has been recently approved (in 2013) and documents showed that approval procedure was carried out in line with the EU and national requirements; non-conformities identified during inspection which resulted in conditional approval were followed-up before granting the final approval by documentary check.

For the other factory vessel only the approval decisions (from 2000, 2002 and 2010) and records of the last inspection in 2010 were available (report and check-list). Some non-conformities were identified during that inspection but in this case, there was no evidence available of their follow-up.

##### Processing establishments and cold stores

The audit team visited seven approved establishments (six processing plants and one cold store) and noted that:

- Official controls have been regularly carried out by CVC inspectors in line with the procedures and instructions and respecting the prescribed risk-based frequency. Records of official controls including identified non-conformities and deadlines for corrective actions were available on-the-spot. The follow-up of deficiencies was carried out during the following regular inspection or before, depending on the severity of shortcomings.
- Official controls include, inter alia, checks on good hygiene practices (layout, structure, equipment etc.), HACCP audits and verification of traceability. Where traceability exercises were performed by the audit team, establishments were able to identify both the suppliers of raw materials and the destination of products.
- In general, establishments visited presented adequate conditions regarding structure, equipment, maintenance and hygiene (where in operation). However, in some cases structural and hygiene-related deficiencies were noted by the audit team such as lack of temperature recording devices in one cold store room and prolonged immersion of fresh fillets in iced water, and some other minor issues e.g. use of rusty equipment, condensation in areas with exposed products, and poor drainage with pooling of water. Some of these deficiencies (e.g. lack of temperature recording devices and use of rusty equipment) were also identified during the 2008 FVO audit.
- A HACCP plan, in general adequately describing and addressing the main hazards related to the product, was in place and implemented in all establishments visited. However, the audit team noted also some deficiencies related to HACCP design and implementation which were not identified in the previous inspection reports of the CA:
  - in one establishment, HACCP plan did not cover all authorised and performed activities (the plan covered handling and storage of fresh fishery products but storage of frozen fishery products was not included; this type of deficiency was also noted during the 2008 FVO audit);
  - critical control limits were not always adequately set (in one establishment there was no time limit for smoking process and temperature limit for pasteurisation (roe) was left to be defined by clients);
  - although foreseen in the HACCP plan, there were no temperature records for a chilled

room with ready-to eat products in one establishment visited. The CA informed the audit team soon after the visit that the food business operator in question switched on an automatic temperature recording system (temperature of the chilled room 0 - +2 C).

- In addition to HACCP plans, the food business operators implemented prerequisite programmes covering health and training requirements for staff, sanitation and pest control programmes, requirements for drinking water etc. In cases reviewed by the audit team, records of implementation of prerequisite programmes were generally kept in good order.
- Own-check analyses (microbiology, chemistry, organoleptic properties (freshness) and parasites) of fishery products were generally performed on a regular basis and covered the main hazards. However, in establishments dealing with fish species where histamine hazard is relevant, samples were not taken in accordance with Regulation (EC) No 2073/2005 (one or six units were taken, always resulting in one analytical result) or were not taken at least in the last three years. Nevertheless, the CVC inspectors stated that they rely on own-checks in this regard and have not performed official sampling in these establishments. For one of them, the audit team was informed that sampling in line with EU requirements is planned under own-checks in 2014.
- Own-checks analyses for, inter alia, *L. monocytogenes* were carried out in establishments producing ready-to-eat fishery products and non-compliant results were communicated to the CVC. In two such cases, related to one establishment, this communication resulted in RASFF notifications being issued by the VFB (see also Section 5.4). The establishment carried out an investigation and took several corrective measures to address the issue (increased sampling/testing of raw material (which identified three possible suppliers of contaminated material), improvements in cleaning and sanitation procedures, shortening of shelf-life for products after thawing). However, the audit team noted that shelf-life evaluation studies for smoked product could not adequately demonstrate that the maximum permitted EU limit would be respected at the end of the product's shelf life (e.g. no initial level of contamination was known). The product continued to be placed on the market as long as the number of *L. monocytogenes* was below 100 cfu/g upon leaving the food business operator's immediate control, even if these bacteria were detected in 25 g. During official controls in 2013, attention was paid to shelf-life determination however this deficiency was not detected. The audit team was informed shortly after the visit that the food business operator started a new shelf-life study to address this issue.
- In general, the use of additives is controlled by CVC inspectors and examples of official sampling and testing were presented (see also Section 5.3.2). In one case verified by the audit team, a "precept" was issued due to mislabelling of additives. The audit team reviewed in several establishments the use of additives and they were all authorised and correctly labelled, except in one case where a non-authorised additive was used in smoked fishery product and this was not declared on the label (E 250 was used as component of salt for brine injection in smoked salmon).

#### 5.3.1.5 Dioxin controls in Baltic Sea fish

The 2012 FVO audit report recommended to the CA to strengthen the system of controls in place so that it can be ensured that effective measures are implemented to prevent Baltic Sea fish which may contain dioxins, dl- and ndl-PCBs above the maximum limits (MLs) set down in Commission Regulation (EC) No 1881/2006 from being placed on the market.

The CA has taken several steps to address this issue. A notification was sent to food business operators and CVCs to strengthen relevant own-checks with a deadline set at the end of October 2012 and specific training was provided to official staff in autumn that year. The comprehensive

check-list for official control of establishments was updated at the beginning of 2014 including the addition of a specific point to verify the operator's measures to ensure that Baltic herring and sprat exceeding the national limits are not being placed on the market. As indicated in the 2012 FVO audit report, the national maximum limits are 17 cm length/ 32g weight for Baltic herring and 12.5 cm length/ 11g weight for sprat.

The CVC inspectors have been assessing the effectiveness of measures implemented by food business operators during official controls at least once per year, as required by national rules (see also Section 5.3.1.1).

The audit team visited three establishments which have been dealing with fish species of concern (Baltic herring and sprat) and noted that:

- The food business operators were aware of the size/weight limits for the species concerned and the dioxins/PCBs-related risk was included in their HACCP plan or other procedures in place, including forms to record quantities of fish exceeding the national limits (oversized fish).
- One of the establishments, which regarding species of concern was only receiving Baltic herring from coastal waters, kept records of regular removal of large quantities of oversized fish from the production (at the sorting stage as foreseen in procedures). Records of removed quantities were available only for 2014; the audit team was informed that removal of oversized fish was also carried out in 2013 but records were lost during a previous third country's audit in that establishment.
- Implemented practices in two other establishments differed from documented procedures which were rather vague and sometimes inconsistent e.g. laboratory analysis being described as a monitoring procedure at critical control point but visual examination at sorting stage (with removal of oversized fish) was instead presented as the monitoring procedure currently implemented; updated EU ML was cited in the product description but the old EU ML was indicated as critical limit in HACCP table; sample size and batch rejection criteria were not defined where samples of incoming batches were checked for oversized fish (according to records, sample size was approximately 1 kg per batch). In the latter case, the food business operator provided evidence of staff training including checks related to dioxins.
- According to the food business operator in one establishment receiving mostly mixed catch of Baltic herring and sprat, no oversized fish has been found at least in the last four years (by checking samples of incoming batches). This situation differs from that described in the 2012 FVO audit report (i.e. data from MA and Estonian Environmental Research Centre - EERC for 2010 and 2011) that approximately 5 to 10% of landed Baltic herring and sprat is of a size considered to potentially contain levels of dioxins, furans and PCBs which exceed EU maximum levels. The records in this establishment could not always demonstrate that oversized sprat have been considered in their own-checks.
- In another establishment receiving mostly mixed catch of Baltic herring and sprat (and visited also during the 2012 FVO audit), dioxins were not considered as risk in sprat. According to the food business operator, visual examination had been carried out at the sorting stage. Records were kept showing, inter alia, quantities of removed oversized fish (above 17 cm). However, the audit team noted Baltic herring larger than 17 cm in blocks of frozen fish intended for human consumption (marked as "15+" (cm) sorting grade). The food business operator stated that analysis for dioxins and PCBs are occasionally carried out and test reports (in accordance with a third country requirements) for samples taken in February 2014 were provided.

- In all establishments visited, oversized fish was categorised as Category 3 animal by-products (as defined by Regulation (EU) No. 1069/2009). In two establishments which recorded the removed quantities of oversized fish, the latter were received by feed (fishmeal) producers.

## Conclusions

Official controls on production and placing of fishery products on the market cover all stages of production and are generally implemented in accordance with EU requirements, albeit these controls were not always performed at the planned frequency. In particular, the controls of primary production do not cover all types of fishing vessels and landing sites and generally do not verify handling conditions of fishery products at these stages. In some establishments visited, the deficiencies in infrastructures, HACCP programmes and own-checks (histamine testing and shelf-life studies for *L. monocytogenes*) detected by the audit team had not been previously identified by the CA.

Steps have been taken by the CA to strengthen the system of controls in order to prevent Baltic Sea fish which may contain dioxins and PCBs above the MLs set down in Commission Regulation (EC) No 1881/2006 (oversized fish) from being placed on the market. However, controls are currently not yet sufficiently rigorous to ensure that all relevant measures are consistently put in place and/or are always implemented effectively by the food business operators. The currently applied categorisation for oversized Baltic Sea fish declared unfit for human consumption (as Category 3 animal by-products) does not prevent this material from entering the feed chain for food producing animals.

Recommendation no. 2 of the 2008 FVO audit has been addressed. Recommendation no. 1 (concerning official controls in primary production/fishing vessels), recommendation no. 3 (concerning deficiencies found by the audit team in establishments visited) and recommendation no. 5 (as regards own-check sampling schemes and testing methods) of that audit were partially addressed. The latter applies also to recommendation no. 1 of the 2012 FVO audit report.

### 5.3.2 Official controls of fishery products

#### Legal requirements

Article 7 of Regulation (EC) No 854/2004 and Chapter II and III of Annex III to Regulation (EC) No 854/2004

#### Findings

Decree 9 of 15.01.2014 provides minimum sampling frequencies for fish establishments according to their risk category: high risk – three samples per year, medium risk – two samples per year and low risk – one sample per year.

At the beginning of each year, the VFB central level prepares a sampling plan with numbers of samples to be taken by CVCs and the types of tests, taking into account availability of budgetary resources. Annual sampling plans since 2012 covered microbiological criteria (*L. monocytogenes*, *Salmonella* spp., *Escherichia coli*), heavy metals (Lead (Pb), Cadmium (Cd) and Mercury (Hg) in 2012 and 2013, and Arsenic (As) in 2014), histamine, parasites, total volatile basic nitrogen (TVB-N) and additives (benzoic and sorbic acid). Total planned numbers of samples were 161, 166 and 151 in 2012, 2013 and 2014, respectively. In addition, numbers of sample units are indicated in line with EU requirements, where applicable (microbiological and histamine analysis).

Samples allocated to counties in the annual sampling plan are further allocated to establishments by respective CVCs, taking into account risk categorisation.

In addition to above sampling plans, a Decree on monitoring of contaminants is issued annually by

the VFB covering various food commodities and parameters. The monitoring plan for 2014 (Decree 47 of 21.02.2014) includes, inter alia, sampling instructions and methods for parameters to be analysed in the counties specified (reference is made to Commission Regulations (EC) Nos 1881/2006, 1882/2006, 333/2007 and 401/2006). For fishery products, the monitoring plan for contaminants in 2014 covers PAHs.

Decree 15 of 28.01.2013 provides guidelines for microbiological sampling and Decree 3 of 10.01.2014 provides guidelines on sampling documentation.

The VFB central level informed CVC inspectors in November 2013 on fish species of concern regarding histamine.

Samples taken by inspectors are analysed in official laboratories. The sampling records which accompany samples to laboratories do not identify food business operators/establishments where samples were collected.

As described in the 2012 FVO audit report, the EERC is responsible for co-ordinating the national monitoring programmes for dioxins, furans and PCBs and given the outcome of these programmes since 2005, it was decided not to test further samples of Baltic Sea fish in 2011 and 2012. In 2013, the VFB concluded a new contract (no. 3.4-29/334 of 08.11.2013) with EERC on monitoring which includes, inter alia, Baltic herring (23 samples) and sprat (6 samples) from different locations of Baltic Sea. In addition to dioxins and PCBs, samples should be analysed also for organic tin compounds, perfluorooctane sulfonate/ perfluorooctanoic acid (PFOS, PFOA), polybrominated diphenyl ethers (PBDEs) and heavy metals (Pb, Cd and Hg and As). According to the contract, results of these analyses should be available in December 2014 and the final report issued in April 2015.

The VFB informed the audit team that poisonous fishery products and biotoxins in fish are not considered a risk in production of fishery product in Estonia.

The VFB does not carry out sampling of drinking water and ice. Analyses of drinking water and production of ice only from this water are responsibility of food business operators and are checked during official controls. The audit team was further informed that public water supply is under surveillance of Estonian Health Board which would inform the VFB on problems identified, in accordance with co-operation agreement between the two authorities. In addition, the Health Board shall inform general public about public health risks identified in water supply.

With regard to organoleptic examinations the audit team noted that:-

- According to inspectors interviewed, they would generally carry out freshness assessment according to Council Regulation (EC) No 2406/96 if fish is available during visits to establishments. Evidence of these occasional checks was available in two establishments visited. Official organoleptic checks are not foreseen at other stages of production.
- Inspectors verify whether food business operators in fish establishments carry out organoleptic checks of fishery products and freshness categorisation of incoming fish; the latter is to be checked at every visit (see Section 5.3.1.1).

According to data provided by the VFB, a number of official samples were taken in 2012 and 2013 on the basis of annual sampling plans (see above). Test reports of analyses performed on official samples were available in all processing establishments visited and depending on the type of production they covered freshness indicators (TVB-N), contaminants (heavy metals), microbiological parameters (mainly *L. monocytogenes* in ready-to-eat products), parasitological checks and additives (benzoic and sorbic acid). The numbers of samples were generally in accordance with the establishment's risk category.

The audit team also noted that:

- According to inspectors interviewed, freshness indicators would be generally checked in case of suspicion.
- Samples for histamine analysis were not taken at establishments visited (see also Section 5.3.1.4). Examples of test reports from the official laboratory showed that nine units were analysed as required by EU rules. According to the information received in the laboratory visited, official samples in 2013 were only taken at Border Inspection Posts – BIPs.
- According to data provided by the VFB, 13, 20 and ten official samples were analysed for PAHs under monitoring programmes in 2009, 2011 and 2013, respectively. One of five samples resulted non-compliant in 2013 (when focus was on products of non-Estonian origin at retail level) and additional five samples from the same origin were analysed with compliant results.
- In one case of non-compliant results examined by the audit team (*L. monocytogenes* in 2013), the whole production lot in question (which was still kept in the establishment) was destroyed.
- According to data provided by the VFB, a number of official samples taken at BIPs were analysed for histamine, heavy metals, microbiological criteria, residues, parasites and additives in 2012 and 2013. In one establishment visited, the audit team noted that several samples from imported fish products have been taken at the BIP for microbiological (*Salmonella* spp.) and parasitological analyses. These results were compliant.

## Conclusions

Official controls of fishery products are generally carried out in accordance with EU requirements. However, organoleptic checks are not randomly carried out at all stages of production to verify compliance with the freshness criteria established in accordance with EU legislation.

The recommendation no. 4, to the extent verified by the audit team, has been addressed in a satisfactory way.

## 5.4 FOLLOW-UP OF RASFF NOTIFICATIONS

### Legal requirements

Articles 50 and 52 of Section I, Chapter IV to Regulation (EC) No 178/2002.

### Findings

Decree 169 of 31.12.2013 on implementation of RASFF procedures establishes, inter alia, rules for exchange of information between VFB central level (national contact point for RASFF), CVCs and BIPs and the responsibilities of the parties involved in the procedure.

The audit team noted that:-

- Four RASFF notifications were related to *L. monocytogenes* in ready-to-eat food in one establishment visited. One was issued in 2010 and three in 2013 (two of which were based on establishment's own checks – non-compliant results were communicated by the food business operator to CVC). In addition to these, the audit team reviewed a RASFF notification issued in 2014 and related to benzo(a)pyrene and PAHs in another establishment (not visited).
- Notifications were in general adequately followed-up by the CA. Instructions were sent from VFB central level to CVC which in turn requested actions from the food business operators. The latter identified the recipients of contaminated production lots (and informed

them where relevant), withdrawal took place and information was available on (intended) destruction or disposal (in case of *L. monocytogenes*, as Category 3 animal-by-products used for production of thermally processed feed for fur animals). Feedback on these and other measures taken was provided to CVCs and where applicable, VFB complemented the notifications in RASFF system with follow-up information (traceability of consignments).

- The food business operator involved in RASFF notifications due to *L. monocytogenes* adopted several measures to identify the source of contamination, limit its spread within the establishment and improve safety of the final product. However, the shelf-life evaluation studies were not adequate (see Section 5.3.1.4).
- With regard to benzo(a)pyrene /PAHs case, the food business operator provided the CA with test reports from an Estonian laboratory showing compliant results for their products. The VFB explained that there are differences in analytical approach between laboratories in Estonia (analysis of homogeneous content) and the Member State which has issued several such notifications (separate analysis of fish and oil). This issue was discussed at the MA (in October 2013) which raised it further at the EU level; according to the MA, a conclusion has not been adopted yet.

## Conclusions

RASFF notifications are followed-up in accordance with EU requirements.

## 5.5 LABORATORIES

### Legal requirements

Articles 11, 12 and 33 of Regulation (EC) No 882/2004, Article 1 and Annex I to Regulation (EC) No 2073/2005 and Article 2 and Section II of Annex II to Regulation (EC) No 2074/2005. Regulation (EC) No 1881/2006. Regulation (EC) No 333/2007. Regulation (EU) No 252/2012.

### Findings

Food Act contains general provisions regarding authorisation of laboratories which carry out analyses of official samples and national Regulation 88 of 06.06.2007 provides further details on authorisation procedure.

The audit team visited the Veterinary and Food Laboratory (VFL) in Tartu and noted that:

- The VFL is accredited to ISO 17025 by the national accreditation body - Estonian Accreditation Centre (*Eesti Akrediteerimiskeskus* – EAK), a full member of the European Co-operation for Accreditation. Methods used for fishery products are included in the scope of accreditation and according to VFL, only reference methods have been used. The scope of testing covers most of the parameters foreseen by the VFB for official control of fishery products.
- According to VFL, dioxins and PCBs analyses are subcontracted to a laboratory in another Member State. PAHs analyses are carried out in the Health Board laboratory.
- The VFL central laboratory in Tartu and its three branch laboratories in Tallinn, Rakvere and Saaremaa have been authorised by the VFB in line with national rules (by Decree 158 of 09.04.2014 which superseded previous authorisations of 2010). The VFL has been also authorized as the National Reference Laboratory (NRL) for, inter alia, analyses of several microbiological parameters and chemical elements (heavy metals) in food.
- The central VFL stated that in practice official analyses of fishery products (except PAHs) are only carried out by VFL laboratories thus the NRL duties are performed in relation to

their branch laboratories. Documented examples of activities in the microbiology area were provided to the audit team i.e. recently organised ring test for various parameters for VFL branch laboratories and meetings with these laboratories. According to VFL, official analyses of chemical elements (heavy metals) are only carried out by the central VFL.

- The most recent (surveillance) assessment by the EAK was carried out in May 2014. The non-conformities raised did not relate to analyses of fishery products. The EAK assessments include visits to VFL branch laboratories.
- According to the VFL quality manager, their policy is to cover with internal audits all relevant points of ISO 17025 in each department over a five-year cycle. Horizontal (covering a specific topic in several departments and/or branch laboratories) and vertical (within one department) internal audits have been carried out. Evidence of both types was available e.g. horizontal audit on sample handling (including two branch laboratories) and vertical audit in the chemistry department in 2013, including follow-up of deficiencies.
- Since the 2008 FVO audit, the VFL chemistry department has participated in several proficiency testing (PT) schemes using fish/seafood matrix (heavy metals in 2008-2010, TVB-N in 2010 and histamine in 2008 and 2013) with satisfactory results except in one case in 2010 when for Pb they were questionable. Heavy metals have also been tested under PT schemes in other matrices e.g. meat and honey in 2013. Since 2008, the microbiology department has participated every year in PT schemes for *Salmonella* spp. and *L. monocytogenes* in various matrices, in some years also for *Escherichia coli* and *Clostridium perfringens*. The results were satisfactory.
- PT schemes were provided by EU Reference Laboratories (EURLs) and commercial providers. According to VFL, their policy is to participate in PT at least once in five years for every parameter where schemes are available.
- Annual training plans for different departments include internal and external training (e.g. on analytical methods for fishery products in 2012, attendance to meetings and courses organised by EURLs). Training reports are evaluated during annual management review, as seen in the review report for 2013. It was also mentioned that VFL staff participate as experts in assessments carried out by the EAK in other national laboratories.
- There is general information (warning) for clients in place at the sample reception area on the circumstances under which a sample could be rejected e.g. late arrival, spoilage, insufficient volume, incomplete documentation etc. More specific sample acceptability criteria were not established (e.g. for temperature or volume limits etc.). According to the VFL, decision on rejection of a sample is taken by the relevant head of department.
- Analytical method for histamine was examined by the audit team. The reference method (HPLC) is used as foreseen in the Regulation (EC) No 2073/2005. Standard operating procedure, validation protocol and results were in place including calculations of detection limit (1 mg/kg), repeatability, random and systematic errors and measurement uncertainty. However, recovery of the method has not been assessed and reproducibility is only presented as a PT z-score which has to be below +/- 2. Standard solutions (1 – 50 mg/l) were used for the calibration carried out during the validation exercise (in 2006).
- External servicing of the HPLC instrument has been carried out regularly and a maintenance chart was available. According to the VFL, calibration is performed after replacement of the column. Documents subsequently provided to the audit team showed that the column was last replaced in May 2013 and two different concentration levels were used to verify the instrument performance (in August 2013 as there were no samples analysed in-between; verification was also done just before the column replacement). However, there were no

criteria for assessment of this performance or to verify the validity of former calibration.

- No internal positive or negative controls have been carried out for histamine analyses. According to the VFL, control material from a previous PT sample would be used to verify the result in case of non-compliance. No such results have been obtained to date.
- The laboratory premises and equipment seen were in good state of maintenance. However, some poor practices related to analytical standards were observed i.e. combined storage of analytical standards and PT samples and no expiry date established for the histamine standard (package opened in 2010).

## **Conclusions**

The laboratory visited operates and is accredited to ISO 17025, and successfully participates in regular proficiency testing. Analytical methods used in the context of official controls are covered by the scope accreditation. As a NRL, it generally fulfils the requirements of EU legislation. However, deficiencies in the validation of method used for histamine determination and lack of certain quality controls do not enable the laboratory to fully demonstrate the reliability of these analytical results.

## **6 OVERALL CONCLUSIONS**

The report concludes that there is an organised and documented official control system in place which is in accordance with the relevant provisions of Regulation (EC) No 882/2004. In general, this control system is consistently and adequately implemented and covers the fishery products production chain. Some shortcomings were identified in the establishment approval process.

Official controls are generally implemented in accordance with EU requirements., Nonetheless, certain weaknesses were identified in the control of fishing vessels and landing conditions (including organoleptic checks), HACCP evaluation and verification of food business operators' own-checks for some microbiological criteria.

Furthermore, although steps have been taken by the CA to strengthen the system of controls over Baltic Sea fish which may contain dioxins and PCBs above the EU maximum limits, some gaps remain in measures put in place and their implementation by some food business operators.

In the laboratory visited, methods used for official analyses are included in the scope of accreditation. However, deficiencies in validation and internal quality controls were noted in method for histamine analysis.

## **7 CLOSING MEETING**

During the closing meeting held in Tallinn on 20 June 2014, the audit team presented the main findings and preliminary conclusions of the audit to the CA.

During this meeting, the CAs acknowledged the findings and preliminary conclusions presented by the audit team.

## **8 RECOMMENDATIONS**

The CA should provide Commission services with an action plan, including a timetable for its completion, within 25 working days of receipt of the report, in order to address the following recommendations for fishery products exported to the EU.

| N°. | Recommendation   |
|-----|--|
| 1.  | The CA should ensure that all establishments requiring approval in line with Article 6(3)(b) of Regulation (EC) No 852/2004 are approved.  |
| 2.  | The CAs should ensure that all types of fishing vessels are regularly inspected as required by Chapter I, part 1 (b) of Annex III to Regulation (EC) No 854/2004 and that requirements of Chapter I, Section VIII of Annex III to Regulation (EC) No 853/2004 are met.   |
| 3.  | The CA should ensure that official controls on the landing of fishery products are carried out regularly with checks on the hygiene conditions of landing as required by Chapter I, part 1 (a) of Annex III to Regulation (EC) No 854/2004.  |
| 4.  | The CA should ensure, through assessment of the HACCP plans in approved establishments, that food business operators implement and maintain procedures based on HACCP principles that fully comply with Article 5 of Regulation (EC) No 852/2004. In particular, that limits set for critical control points are in line with EU requirements and food business operator' own-checks guarantee that products comply with microbiological criteria laid down under Regulation (EC) No 2073/2005 ( <i>Listeria monocytogenes</i> and histamine). |
| 5.  | The CA should ensure that random organoleptic checks of fishery products are carried out at all stages of production, processing and distribution as required by Chapter II, part A of Annex III to Regulation (EC) No 854/2004.   |
| 6.  | The CA should ensure that sampling plans for histamine used in the context of food business operators' own checks comply with the requirements laid down in Regulation (EC) No 2073/2005.  |
| 7.  | The CA should ensure that the system of controls in place is further strengthened so that effective measures are implemented to prevent Baltic Sea fish which may contain dioxins, dl- and ndl-PCBs above the MLs set down in Commission Regulation (EC) No 1881/2006 from being placed on the market.   |
| 8.  | The CA should ensure that Baltic Sea fish which may contain dioxins and PCBs above the MLs set down in Commission Regulation (EC) No 1881/2006 (oversized fish declared as animal by-products unfit for human consumption) is correctly categorised by food business operators in line with Regulation (EU) 1069/2009.   |
| 9.  | In order to fully demonstrate the reliability of the analytical results of official control testing for histamine, the CA should ensure that the deficiencies found at the laboratory visited by the audit team are corrected, in particular with regard to method validation and internal quality controls.   |

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=2014-7132](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2014-7132)

## ANNEX 1 - LEGAL REFERENCES

| Legal Reference  | Official Journal  | Title   |
|------------------|---|---|
| Dec. 2008/392/EC | OJ L 138, 28.5.2008, p. 12-20   | 2008/392/EC: Commission Decision of 30 April 2008 implementing Council Directive 2006/88/EC as regards an Internet-based information page to make information on aquaculture production businesses and authorised processing establishments available by electronic means |
| Reg. 2406/96     | OJ L 334, 23.12.1996, p. 1-15   | Council Regulation (EC) No 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery 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   |

| <b>Legal Reference</b> | <b>Official Journal</b>        | <b>Title</b>  |
|------------------------|--------------------------------|---|
| 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. 1881/2006         | OJ L 364, 20.12.2006, p. 5-24  | Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs   |
| Reg. 1882/2006         | OJ L 364, 20.12.2006, p. 25-31 | Commission Regulation (EC) No 1882/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs   |
| Reg. 333/2007          | OJ L 88, 29.3.2007, p. 29-38   | Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs   |
| Reg. 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)   |

| <b>Legal Reference</b> | <b>Official Journal</b>     | <b>Title</b>   |
|------------------------|-----------------------------|--|
| Reg. 252/2012          | OJ L 84, 23.3.2012, p. 1-22 | Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006 |