FINAL REPORT OF AN AUDIT
CARRIED OUT IN
SWEDEN
FROM 18 MAY 2015 TO 29 MAY 2015
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 Sweden carried out from 19 to 29 May, as part of its programme of audits in Member States.

The objectives of the audit were to assess whether the organisation of the Competent Authority (CA) and the implementation of national provisions, against which the CA controls fishery products is compliant with EU requirements and to follow-up the recommendations of the previous audit reports DG(SANCO) 2010-8529 and DG(SANCO) 2013-6767.

The report concludes that there is an official control system in place, covering fishery products and their production chain. This control system allows only partially the competent authority to provide appropriate guarantees with regard to the food safety of fishery products. In particular Sweden cannot provide sufficient guarantees that fatty fish from the Baltic region exceeding EU limits for PCBs/dioxins is not traded to other Member States. Other weaknesses were identified concerning the lack of official controls of fishery vessels for primary production, training of staff, traceability, HACCP evaluation and absence of systematic analytical testing of fishery products. Six of eight of the recommendations of the above mentioned audits on fishery products are not fully addressed.

The report addresses to the Swedish competent authority a number of recommendations aimed at rectifying identified shortcomings and enhancing the control system in place.
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<th>Explanation</th>
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<tbody>
<tr>
<td>CAB</td>
<td>County Administration Board</td>
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<tr>
<td>CCA/CA</td>
<td>Central Competent Authority/Competent Authority</td>
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<td>CCP</td>
<td>Critical Control Point</td>
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<td>DG MARE</td>
<td>Directorate-General for Maritime Affairs and Fisheries of the European Commission</td>
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<td>DG SANTE/SANCO</td>
<td>Directorate-General for Health and Food Safety of the European Commission, before 2015 named DG SANCO</td>
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<td>EC</td>
<td>European Community</td>
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<td>ECOS</td>
<td>Database for planning of inspections and reporting in municipalities</td>
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<td>EEA</td>
<td>European Economic Area</td>
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<td>ELISA</td>
<td>Enzyme-linked Immuno-Sorbent Assay</td>
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<td>ELVIS</td>
<td>Database for planning of inspections and reporting in municipalities</td>
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<td>EU</td>
<td>European Union</td>
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<td>EUROSTAT</td>
<td>Statistical Services of the European Union</td>
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<td>FBO</td>
<td>Food Business Operator</td>
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<td>FVO</td>
<td>Food and Veterinary Office</td>
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<td>HACCP</td>
<td>Hazard Analysis and Critical Control Points</td>
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<td>HPLC</td>
<td>High Performance Liquid Chromatography</td>
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<td>ICES</td>
<td>International Council for the Exploration of the Sea</td>
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<td>MS</td>
<td>EU Member State/s</td>
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<td>NFA</td>
<td>National Food Administration</td>
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<td>NRL</td>
<td>National Reference Laboratory</td>
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<td>PAH</td>
<td>Polycyclic Aromatic Hydrocarbons</td>
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<td>PCBs</td>
<td>Polychlorinated Biphenyls</td>
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<tr>
<td>PIMKO</td>
<td>Planering Inom och Mellan Kontrollområden. IT tool for planning of NFA inspections</td>
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<td>QMS</td>
<td>Quality Management System</td>
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<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
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<td>SAMWM</td>
<td>Agency for Marine and Water Management</td>
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<td>SWEDAC</td>
<td>Swedish Board for Accreditation and Conformity Assessment</td>
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<tr>
<td>TVB-N</td>
<td>Total Volatile Basic Nitrogen</td>
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<td>TWI</td>
<td>Tolerable Weekly Intake</td>
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1 INTRODUCTION

The audit took place in Sweden from 18 to 29 May 2015 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 Uppsala on 18 May with the National Food Administration (NFA) which is the central competent authority (CCA) within the scope of this audit. A representative of the municipalities was present. This meeting was not attended by representatives from the County Administration Boards (CAB), responsible for official controls on primary production of fishery products. 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.

2 OBJECTIVES AND SCOPE

The objectives of the audit were to:-

- Assess whether the organisation of the Competent Authority (CA) and the implementation of national provisions, against which the CA controls fishery products is compliant with EU requirements.
- Follow up the recommendations of the previous audit reports DG(SANCO) 2010-8529 and DG(SANCO) 2013-6767.

In terms of scope the audit focused on the organisation and performance of the CAs, 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 a technical basis for the audit. Full legal references to EU legal acts quoted in this report are provided in that Annex and refer, where applicable, to the last amended version.

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

<table>
<thead>
<tr>
<th>COMPETENT AUTHORITY</th>
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<tbody>
<tr>
<td>Central level</td>
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<tr>
<td>Municipality Level</td>
<td>2</td>
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<td>Local level</td>
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<tr>
<th>LABORATORY</th>
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<td>Official</td>
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<tr>
<th>LANDING AND FIRST SALE</th>
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<tr>
<td>Auction halls</td>
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<tr>
<th>FACILITIES HANDLING FISHERY PRODUCTS</th>
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<tbody>
<tr>
<td>Factory vessels</td>
<td>1</td>
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</tbody>
</table>
Processing plants | 5
Cold stores | 1 with block freezing

Representatives from the NFA accompanied the audit team during the whole audit.

3 **LEGAL BASIS**

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

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**

Two previous audits took place with relevance in relation to the present one:

In 2010 the audit (ref. DG(SANCO)/8529/2010) concerned official controls of fishery products. The report of this audit highlighted deficiencies in relation to official controls over fishing vessels, factory vessels and auction halls, as well as absence of official controls of fishery products, controls on parasites and sampling for histamine.

Recommendations were made with regards to:

- Training of staff (Recommendation 1).
- Only full compliant establishments should be approved (Recommendation 2).
- Factory vessels should be improved (Recommendation 3).
- Fishing vessels and auction halls should be regularly inspected (Recommendation 4).
- Official controls should be implemented including laboratory testing (Recommendation 5).
- HACCP plans in establishments should be in place and assessed (Recommendation 6).

In 2013 an audit (ref. DG(SANCO)/6767/2013) concerning controls of dioxins, furans and PCBs in fish from the Baltic region was carried out. The report of this audit highlighted the lack of an effective controls system to prevent fish from the Baltic region exceeding EU limits for dioxins/PCBs to be traded to non-eligible Member States (MS) and the lack of instructions and documentation for the staff responsible for these controls.

Recommendations were made with regards to:

- Implementation of an effective control system to ensure that fish from the Baltic region which exceed EU limits for dioxins and PCBs are not traded to other MS (Recommendation 1).
- Ensuring that inspectors had the necessary instructions and information available (Recommendation 2).
Both reports are published on the Health and Food Safety Directorate-General’s (SANTE) Internet site at http://ec.europa.eu/food/fvo/ir_search_en.cfm.

4.2 PRODUCTION AND TRADE INFORMATION

In Sweden and at foreign ports landings by Swedish vessels in 2014 amounted to around 185,000 tonnes. 60% of the landed fish was caught in the Baltic. The main species were herring, Clupea harengus (47%), sprats, Sprattus sprattus (30%), the lesser sand eel, Ammodytes tobiatus (10%), cod, Gadus morhua (4%), and mackerel, Scomber scombrus (2%). Around 200 tonnes Baltic salmon, Salmo salar was landed in 2014.

According to data provided by the CA there is also a small volume of fishery products derived from aquaculture. Data from 2013 show a production of around 12,000 tonnes of finfish, of which, 90% rainbow trout, Oncorhynchus mykiss followed by small amounts of arctic char, Salvelinus alpinus and eel, Anguilla anguilla. Around 90% of the Swedish aquaculture harvest goes to Finland.

According to EUROSTAT, in 2013 around 700,000 tonnes of fishery products were received by Sweden via MS or EEA countries, 95% from Norway. According to the NFA Sweden imported around 27,000 tonnes from third countries in 2014. These imports consisted mainly of fishery products from China (15,000 tonnes) followed by Thailand (4,400 tonnes) and Vietnam 2,400 tonnes).

According to the list established by the CA and available on the CA website, there are a total of 279 establishments, two auction halls and 57 factory vessels authorised to place fishery products on the market. Most of the factory vessels are small vessels, which cook crustaceans and Norwegian lobsters on board. There are no freezer vessels registered in Sweden.

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

Since 2013, there have been 11 RASFF notifications, mainly concerning the unauthorised placing on the market of wild caught Baltic salmon and the presence of Listeria monocytogenes in ready to eat fishery products.

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITY

Legal requirements


Findings

Designation of competent authorities and operational criteria

1. The NFA is the CCA for food of animal origin and non-animal origin and is responsible for legislation at federal level. It reports to the Ministry of Enterprise and Innovation. The fishery products area is within Food Control Division under the General Director. The NFA contributes to development of general administrative provisions and assists its four regional branches and the municipalities involved in controls of fishery products as a coordinating and managing office. The NFA is the national contact point for RASFF
2. The NFA is responsible for approval of fishery products facilities, for planning and implementing official controls, for the designation of official laboratories and for the application of enforcement measures. At the time of the audit, two auction halls, 288 establishments and 56 factory vessels were approved. The factory vessels mainly cook shrimp or Norwegian lobster immediately after the catch.

3. NFA has transferred the responsibility for official controls of establishments in three municipalities: Gothenburg (35 establishments), Stockholm (15) and Falkenberg (2) by decision to the municipalities concerned.

4. The Agency for Marine and Water Management (SAMWM) – under the Ministry of Environment - is responsible for the controls of fishing vessels concerning e.g. catch quotas and traceability but not for the food safety aspects.

5. There are 21 CABs in Sweden. They report to the Ministry of Finance. They are responsible for official controls on primary production of the food chain, thus as far as this audit is concerned: fish farms, fishing vessels and landing sites.

6. Both the NFA and the municipalities are responsible for implementing official controls at establishments. It is their responsibility for planning and execution of on-the-spot checks and enforcement. They also participate in official sampling activities in coordination with the laboratories.

7. The NFA laboratory in Uppsala is the National Reference Laboratory (NRL) for microbiology (Listeria spp and E.coli) and chemistry where they cover heavy metals/pesticides, Polycyclic Aromatic Hydrocarbons (PAH), Dioxins and Polychlorinated Biphenyls (PCBs). The National Veterinary Institute is the NRL for Salmonella. There are no other official laboratories in Sweden with responsibilities falling within the scope of this audit. Official samples are mainly analysed at private laboratories listed by NFA. The two municipalities visited use a contracted laboratory, chosen by public tender. In practical terms there are two private laboratory companies in Sweden which test the main part of official and the food business operators’ (FBOs) samples for fishery products. The NFA as NRL does not coordinate or facilitate activities of the private laboratories which test official samples. It organises proficiency tests for microbiological parameters in food and water in which the two main private laboratories participate.

8. Municipalities and NFA have legal provisions in place to ensure that their staff have access to FBOs and can take the necessary measures to enforce rectification of non-compliances. As part of the Public Employment Act, Swedish legislation includes provisions with regard to confidentiality and conflict of interest. At regional level additional safeguards were introduced by the regional entities to further promote objectivity and the avoidance of conflicts of interest (e.g. staff rotation every two years for individual control areas).

9. The main tool for harmonisation of official controls is based on "PIMKO", a planning tool provided by the Control Division of NFA. It provides guidelines for inspections and background information. PIMKO provides tools to plan and prioritise controls on a risk basis.

10. Collection of inspection results is not harmonised and different reporting tools are present in the municipalities and NFA. The NFA uses "ELVIS", while Gothenburg Miljöreda and Stockholm use a system called "ECOS". The extraction and collating of
information is not easy. The IT services of the municipalities prepare a data-file which is sent once a year to the NFA and decoded there for the Swedish annual report.

11. Co-ordination between the NFA and municipalities is achieved inter alia through the regular meetings between the Control Division of NFA and the responsible staff of the municipalities.

12. NFA conducts internal audits on food related controls carried out by CABs, municipalities and their own staff. CABs have the obligation to audit municipalities every five years. However, this was not the case in one municipality visited. The audit team reviewed reports of audits conducted by NFA and CAB which had been sent to the audited CAs for corrective actions.

Training of staff performing official controls

13. The audit team noted that staff participate in mandatory and continuous education. Training activities are documented and the records were presented to the audit team. Training includes participation in in-house training events, meetings and external training sessions. In two cases, however, inspectors interviewed by the audit team had not received trained concerning the specific control of fishery products. The audit team noted that the level of specific technical knowledge about fishery products and related risks was quite different in the regions and municipalities visited.

14. The staff met during different visits were in general qualified, knowledgeable and experienced. The audit team noted, however, that staff, were in some cases unaware of technical aspects e.g. how to smoke fishery products to avoid PAH, labelling of fishery products, HACCP plans and verification techniques in general.

Documented control procedures

15. Staff of NFA and the municipalities have at their disposal the relevant documents such as general and specific procedures on official control activities and report forms. In the PIMKO system official controls are split into 15 areas according to the control subject concerned (e.g. HACCP, pest control, staff hygiene ...). Each chapter of the NFA’s guidance document individually deals with one of these areas. However, there were no detailed checklists in place with the exception of the municipality of Stockholm. NFA has provided a detailed document for sampling which is available to all inspectors.

16. The municipality of Stockholm has developed a pilot system to verify the effectiveness of official controls. They have introduced different categories/ tolerances inter alia safe cold storage in restaurants, labelling of allergens at school kitchens, traceability of beef each with a defined limit of deviation. Inspection results will be compared to these thresholds to ensure objective indicators that can tell whether or not controls are effective.

17. CABs are responsible for the control on primary production. The audit team noted that there is no common defined procedure in place to control fishery vessels and landing sites. The audit team received from the CABs two checklists to be used for control of primary production.

18. Completed report templates filled in by the CAs during the official controls on approved facilities were available at the CAs visited. Other than for the municipality of Gothenburg, the reports described the scope of the inspection, the results and non-compliances, deadlines and follow-up measures (if applicable). CA staff hands over only
a brief flyer to an FBO where there are no non-compliances. If non-compliance is detected during an inspection a letter must be sent to the FBO with a description of the problem and the remedial measures to be taken to rectify matters.

Control activities, methods and techniques

19. Tasks related to official control are in general carried out using various control tools such as audit, inspection, sampling and laboratory testing. These official controls include, *inter alia*, the following activities: the examination of any own-check system in place in a facility, including HACCP plans and related records, the inspection of premises, equipment, raw materials, ingredients, additives and labeling as well as regular checks on the hygiene conditions and cleaning and maintenance procedures of FBO.

20. The audit team noted that several inspections witnessed were merely interviews with the FBOs and very little verification such as a cross-check was done.

Enforcement measures

21. The legal powers for intervention in case of administrative offences and criminal and administrative fines are foreseen in the Swedish Food Act (*livsmedelslagen* (2006:804)). In 2011 specific sanctions were established by Ordinance No 2011:1494 on certain fish species from the Baltic region. This latter regulation contains rules concerning the placing on the national market of certain kinds of fish (salmon, herring, arctic char, river lamprey, and brown trout) even if they contain levels of dioxins that exceed thresholds of Regulation (EC) No 1881/2006. This Ordinance also contains criminal sanctions for transgressions of the ban on placing such products on the EU market.

Conclusions on Competent Authorities

22. CAs have been adequately designated for the official control of fishery products and their production chain. These authorities have a structure, organisation and legal powers that should, allow for adequate official control.

23. However, shortcomings were found linked to Regulation (EC) No 882/2004, as regards knowledge of staff (Article 6) and there were weaknesses in the CA control activities, methods and techniques (Articles 10(1) and 10(2)(b-vi)(e)(g)(h)) which do not allow the authorities to ensure that the official control system implemented is effective and appropriate as required under Article 4 (2)(a) of Chapter II of Regulation (EC) No 882/2004.

5.2 REGISTRATION/APPROVAL OF FOOD BUSINESS OPERATORS ESTABLISHMENTS

Legal requirements

Findings

24. The NFA is responsible for the approval, suspension and withdrawal of establishments and factory vessels. All FBOs, including vessel operators, must register with the local Trade Register Office. Additionally fishing vessels must also register with SAMWM.

25. CAB is responsible for registering fishing vessels for primary production concerning food safety. The audit team was informed that 119 vessels are to-date registered by the CABs. Data obtained from the internet site of the Commission’s Directorate-General for Maritime Affairs and Fisheries shows that SAMWM has registered 1,350 vessels, most of them fishing for primary production. Aquaculture establishments are also registered by the CABs.

26. NFA updates and publishes the list of approved establishments and factory vessels on the internet. The procedure for the approval of establishments usually comprises the following steps:-

- Application (by the FBO) for approval.
- Assessment, by regional NFA staff, of the administrative and technical files included in the application.
- On the spot visits by NFA staff, accompanied by municipality staff if applicable.
- Decision on permanent approval. There are no provisions for provisional approval.
- Communication of the approval to the FBO and the central NFA (which is responsible for its publication on the relevant webpage).

27. The audit team noted that all establishments visited had been approved by the CA for activities carried out on-site and the approval documents were available to the audit team. The approval documents of the CAs, however, do not contain blueprints of the establishments. This creates particular challenges for the inspectors on the spot: in one case inspectors were not aware of certain buildings forming part of one establishment. In another case the FBO contested the CA's contention that particular cold stores formed part of his approved establishment. Therefore the CA cannot be ensure that establishments are approved in accordance with Article 31(2)(e) of Regulation (EC) No 882/2004.

28. The audit team reviewed files related to approval and withdrawal from the NFA list and noted that several establishments had been approved either without a HACCP system or with one that was not appropriate for the activities being carried out.

Conclusions on registration and approval

29. The current implementation of the procedures for approval of facilities handling fishery products does not ensure in all cases that FBO’s establishments are approved in line with EU requirements.
5.3 OFFICIAL CONTROLS

5.3.1 Official controls of production and placing on the market

Legal requirements


Findings

Official control system in place

30. The Multi Annual Control Plan is the basis for planning official control activities to ensure that they comply with Swedish food laws. In its latest version 2013-2016 it outlines the priorities for food controls. It describes that risk-based controls on food should be improved and promoted by enhanced efforts in training of staff, by HACCP, by improved traceability and by verifications (audit and inspection). It also argues that sampling to verify the FBOs own-controls should be enhanced.

31. An official control system covering the production and placing on the market of fishery products is implemented by NFA, municipalities and CABs. These systems cover aquaculture and approved establishments but not fishery vessels and landing sites.

32. PIMKO is also used as a tool for the risk assessment of FBOs. After the initial risk assessment with a point system, applied at the time of approval, a risk category is assigned to the establishment and a number of hours for control activities per establishment is allocated. The main criteria are the production quantities and the risk level of the product and the vulnerability of potential consumer groups. The previous compliance record is expressed in ‘A’, ‘B’ and ‘C’ with a reduction or addition of allocated hours according to the category.

33. Inspection visits are in general unannounced, and at the establishment visited, occur in accordance with the allocated control hours. Additional inspections may take place due to export issues, RASFF notifications, sampling, consumer complaints or other reasons.

Primary production

34. Sweden currently has a small aquaculture industry where only a few species are farmed at a large scale. The industry focuses almost entirely on the production of salmonid species namely: rainbow trout, arctic char and salmon smolt. These species are either farmed for consumption or for fish stocking purposes. Besides those, smaller quantities of other species are farmed on and offshore in fresh and in salt water, including eel, perch, pike-perch mussels and crayfish. According to the Swedish Bureau for Statistics Swedish aquaculture production was 9,888 metric tonnes of food fish derived from 70 holdings, with a fresh weight of 11,663 tonnes. The dominant species is rainbow trout (9,757 tonnes), with 84% of the total production of fish for consumption. The production of arctic char amounts to 1,808 tonnes. The production of eel is estimated at 92 tonnes.

35. The production of fish for stocking is estimated at 1,016 tonnes. The dominant species is rainbow trout with 679 tonnes. Other trout production amounts to 202 tonnes and char is
estimated at 86 tonnes. For conservation reasons 2.8 million salmon and sea trout fry were released in 2013, mainly into rivers running into the Baltic.

36. The CABs are responsible for verifying that the requirements of Chapter I of Section VIII to Annex III of Regulation (EC) No 853/2004 concerning food safety at primary production are met. CAB provided information about the registration of fishery vessels and landing sites. CAB stated that 119 vessels are registered to-date, which represents less than 10% of the fishery vessels registered by SAWMN. A checklist to be used for primary production had recently been developed and was made available to the audit team. It is not specific for vessels or landing sites. One fishery vessel had been inspected using this new checklist at the time of the FVO audit. This is contrary to Article 10(2)(b)(i) of Regulation (EC) No 882/2004 together with Article 1(b) of Annex III of Regulation (EC) No 854/2004 and do not cover the requirements of Chapter I of Section VIII to Annex III of Regulation (EC) No 853/2004, and the landing of fishery products which is not in line with point 1(a) of Annex III, Chapter 1 of Regulation (EC) No 854/2004.

**Landing and first sale**

37. The CABs are responsible for checking the hygiene conditions during landing of fishery products. CAB informed the audit team that one check on a fishery vessel had been carried out at the date of the audit. The official control system does not cover controls on the landing of fishery products which is not in line with point 1(a) of Annex III, Chapter 1 of Regulation (EC) No 854/2004.

38. The audit team visited one auction hall that was in operation at the time of the visit. The facility was approved in 2007 and is currently used mainly for secondary sale of fishery products first landed in Denmark and Norway. Small Swedish fishing vessels occasionally supply this auction hall.

39. The audit team noted that:

- This facility had been visited several times over the last two years in line with the minimum hours defined by PIMKO. It was categorized ‘C’ because of a past bad compliance record, mainly concerning labelling. Reports of inspections, including deadlines for completion of corrective actions were available on-the-spot.
- The audit team noted that no specific checklist is used during these controls. The CA was not aware that a cold store was part of this approved facility.
- The structural and hygiene conditions of the facility and operations were considered generally in line with EU requirements.
- A HACCP plan was available. According to information provided by the FBO this plan had been bought from an external consultant. The FBO could not explain Critical Control Points (CCPs) and how they were managed or show any monitoring data.
- The last laboratory analyses were done in 2009 by the FBO.
- According to the FBO salmon caught in the Vänern Lake was present in the auction hall, but the FBO could not produce any documentary evidence or invoices supporting this. The FBO stated that he was not aware of the specific health risks associated with salmon from the Baltic Sea or the two big Swedish lakes.

**Facilities, including vessels, handling fishery products**
40. The audit team visited, in three different regions, five establishments, one cold store and one factory vessel and noted that all these facilities are visited at regular intervals, according to their risk category, to check compliance with EU requirements including maintenance of the conditions for approval.

41. In most of the establishments visited the general structural and hygiene conditions were adequate overall. The inspectors identified various shortcomings related to hygiene conditions of storage and of operations, equipment (cold store not fitted with a temperature recording device) and maintenance of premises and equipment (condensation on ceiling and rust on equipment). Nevertheless there was not always a good coherence between the CA reports seen and the compliance level of the establishments visited and the official control systems failed to identify serious hygiene problems in the establishments under their control which is not in line with Article 10(2)(b) of Regulation (EC) No 882/2004. In particular the audit team noted:-

- Unacceptable storage conditions (smoked fish covered with re-frozen melt-water, uncovered carcasses of small ruminants, no labelling, untraceable products, ice formed on walls and on consignments).
- Not all establishments had implemented a documented system based on HACCP principles. Hazard analysis did not cover all the process steps. No monitoring of identified hazards was in place and relevant hazards were not properly identified which is not in line with the requirements for HACCP systems as set out in Article 5 of Regulation (EC) No 852/2004.
- Automatic temperature recording was not always in place.
- Birds were present in an area with exposed fishery products awaiting to be block frozen and then wrapped.

42. The compliant establishments have sampling plans which cover surfaces, equipment, water, raw material and final product and cover a wider range of parameters than those included in EU rules. Sampling and analysis take place at regular intervals, either in in-house or official accredited laboratories and non-compliant results are followed up and communicated to the CA if relevant. In some establishments there was no sampling protocol in place for relevant risks (PAH for smoking-houses, Listeria monocytogenes in ready-to-eat products, histamines in mackerel and tuna, dioxin/PCBs in fatty fish from the Baltic).

43. The water used in the establishments visited comes usually from the public networks. These networks are under control of the municipalities and the results of analyses are made publicly available. Additionally an FBO has to perform microbiological analysis regularly using accredited laboratories. The audit team’s review of results for two establishments presented acceptable values for the parameters tested (E. coli, coliform bacteria, Enterococci and total plates count) in line with Directive 98/83/EC.

44. The audit team visited one small factory vessel approved by NFA. The trawler fishes shrimp, Norwegian lobster and white fish. Lobsters and shrimp are cooked and chilled on board. There were some shortcomings concerning the hygiene in the storage hold, the risk analyses concerning cooking on board and the application of additives. The inspector identified all shortcomings and reported it back to the FBO.

45. Reports and documented evidence of corrective actions taken by the FBO were provided to the audit team in the establishments visited. In the sites visited, the inspection reports differed between those under NFA and those under municipal control. After most
inspections a copy of the report is given to the FBO, which includes the findings, measures to be taken, and deadlines for any corrective actions. In one municipality only a summary docket was given to the FBO where a facility was compliant.

46. In some cases follow-up inspections were carried out. One establishment was inspected to follow-up a RASFF in 2013 on illegal trade in Baltic salmon. The CA explained that a follow-up inspection concerning labelling and traceability would be done according to the seasonal occurrence of the salmon in the next year. The report of the inspection in 2014 during the salmon season seen by the audit team did not show that traceability and labelling had been checked. This is not in line with Article 54(1) of Regulation (EC) No 882/2004.

47. Because of the absence of checklists or detailed inspection reports, the audit team could not verify what the inspectors had checked during previous controls.

Conclusions on the official control systems in place

48. Official controls on production and placing on the market cover all stages of production and are in general implemented in accordance with EU requirements. However, compliance with the requirements for official controls laid down in Article 4.2, 4.4 and 4.5. of Regulation (EC) No 854/2004 may be affected by the frequent lack of verification of compliance with the relevant conditions.

5.3.2 Official controls of fishery products

Legal requirements


Findings

49. The MANCP states, *inter alia*, that sampling and analysis should be used extensively to verify the FBO's own-checks. In support of this, a special control manual on sampling is to be developed. A draft of the proposed sampling manual was presented to the audit team. However, to-date there has been no regular testing carried out to verify the results of FBOs' own-checks.

50. The CAs stated that during an audit, instead of taking official samples according to an annual plan drawn up by the CA, they would rather verify the FBO own-checks, which the CA considered to be sufficient to ensure compliance with the EU legislation. This presumption could not be confirmed by the findings regarding missing or incomplete testing of some FBOs as described under 5.3.1.

51. Official tests are only conducted in the framework of projects (initiatives covering particular emerging risks identified by the CAs, e.g. *Listeria monocytogenes* in ready-to-eat food, or PCBs in traditional smoke-houses). Additional samples were requested by the CAs due to complaints and foodborne outbreaks mainly in canteens/restaurants. Official samples are sent to the NFA laboratory or private laboratories, which were accredited and listed by NFA.

52. *Organoleptic checks* are carried out in case of suspicion. No official samples have been
collected so far.

53. The audit team noted freshness indicators like total volatile basic nitrogen (TVB-N) testing is available in the official laboratory visited and is used in cases of suspicion.

54. There is no regular official histamine testing carried out at establishment level. According to the information provided by the NFA in 2014 10 consignments from third countries were tested for histamines. For three of the consignments only one sample was taken instead of the required nine. Seven samples were taken in four different municipalities at retail level. There is no laboratory in Sweden accredited for histamine testing. The audit team was informed that some official samples are sent to Swedish-owned accredited laboratories with branches in other MS. The method used by the private laboratories is a proprietary method not certified by a third party and not a HPLC method. The same laboratories were used by the FBOs visited. Some of the FBOs tested for histamines in line with their own check programme. Since 2015 NFA requests that FBOs must take nine samples. In 2015 the municipality of Stockholm intends to implement a programme to test for histamine in fishery products. The programme had not started at the time of the audit. Histamine sampling is not always done in line with Regulation (EC) No 2073/2005 as only one sample was taken in place of nine in several cases.

Residues and contaminants

55. There is a National Residues Control Plan in place which includes fishery products from aquaculture.

Dioxins/PCBs in fatty fish from the Baltic fish

56. Article 7 of Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs provides for a derogation for Finland, Sweden and Latvia on the placing on the market of wild caught salmon, herring larger than 17 cm, char, river lamprey and trout on products thereof originating in the Baltic region intended for consumption in their territory with levels of dioxins/PCBs higher than those in place in the other MS, provided that a system is in place to ensure that consumers are fully informed of the dietary recommendations with regards to the restrictions on the consumption of wild caught salmon from the Baltic region and that these products are not marketed in other MS.

57. There is a specific monitoring plan in place for the dioxins/PCBs for fish from the Baltic Sea and the lakes Vänern and Vättern. 35 samples were taken in 2013 and 30 in 2014 from the Baltic region. Almost all salmon from different International Council for the Exploration of the Sea (ICES) areas of the Baltic and white fish from the lakes tested non-compliant. Dioxin/PCB accumulating fatty fish from the lakes were not tested in 2013 and 2014. 30 herring samples were taken from the ICES area numbers 25, 30, 29-S and 29-N. The results for herring were all compliant, however, only 2 of 10 planned samples were taken in area 29-N.

58. A recent NFA study from 2013 examined the risk and benefit of consumption of herring and salmon fish from the BS. It concluded: “the scenario calculations of dioxin and dl-PCB intake from fish suggest that a continued exemption can, in the worst case, result in thousands of children and women in childbearing years facing the risk of exceeding the TWI” \(^1\) (TWI=Tolerable Weekly Intake).

\(^1\) (page 14, Livsmedelsverkets rapportserie nr 21/2013)
59. The NFA organised information campaigns to make the public aware concerning the risk of high consumption of fish from the Baltic Sea and the lakes Vänern and Vättern. Several studies were conducted on the risk from dioxins and PCBs in fish. One study by NFA in 2014 examined the awareness of school kitchens about the risk of fatty fish from the Baltic region. The study also examined the traceability/labelling and illegal export to MS without derogation. It found that:-

- an excessive proportion of school kitchens could not demonstrate compliance with the NFA dietary advice on the consumption for vulnerable groups.
- Fatty fish from the Baltic region is exported to countries which do not have an exemption on EU dioxin/PCB limits in fish.
- Most consignments checked by the NFA were incorrectly labelled.

60. No official testing for heavy metals is in place for wild caught fish in Sweden. Most FBOs visited did not test for heavy metals in fish but relied in some cases on the guarantees provided by their suppliers.

61. No regular official testing of PAH in smoked fishery products is done by the NFA or the municipalities.

62. The audit team was informed about a study carried out on the levels of PAH in fishery products by NFA in the first semester of 2014 covering traditionally smoking procedures. None of the 18 samples examined showed PAH levels above the EU applicable legal limits at the time of the investigation. In 2015 the municipality of Gothenburg intends to implement a programme to test PAH levels in fishery products. The programme had not started at the time of the audit.

63. In 2013 the NFA examined a wide range of fishery products on microbiological parameters with in total 810 tests. They covered, inter alia, Bacillus cereus, Campylobacter, Clostridium perfringens, E.coli, Enterobacteriaceae, Staphylococcus producing coagulase, Listeria monocytogenes and Salmonella. No official tests have been conducted since then. Some, but not all, FBOs producing ready-to-eat products tested for Listeria monocytogenes as part of their own-checks.

64. There is no official sampling in place for testing for the presence of parasites.

65. Specific provisions like compulsory labelling for poisonous fishery products of the family Gempylidae (Escolar) are in place and known by FBOs handling this kind of fish.

66. There is no official sampling in place to monitor the application of additives used by FBO in crustacean fishery products which is not in line with Regulation (EC) No 1333/2008.

Conclusions on official controls of fishery products

67. Official controls of fishery products are not always carried out according to EU requirements. The lack of verification of FBOs’ own-checks for heavy metals, histamines, dioxin/PCB, parasites and additives could lead to non-compliant fishery products placed on the market.
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

68. The NFA is the Swedish national contact point for the RASFF network. It receives NFA and municipality notifications concerning products which are potentially hazardous to consumer health. Notifications are checked and followed-up where necessary, and then sent to the European Commission, for further distribution to MS. NFA informs their regional branches and municipalities concerning RASSFs received via the European Commission from other MS.

69. The audit team assessed two RASFF notifications concerning Swedish salmon from the Baltic region illegally traded to another MS and one caused by histamine contents in a product traded from a MS. From the procedures implemented the audit team noted that:
   - Information related to the existence of a serious direct or indirect risk to human health deriving from fishery products was rapidly notified to the Commission under the rapid alert system.
   - In one case the notification resulted in an on-the-spot visit and was followed, in good time, by the relevant supplementary information.
   - Results of investigations were properly followed up internally between the different CAs and departments and communicated to the EU.

Conclusions on RASFF

70. There is a system in place to adequately investigate problems that occur and to take action in response to RASFF notifications.

5.5 LABORATORIES

Legal requirements


Findings

71. The NFA is the NRL for Listeria monocytogenes, E. coli, PAH, heavy metals/pesticides, dioxins and PCBs. The NFA is accredited by SWEDAC (Swedish Board for Accreditation and Conformity Assessment) to ISO 17025 for testing for Listeria monocytogenes, E. coli, PAH, heavy metals (Pb, Cd, Hg) and Salmonella in fish matrices using methods of analysis in accordance with the legislation. The NFA has several methods accredited for testing microbiological parameters in water including Clostridium perfringens, E. coli and coliforms. Their methods of analysis are in
accordance with Article 5 of Regulation No 2073/2005.

72. The NFA is accredited according to the standard ISO/IEC 17043:2010 to organise proficiency tests for microbiological parameters in food and water.

73. The NFA is not accredited for testing for histamine in fish. There are two private laboratories doing this testing for the CAs and the FBOs visited. Both use ELISA methods for which none of its laboratories based in Sweden is accredited. These proprietary methods have not been certified by a third party and therefore they do not to comply with Article 5 of Regulation No 2073/2005.

**Conclusions on laboratories**

74. The CAs have access to adequate laboratory network for the performance of official control analyses. The NFA laboratory has the capability and is accredited for testing of *Listeria monocytogenes*, heavy metals, PAH and Salmonella in fishery products in line with the provisions of Regulation (EC) No 882/2004.

75. Designated official laboratories are accredited for the correct methods and matrices but do not use the HPLC reference method for histamine which is not in line with Regulation (EC) No 2073/2005.

### 5.6 FOLLOW-UP OF PREVIOUS RECOMMENDATIONS

The table below summarizes the follow-up to the relevant recommendations made in report DG SANCO 2010-8529-MR Final.

<table>
<thead>
<tr>
<th>No.</th>
<th>Recommendation</th>
<th>Assessment</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>The CAs should ensure that staff performing official controls on fishery products receive appropriate training as required in Article 6(a) of Regulation (EC) No 882/2004.</td>
<td>Partially addressed / See findings No. 13, 14, 20. Some inspectors met by the audit team have not followed specific training for fishery products. See recommendation No 1 of the current audit report.</td>
</tr>
<tr>
<td>2</td>
<td>The CAs should ensure that only establishments which fully comply with the requirements foreseen in Regulations (EC) Nos 852/2004 and 853/2004 are approved in accordance with Article 3 of Regulation (EC) No 854/2004.</td>
<td>Partially addressed / See findings No 27, 28. Some prerequisites for an approval were not checked before approval or re-approval (blueprints, missing HACCP systems). See recommendation No 2 of the current audit report.</td>
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<td>3</td>
<td>The CAs should ensure that factory vessels are approved as required under Article 4.2 of Regulation (EC) No 853/2004.</td>
<td>Fully addressed.</td>
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<tr>
<td>4</td>
<td>The CAs should ensure that all fishing vessels and fish auction sites</td>
<td>Partially addressed / See finding No 36. There are still no systematic checks on</td>
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are regularly inspected as required under Annex III, Chapter I, part 1 (b) of Regulation (EC) No 854/2004. See recommendation No 3 of the current audit report.

5 The CAs should ensure that official controls of fishery products (organoleptic, examinations, freshness indicators, histamine, microbiological checks, parasites, poisonous fishery products) are implemented, as required under Annex III, Chapter II, of Regulation (EC) No 854/2004. Partially addressed / See finding(s) No 59, 60, 61, 63, 64, 75.

There are still no or in some cases inadequate official controls in place for histamines, heavy metals, parasites and dioxins/PCBs. See recommendation No 10 of the current audit report.

6 The CAs should insure through the official assessment of the HACCP programmes in the approved establishments (see Article 10.2(d) of Regulation (EC) No 882/2004) that FBOs take into account the provisions of Article 5 of Regulation (EC) No 852/2004. Not addressed / See findings No 39, 41. See recommendation No 6 of the current audit report.

The table below summarizes the follow-up to the relevant recommendations made in report DG SANCO 2013-6767-MR Final.

<table>
<thead>
<tr>
<th>No.</th>
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<tbody>
<tr>
<td>1</td>
<td>To implement an effective official control system in order to ensure that fish from the Baltic region exceeding EU MLs for dioxins and PCBs is not traded to other Member States as required in Article 7 of Regulation (EC) No 1881/2006.</td>
<td>Not Addressed / See findings No 10, 14, 17, 20, 25, 36, 39, 42, 46, 59</td>
</tr>
<tr>
<td></td>
<td>Deficient traceability at the stages of primary production, first sale, processing and trade does allow non-compliant batches of Baltic fish to be traded in MS. See recommendation No 8 of the current audit report.</td>
<td></td>
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<tr>
<td>2</td>
<td>In the context of implementing this effective official control system, ensure that documented procedures with the necessary information and instructions are available to staff performing the respective official controls as required in Article 8 of Regulation (EC) No 882/2004.</td>
<td>Fully addressed.</td>
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6 OVERALL CONCLUSIONS

The report concludes that there is an official control system in place, covering fishery products and their production chain. This control system allows only partially the competent authority to provide appropriate guarantees with regard to the food safety of fishery products. In particular Sweden cannot provide sufficient guarantees that fatty fish from the Baltic region exceeding EU limits for PCBs/dioxins is not traded to other Member States. Other weaknesses were identified concerning the lack of official controls of fishery vessels for primary production, training of staff, traceability, HACCP evaluation and absence of systematic analytical testing of fishery products. Six of eight of the recommendations of the two previous audits concerning fishery products are not fully addressed.

7 CLOSING MEETING

During the closing meeting held in Stockholm on 29 May 2015, with representatives of NFA, CABs and the MUP the audit team presented the main findings and preliminary conclusions of the audit to the CAs. During this meeting, the CAs acknowledged the findings and preliminary conclusions presented.

8 RECOMMENDATIONS

The CCA should provide Commission services with an action plan, including a timetable for its completion, within twenty-five working days of receipt of the translated draft report, in order to address the following recommendations:

<table>
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<tr>
<th>No.</th>
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<tr>
<td>1.</td>
<td>The Swedish authorities should ensure that staff performing official control tasks have adequate knowledge about technical issues and control techniques that enables them to perform their tasks competently as required by Article 6 and 10 of Regulation (EC) No 882/2004. Recommendation based on conclusion No 23. Associated findings No 13, 14, 20.</td>
</tr>
<tr>
<td>2.</td>
<td>The Swedish authorities should ensure that procedures for establishment approval are implemented in accordance with the requirements defined in Regulation (EC) No 882/2004, in particular its Article 31(2)(c) and that the list of approved establishment only indicates establishments that are compliant with all applicable requirements, in particular those of Regulations (EC) Nos 852/2004 and 853/2004. Recommendation based on conclusion No 29. Associated findings No 27, 28.</td>
</tr>
<tr>
<td>3.</td>
<td>The Swedish authorities should ensure that the official control system in place on fishery vessels covers the requirements of Article 10(2)(b)(i) of Regulation (EC) No 882/2004 and in particular the requirements of Chapter I of Section VIII to Annex III of Regulation (EC) No 853/2004. Recommendation based on conclusion No 48. Associated findings No 31, 36.</td>
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<td>No.</td>
<td>Recommendation</td>
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<td>4.</td>
<td>The Swedish authorities should ensure that there is an official control system in place for the controls of landing of fishery products as required by point 1(a), Annex III, Chapter 1 of Regulation (EC) No 854/2004. Recommendation based on conclusion No 48. Associated finding No 37.</td>
</tr>
<tr>
<td>5.</td>
<td>The Swedish authorities should ensure that there is an official control system in place which identifies serious hygiene problems in the establishments under their control in line with Article 10(2)(b) of Regulation (EC) No 882/2004. Recommendation based on conclusions No 48. Associated findings No 39, 41.</td>
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<td>7.</td>
<td>The Swedish authorities should ensure that there is an official control system in place that ensures the traceability of fishery products in line with Article 18(2) of Regulation (EC) No 178/2002. Recommendation based on conclusion No 48. Associated findings No 39, 45.</td>
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<tr>
<td>8.</td>
<td>The Swedish authorities should ensure that the necessary measures are taken to prevent that specific wild caught fatty fish from the Baltic sea exceeding EU limits for dioxins and PCBs is marketed in other Member States than Sweden, Finland and Latvia in line with Article 7 of Regulation (EC) No 1881/2006. Recommendation based on conclusions No 22, 48, 67. Associated findings No 10, 14, 17, 20, 25, 36, 39, 42, 46, 59.</td>
</tr>
<tr>
<td>9.</td>
<td>The Swedish authorities should ensure that follow-up measures are put in place in line with Article 54(1) of Regulation (EC) No 882/2004. Recommendation based on conclusion No 48. Associated finding No 45.</td>
</tr>
<tr>
<td>10.</td>
<td>The Swedish authorities should ensure that all official controls are carried out as listed in Chapter II of Annex III to Regulation (EC) No 854/2004, in particular for heavy metals, histamines, dioxine/PCBs and parasites. Recommendation based on conclusions No 67. Associated findings No 59, 60, 61, 63, 64.</td>
</tr>
<tr>
<td>11.</td>
<td>The Swedish authorities should ensure that monitoring of the application of additives is carried out in line with Article 5 of Regulation (EC) No 2073/2005. Recommendation based on conclusion No 67. Associated finding No 54, 75.</td>
</tr>
<tr>
<td>12.</td>
<td>The Swedish authorities should ensure that monitoring of the application of additives is carried out in line with Article 5 of Regulation (EC) No 1333/2008. Recommendation based on conclusion No 67. Associated finding No 66.</td>
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</table>

The competent authority's response to the recommendations can be found at:

<table>
<thead>
<tr>
<th>Legal Reference</th>
<th>Official Journal</th>
<th>Title</th>
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<tr>
<td>Regulation</td>
<td>OJ Number</td>
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