EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

Ares(2013)3237113

DG(SANCO) 2013-6666 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

THE CZECH REPUBLIC

FROM 18 TO 27 JUNE 2013

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

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of a Food and Veterinary Office audit in the Czech Republic carried out from 18 to 27 June 2013, as part of its programme of audits in member states.

The objectives of the audit were to verify that overall, official controls take place in compliance with EU Law, 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 the Czech Republic has an adequate and effective official control system in place, covering fishery products and their production chain to verify compliance with the applicable EU requirements. This control system allows, in general, the competent authority to provide adequate guarantees with regard to the food safety of fishery products. However, those guarantees are weakened by the shortcomings observed during the audit, notably concerning the absence of formal guidance in relation to inspections in the fishery products sector, incorrect methodologies for HACCP systems and own-checks as well as the absence of controls on polycyclic aromatic hydrocarbons and parasites.

The report addresses to the Czech Republic's competent authority a number of recommendations aimed at rectifying identified shortcomings and enhancing the control system in place.

Table of Contents

Abbreviations and definitions used in this report

Abbreviation	Explanation
CA	Competent Authority
CAFIA	Czech Agriculture and Food Inspection Authority
CCP	Critical Control Point
CSVA	Central State Veterinary Administration
DG SANCO	Health and Consumers Directorate General of the European Commission
EC	European Community
EU	European Union
FBO	Food business operator
FVO	Food and Veterinary Office of the European Commission
HACCP	Hazard Analysis Critical Control Points
HPLC	High Performance Liquid Chromatography
ISO/IEC	International Organisation for Standardisation
ISCVBM	Institute for State Control of Veterinary Biologicals and Medicines
MI	Methodological Instruction
NRL	National Reference Laboratory
OJ	Official Journal of the European Union
PAH	Polycyclic Aromatic Hydrocarbons
PCBs	Polychlorinated Biphenyls
RSVA	Regional State Veterinary Administration
SVA	State Veterinary Administration
SVI	State Veterinary Institute

1 Introduction

The audit took place in the Czech Republic from 18 to 27 June 2013 and was undertaken as part of the Food and Veterinary Office's (FVO) audit programme.

The audit team comprised two inspectors from the FVO. An opening meeting was held in Prague on 18 June 2013 with the Competent Authority (CA). 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 audit 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 including those of aquaculture origin 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 chains 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. 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 CAs and food business operators (FBOs) in four regions were visited: Středočeský kraj, Prague region, Plzeň region, Hradec Králové.

Competent authority		
Central level	1	Central State Veterinary Administration, Prague
District level	2	Regional State Veterinary Administrations in Středočeský kraj and Hradec Králové
Laboratory		
	1	State Veterinary Inspection Laboratory, Prague
Primary production		
Aquaculture farms	2	
Facilities handling fishery products		
Processing Plants	5	
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 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.

4 Background

4.1 General background

This was the first FVO audit covering the fish sector since the accession of the Czech Republic in 2004.

4.2 Production and trade information

According to information provided by the CA, the main fishery products placed on the market are as follows:

The main fishery product of Czech Republic origin is freshwater aquaculture fish with an annual harvest of approximately 20,000 tonnes of carp (*Cyprinus carpio*). In general, and during the Christmas season, 90% of this carp is sold directly to the final consumer. Other species of fresh-water fish (mainly trout (S*almo trutta*) and pike (*Esox lucius*)) account for approximately 1,000 tonnes per year.

Fishery products from seawater fish, chilled and frozen, are obtained mostly by intra-EU trade (and Norway) and used to produce consumer size packages of chilled and frozen fishery products. In addition, these chilled and frozen fishery products can be used for the manufacture of preserved (marinated) and smoked fishery products. The main species involved is this production are herring (*Clupea* spp.), salmon (*Salmo salar*) and mackerel (*Scomber* spp.).

According to the list set up by the CA and available on its web site, there are a total of 49 processing establishments and 97 cold stores authorised to place fishery products on the market.

5 Findings And Conclusions

5.1 Competent Authority

Legal requirements

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

Findings

Structure and organisation

The structure and organisation is described in the country profile for the Czech Republic: http://ec.europa.eu/food/fvo/follow_up_en.cfm?co_id=CZ.

The Ministry of Agriculture is responsible for the legislation on food of animal origin and the

Multi-Annual National Control Plan.

The Czech State Veterinary Agency (SVA) is the CA for the control of foodstuffs in the scope of this audit. The SVA is responsible for official controls on fishery products from primary production to retail level. The responsibility at retail level is shared with the Czech Agriculture And Food Inspection Authority (CAFIA). Retailers slaughtering fish and/or processing raw material are controlled by the SVA; retailers only selling fishery products in final consumer packaging are under the control of CAFIA.

The SVA is also responsible for the official control of the seasonal sales of carp. During the Christmas season carp is sold in mobile containers, so-called 'barrel-sales' to final consumers[1].

The SVA consists of a central level, the Central State Veterinary Administration (CSVA), and their representatives at regional level, 13 Regional State Veterinary Administrations (RSVAs) and one Municipal Veterinary Administration for Prague. The different RSVAs have centralised regional services (divisions or departments) that are responsible, inter alia, for food hygiene, animal health and animal welfare. To implement their field tasks the RSVAs are divided in smaller units (e.g. inspectorates).

The CSVA is responsible for:

- issuing guidelines and instructions how official controls should be carried out;
- providing a computer system (SVA-IS) for dissemination of information and collection of control results;
- coordinating and liaising with other departments and regional entities;
- organising of training courses;
- inspecting/auditing sub-ordinate authorities;
- assessing the control results in SVA-IS;
- coordinating the five laboratories of the State Veterinary Institute (SVI) and the laboratory of the Institute for State Control of Veterinary Biologicals and Medicines (ISCVBM).

The main tasks of the RSVA are to support and supervise the official staff at the inspectorates. With regard to this audit, the RSVAs are responsible for:

- establishing annual FBO audit programmes to be executed by the RSVAs;
- collecting monitoring samples;
- approval of establishments;
- carrying out external audits and inspections of FBOs;
- performing inspections of its own veterinary supervision including internal audits.

1 *It is estimated that around 90 % of the annual carp production in the Czech Republic is sold and consumed in this period.*

Powers, Independence and Supervision and Enforcement

The State Inspection Act 552/1991 governs the procedure for the CA to carry out the official controls. The RSVAs have the power to suspend establishments under their supervision, to gain access to FBOs premises and documents, to seize product and consignments and, to withdraw registration or approval. The CSVA supervises and supports the RSVAs by regular inspection visits and internal audits.

The Labour Code No 262/2006 stipulates that officials may not be a member of management of private companies. Any side-activity of inspectors has to be pre-approved in writing by their superior. The audit team noted that the RSVA inspectors have been in charge of the official controls of the same FBO for more than five and in one case ten years. The audit team was informed by a RSVA director that he would have liked to rotate inspectors every two or three years in his region, but in the case of fishery products the need for specific knowledge prevents him implementing such a rotation.

The audit team noted that corrective measures were taken by inspectors when non-compliances were detected, e.g. the seizure and recall of a consignment of smoked fishery products with a positive result from a *Listeria monocytogenes* analysis.

Training

There is an annual training programme set up by the CSVA. One specific training course covering fishery products was organised in 2011. The tutors during this training were Czech FBOs. Some inspectors responsible for fishery products stated that they had not received any specific training for the sector.

HACCP training is organised regularly. The audit team verified invitations, subjects covered and participant lists for training sessions in 2013.

Some inspectors had attended various training sessions under the DG-SANCO initiative Better Training for Safer Food.

Documented Control Procedures

For approval of establishments there are documented control procedures in place. They were drafted centrally by the SVA, and are used by audit teams for the approval audits. These procedures include a checklist and a system of scores to categorise FBOs according to risk-levels.

CSVA has issued guidelines for inspectors carrying out official controls as follows:

- Methodological Instruction (MI) No 1/2007 to harmonise the procedures for the implementation of audits under Regulation (EC) No 854/2004,
- MI No 2/2010 for the approval and registration of food business in accordance with Act No 166/1999 Coll. and Regulations (EC) Nos 852/2004, 853/2004, 854/2004 and 882/2004;
- MI No 4/2006 on sampling of foodstuffs, raw materials, feed and drinking water;
- MI No 1/2013 on approval and registration of aquaculture farms.

With the exception of the primary production there are no specific instructions, guidelines or checklists in place for the control of the fishery products sector.

For the controls at primary production level the Animal Health Department of the CSVA has

developed work instructions. They are primarily focused on the control of animal health issues but contain also elements for food safety controls and in particular for measures concerning:

- Traceability of the fingerlings and fish during the different stages of growth and their movement between ponds;
- prevention of contamination of live fish during handling;
- hygiene measures for facilities including disinfection;
- appropriate storage of feed.

Not covered by the inspection guidelines were the controls on the:

- equipment e.g. containers for catching and transport of live fish;
- the training of FBOs on food hazards.

The CA informed the audit team that the Czech Republic had applied for a derogation under the terms of Article 10 of Regulation (EC) No 853/2004 related to placing live fish from seasonal business on the market. The Czech Republic made a notification to DG SANCO in 2007.

There is a computer system in place to record the results of official controls. The CA officials enter their results of controls into the system. The results are available to all relevant officials throughout the Czech Republic. The audit team verified that inspection reports seen at establishments were available in the SVA-IS database.

Conclusions

The CA designated for the official controls on fishery products has adequate structure, organisation and legal powers to execute official controls and enforcement measures. However, the lack of guidance in relation to the inspection of fishery products could lead to a lack of uniformity and consistency. With the limited availability of specific training there are only a few official inspectors sufficiently trained for the controls on fishery products. Therefore they cannot participate in the rotation commonly applied elsewhere. This leads to long times of residence at the same FBO establishments and could affect inspectors' independence when performing official control tasks.

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

All FBOs visited were approved by the CA and a certificate setting out the scope of permitted activities was present in each establishment. The description of the scope of activities for processing fishery products varied between the regions visited.

The CSVA has published the MI No 2/2010 for the approval and re-approval of establishments. MI

No 1/2007 describes how audits should be conducted and the methods for risk categorisation of establishments.

The audit team reviewed an example of an initial approval. The FBO must apply first for a business licence at the municipality. To grant this licence the municipality gathers the opinions of several authorities involved including the RSVA when the processing of fishery products is being approved . The municipality issues the construction approval only upon a favourable opinion of the RSVA. After construction an inspection takes place and after a positive outcome a business licence is issued by the municipality.

Once the operator has obtained a business licence he can apply for veterinary approval and an audit on the operational and sanitation rules and the HACCP plan takes place. After a positive outcome of this audit a temporary approval is issued.

At the time of the FVO audit, the RSVA inspectors had no working instructions for this initial on-site approval inspection. The CA stated that the legislation provides sufficient clarity.

The CA stated that temporary approvals are granted for a maximum of three months renewable once for a further three months.

Once operations commence the CA carries out a second audit to verify the FBO's compliance during production. Temporary approval may be revoked, prolonged (see above) or transformed into a permanent approval depending on the outcome of this second audit. During the second audit the establishment is categorised according to one of three risk-categories low, medium or high. This classification determines the frequency of the audits which are carried out once every 1 to 3 years.

Permanent approval must be renewed where the FBO:

- changes or expands his activities;
- changes the premises which would require a licence by the municipality;
- changes procedures which affects significantly the technology or hygiene status of production;
- transfers the business to another operator.

The audit team noted that the procedures described in the MI were generally followed.

A copy of the mandatory initial risk assessment for establishments, however, was only available in one of the establishment visited by the audit team.

The audit team noted that an approval document was available in all establishments visited. The approval documents stipulated the activities for which the establishment has been approved.

The audit team noted that several establishments were approved for activities which had ceased years earlier or were planned for the future. In these instances, there was no equipment available for these non-existent activities.

In one establishment the activities of processing and cold storage were split and a separate approval number was given to the cold store. The processing plan, however, still has the activity of cold storage included in its approval. The CA stated that approvals of specific activities are only removed on a specific request by the FBO. Approvals are unrestricted in duration.

Aquaculture farms must be approved by the Animal Health Department of the SVA. Farms may consist of one or several 'units'. Each unit is registered individually and is comprised of one or more

ponds in the same water basin. The CA undertakes a risk categorisation per unit based on animal health aspects. The highest risk of one unit determines the risk status and control frequency for each farm.

Conclusions

The procedures in place for registration and approval of FBOs are in compliance with EU regulations. These rules were applied adequately in general, however, the CA granted approvals for activities which were only planned in the future or maintained approvals for activities which has long ceased to take place.

5.3 Official controls of production and placing on the market

Legal requirements

Article 4 of Regulation (EC) No 852/2004

Article 3 and Section VIII of Annex III to Regulation (EC) No 853/2004

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.

Article 50 of Regulation (EC) No 178/2002

Regulation (EC) No 1333/2008

Findings

5.3.1 Official control system in place

The RSVAs are responsible for official controls at all stages of production of fishery products, including aquaculture farms, processing establishments and cold stores.

The RSVA staff conduct audits and regular inspections. Regular inspections take place, in general, every month and include checks on good hygiene practices (lay-out, structure, equipment, hygiene, pest-controls, etc.), verification of traceability and labelling. Ad hoc visits had been carried out on the basis of consumer complaints in two establishments visited by the audit team.

Audits are carried out by audit teams comprised of two RSVA officials who are assisted by the RSVA inspector assigned to the establishment. This inspector acts as an observer. The frequency of audits is determined by the risk category of the establishment. This risk category is assigned during approval (see section 5.2) and is adapted where necessary (e.g. on the basis of results of previous inspections).

In the regions visited the heads of Food Safety Departments assumed, from time to time, the role of lead auditor to assess the work of their colleagues.

Audits are conducted based on the MI 01/2007. A checklist which is part of this MI was used for all audit reports seen by the audit team.

In most cases reviewed by the audit team there were no deadlines set for corrective measures by the

FBO following these audits. Corrective measures were however followed-up during the regular monthly inspections.

Besides audits, FBOs are inspected monthly. There are no guidelines, checklists or instructions in place setting out how these monthly inspections should be conducted. The inspectors decide themselves about the items to control during a particular check. In 2011 the CSVA issued a letter to the RSVAs that all relevant points for approved establishments must be covered by such inspections. The CSVA stated, that checklists would not facilitate the work of the inspectors. In some establishments the audit teams observed checklists developed by individual inspectors at local level.

The audit team observed that inspections reports had been drawn up for all establishments visited. Such reports contained the objective of the inspection, findings and any shortcomings detected, and corrective actions to be applied.

5.3.2 Primary production

The Animal Health Unit of the SVA carries out official controls at farm level according to the frequency determined during as part of the approval and registration process.

During the inspections several items are checked: traceability, bio-security, hygiene of facilities and feed storage requirements. Checks on training of the FBO staff on health risks is not part of the inspections.

Two aquaculture farms were visited by the audit team. Their approval documentation was available at the farms visited. The main production consisted of several carp species, trout, and small amounts of other fish such as pike and catfish. They supplement the natural feed with grain. The FBOs keep production records covering items such as mortality, feed, harvesting and traceability. Inspection reports were available in both farms visited and inspections were done with the required frequency.

5.3.3 Facilities, including vessels, handling fishery products

The audit team visited six processing establishments and one cold store. Establishments visited were in general compliant with regard to their structure, equipment and maintenance. The audit team reviewed several inspection reports and verified that deficiencies are identified and a follow-up is carried out. The required monthly frequency was met.

HACCP procedures were in place in all processing establishments visited. However, the audit team noted deficiencies in the implementation of these plans by the FBOs and their evaluation by the RSVAs:

- not all HACCP principles were applied correctly; in some cases critical limits were missing, inadequate or not in line with the legal requirements (e.g. the temperature requirement in freezer storage was set to between -18 and -15 °C)

- in most establishments CCPs were selected without taking into account recognised guidance documents on hazard analysis and the implementation of HACCP principles.

Own-checks were performed in all establishments and generally covered the prevailing risks. However, in some establishment visited they did not cover polycyclic aromatic hydrocarbons (PAH)

or histamine analysis in smoked fishery products (including imported mackerel). In one establishment there were no procedures for own-checks on parasites in slaughtered freshwater fish. The FBO and the CA stated that pathogenic parasites posed no risk for freshwater fish in aquaculture.
In another establishment the audit team observed that raw material in open containers and final products crossed during production leading to possible cross-contamination.

In one establishment visited hydrogen per-oxide was used for bleaching fish-fillets. Hydrogen peroxide is not approved as an additive for fishery products.

Conclusions

The official controls at primary production level in aquaculture were generally compliant with EU requirements. There were however no official checks to ensure that staff handling foodstuffs undergo training on health risks .

The official control system at fish processing establishments was satisfactorily implemented by the CA. However, the food safety guarantees provided by the CA are weakened due to the deficiencies noted, and in particular those related to HACCP systems (e.g. CCP determination incorrect critical limits and hazard determination). Other weaknesses included the absence of own-checks on PAH in smoked fishery products, the use of non-authorised substances (hydrogen peroxide) and the crossing of raw materials and finished product all of which could potentially pose a problem for public health.

5.4 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

There is an annual monitoring plan in place which stipulates the substances, matrix and number of samples to be taken each year. The SVA sets the targets for the RSVAs who decide when and where the samples are to be taken. The results are entered into the CA's computer system.

Organoleptic examination

The audit team was informed that organoleptic checks are performed during inspections on a case by case basis. The inspection reports assessed by the audit team did not provide details and therefore it could not be verified if such checks are carried out.

Histamine

Official samples for histamine were taken according to the SVA's annual sampling plan. The audit team observed, that nine sub-samples were taken. Species with high levels of histidine are only imported or introduced via intra-EU trade.

Residues and contaminants

There is an official sampling plan in place to monitor the level of residues in aquaculture. In the RSVAs visited the samples were taken according to this plan with satisfactory results. In 2011, in

total, 1027 and in 2012 1141 samples were taken In 2011 there were four positive on leucomalachite green (three of Czech origin, one from another member state) and two on leucocrystal violet from a member state. In 2012, six samples were positive on leucomalachite green (five with Czech origin, one from another member state), one on malachite green (Czech origin) and two on leucocrystal violet from another member state.

Contaminants in fishery products are monitored by a sampling plan in establishments. It included heavy metals, malachite green, dioxins, Polychlorinated Biphenyls (PCBs) but not PAHs.

Between 2006 and 2010 a national study was conducted to monitor the level of heavy metals (mercury and its toxic form, methylmercury, cadmium, lead) and hazardous organic compounds such as, PCBs and dioxins in freshwater fish originating from open waters. The CA provided the audit team with the report of the results. The results were favourable in general with the exception of the mercury content in one river and two lakes used for sport fishing.

Microbiological checks

Official samples for microbiology testing in fishery products had been taken by the CA in accordance with the hazards of each product category. The audit team noted that 173 official samples were taken in 2011 and 111 in 2012. There were some positive results of *Listeria monocytogenes* in ready-to-eat products: three in 2011 and fifteen in 2012.

Parasites

The CA stated that there are official control in place on parasites in sea-water fish. The audit team could not verify this via inspection reports seen which were silent on this control. There are no official controls on parasites in freshwater fish in place. There were no monitoring samples taken for parasites in fishery products.

Poisonous fishery products

The audit team observed in one establishment that consumer packs containing snake mackerel (*Lepidocybium flavobrunneum)* were labelled with an adequate warning on potential health risks.

Conclusions

There is an official control programme in place which covers most aspects of fishery products control in line with EU legislation. There is no official monitoring for parasites, PAH or additives in fishery products in place.

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

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

There are seven official laboratories coordinated by the SVA. The SVI laboratories in Prague, Jihlava, Olomouc perform testing for heavy metals, PAH, malachite green, histamines and microbiology. SVI Prague analyses also dioxins. The scope of the laboratories in Ceske Budejovice and Hradec Kralove are restricted to *Salmonella* and *Listeria monocytogenes*. The ISCVBM laboratory in Brno conducts analysis on residues of veterinary medicines. All laboratories are accredited against ISO/IEC standard 17025 for the methods applied.

The audit team visited the SVI laboratory in Prague. It has two departments within the scope of the audit: the microbiological department (NRL for *Salmonella*) and the chemical department (NRL for PAH). As part of their NRL role they:-

- Participate regularly in proficiency tests with z-scores < 2 (e.g. Food Analysis Performance Assessment Scheme 2012 for histamines in canned fish, Joint Research Centre for PAH in olive oil and Asia Pacific Laboratory Accreditation Cooperation with essential toxic elements in seafood in 2013).

- Coordinate the work of the official laboratories in technical working groups.

- Disseminate information.

- However, they do not organise comparative ring tests as the number of laboratories is too low. Instead all official laboratories participate directly in internal proficiency tests.

Of the 102 staff members there are 31 staff with a university degree, 43 technicians and 28 administrative staff. They perform annually approximately 12,000 chemical and 20,000 microbiological analyses. About 50% are private samples. The FVO team noted, that:-

- The departments operate in line with ISO/IEC 17020 accreditation and are audited annually by the Czech Accreditation Institute (CAI). The laboratory is adequately equipped with modern analytical equipment suitable for chemical analyses in food including LC-MS/MS, GC-MS and HPLC with FL and UV detectors.

- Training plans were in place for each staff member of university level, technicians follow training sessions at least twice a year.

- There are no target times established by the CSVA for reporting results of official samples. The only requirements stated is “as soon as possible”. The CSVA did an assessment on the time span between sample reception and delivery of results and the average time was between 8 and 15 days;

- The methods used for the analysis of samples of fishery product were accredited; it was stated that the CAI does not accept flexible scope. If a particular matrix is not covered by an

accredited method the laboratory validates the method for this specific matrix.

Conclusions

The laboratory visited performs as required of laboratories accredited to ISO/IEC 17025. The regular participation in external proficiency tests along with internal controls and implemented quality management system assures an adequate performance of the laboratory.

6 Overall Conclusions

The Czech Republic has an adequate and effective official control system in place, covering fishery products and their production chain to verify compliance with the applicable EU requirements. This control system allows, in general, the CA to provide adequate guarantees with regard to the food safety of fishery products. However, those guarantees are weakened by the shortcomings observed during the audit, notably concerning the absence of formal guidance in relation to inspections in the fishery products sector, incorrect methodologies for HACCP systems and own-checks as well as the absence of controls on PAH and parasites.

7 Closing Meeting

During the closing meeting held in Prague on 27 June 2013, 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 and provided a commitment to correct the deficiencies. The CA pointed out that the introduction of checks on parasites in freshwater fish was under discussion but delayed due to budgetary constraints.

8 Recommendations

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

N°.	Recommendation
1.	Ensure that inspectors carrying out official controls on fishery products have work instruction at their disposal in line with Article 8 (1) of Regulation (EC) No 882/2004.
2.	Ensure that inspectors carrying out official controls on fishery products are adequately trained in line with Article 6 (a) of Regulation (EC) No 882/2004.
3.	Ensure that food business operators inform the competent authority immediately of changes to the scope of their activities or to their production facilities, to ensure that their conditions of approval are still fulfilled in line with Article 6(2) of Regulation (EC) 852/2004 and Annex III Chapter I point 1 (b)(i) of Regulation (EC) No 854/2004.
4.	Ensure that official controls at the level of aquaculture for food production cover all

N°.	Recommendation
	subjects listed in Annex I, part II of Regulation (EC) No 852/2004 and in particular point 4(e)
5.	Ensure that the HACCP systems established by FBOs determine the critical control points in line with Article 5 (2) (b) of Regulation (EC) 852/2004.
6.	Ensure that polycyclic aromatic hydrocarbons are covered by the official monitoring programme in line with Annex III, Chapter II D of Regulation (EC) No 854/2004 in combination with Regulation (EC) No 1881/2006.
7.	Ensure that there are official controls on parasites in fresh water fish in line with Annex III, Chapter II point F of Regulation (EC) No 854/2004 in combination with Chapter V point D in the Annex of Regulation (EC) No 853/2004.
8.	Ensure that the layout of processing establishments for fishery products protect against possible cross-contamination in line with Annex II, Chapter I point 2(c) of Regulation (EC) No 852/2004.
9.	Ensure that official controls will prevent and detect the use of unauthorised additives in fishery products in line with Regulation (EC) No 1333/2008.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6666

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

Legal Reference	Official Journal	Title
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. 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. 1333/2008	OJ L 354, 31.12.2008, p. 16-33	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives
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