

Final report

EFTA Surveillance Authority mission to

ICELAND

From 16 to 25 November 2010

regarding the application of EEA legislation related to

the production and placing on the market of fishery products

Please note that the Icelandic Food and Veterinary Authority did not have any material comments or corrections to the content of the report.

Comments and information on the corrective actions already taken and planned by the Icelandic Food and Veterinary Authority are included in Annex 6.

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Executive Summary

This report describes the outcome of a mission carried out by the Authority in Iceland from 16 to 25 November 2010.

The objective of the mission was to verify that official controls related to the production and placing on the market of fishery products were carried out in compliance with the European Economic Area legislation.

The mission team found that the situation in Iceland concerning fishery products was not in conformity with several requirements laid down in the relevant European Economic Area legislation. In particular, the limited number of inspections, audits and sampling carried out by the competent authority is not in line with the requirements of the European Economic Area legislation.

Routine controls are carried out by inspection bodies which can not be seen as impartial as they collect fees directly from the establishments being controlled. The competent authority relies on these regular controls carried out by inspection bodies. However, several shortcomings of the establishments were not reported to the competent authority which thereby was not fully aware of the situation in the establishments. Furthermore, the mission team observed that enforcement actions were not always timely and appropriate.

The situation concerning the implementation of the general and specific hygienic requirements by the food business operators was also found to not to be in conformity with several requirements laid down in the relevant European Economic Area legislation.

These observations made the mission team conclude that the official controls, and the use of enforcement measures, related to fishery products in place in Iceland at the time of the mission were inadequate.

The report includes a number of recommendations addressed to the Icelandic competent authority aimed at rectifying the identified shortcomings and enhancing the control system in place.

1 Introduction

The mission took place in Iceland from 16 to 25 November 2010 as part of the EFTA Surveillance Authority's (the Authority) planned mission programme. The mission team comprised two inspectors from the Authority and an observer from the Food and Veterinary Office of the European Commission.

This was the first mission carried out by the Authority since the implementation of the "Food Hygiene Package" regarding fishery products in Iceland.

The opening meeting was held with representatives of the Icelandic Food and Veterinary Authority, *Matvælastofnun* (MAST), the Ministry of Fisheries and Agriculture and of a local competent authority on 16 November 2010 at MAST's head office in Selfoss. At the meeting, the representatives of MAST provided additional information to that set out in their reply to the pre-mission questionnaire of the Authority.

Throughout the mission, representatives of MAST's head office accompanied the mission team. In addition, the relevant inspection body was usually present during visits to the different establishments under its control. The itinerary was prepared taking into account the possibility to carry out visits without prior warning.

A final meeting was held at the Ministry of Fisheries and Agriculture in Reykjavik on 25 November 2010, where the mission team presented its main findings and some preliminary conclusions.

The abbreviations used in the report are listed in Annex 1.

The meetings with the competent authorities and the visits to establishments during the mission are listed in Table 1.

Table 1: Competent authorities and premises visited

	Number	Comments
Competent authorities	2	An opening meeting in Selfoss and a final meeting in Reykjavik with representatives of MAST, the Ministry of Fisheries and Agriculture and one local competent authority.
Inspection bodies		The relevant inspection body was present during most of the visits.
Laboratories	2	A laboratory dealing with official samples and a private laboratory mainly dealing with samples from food business operators.
Landing sites	1	This visit was carried out without prior notice.
Auction halls/fish markets	2	
Aquaculture farm	1	
Fishing vessels	1	A factory vessel visited at quayside.
Establishments processing fishery products	13	Six visits were carried out without prior warning. One establishment was observed from the outside only and two were closed at the time of the visits.

2 Objectives of the mission

The following main European Economic Area (EEA) acts fall within the scope of the mission:

- a) The Act referred to at Point 7.1.13 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 178/2002 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* as amended and adapted to the EEA Agreement;
- b) The Act referred to at Point 6.1.16 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 852/2004 on the hygiene of foodstuffs*, as amended and corrected in the EEA Agreement ;
- c) The Act referred to at Point 6.1.17 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin*, as amended and adapted to the EEA Agreement;
- d) The Act referred to at Point 1.1.12 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption*, as amended and adapted to the EEA Agreement; and
- e) The Act referred to at Point 1.1.11 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, as amended and corrected in the EEA Agreement.

Other relevant legislation is listed in Annex 2.

The mission covered all stages of fishery products and fish processing, with a particular focus on the following areas:

- a) Official controls related to food business operators' compliance with general and specific rules on the hygiene of food of animal origin and in particular fishery products;
- b) The implementation of these rules by food business operators;
- c) Follow-up of conclusions and recommendations contained in the report from the last mission to Iceland carried out from 23 to 30 September 2008 regarding the application of EEA legislation related to the production and placing on the market of fishery products.

Other issues observed on-the-spot as not complying with EEA legislation applicable to Iceland were also addressed during the mission and in this report, see Chapter 5.6.

3 Legal basis for the mission

The legal basis for the mission is:

- a) Point 4 of the Introductory Part of Chapter I of Annex I to the EEA Agreement;

- b) Article 1(e) of Protocol 1 to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice (Surveillance and Court Agreement);
- c) The Act referred to at Point 1.2.74 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States*; and
- d) 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 rules*.

4 Background

4.1 Previous missions

The previous mission concerning fishery products was carried out in Iceland from 23 to 30 September 2008. The report from that mission included a number of conclusions and a recommendation addressed to the Icelandic competent authority aimed at rectifying the identified shortcomings and subsequently the Icelandic competent authorities notified the Authority of corrective measures taken or planned to be taken.

The final report from the mission is available on the website of the Authority, www.eftasurv.int.

4.2 Information on production and trade

See Annex 3 for figures provided by MAST in its reply to the Authority's pre-mission questionnaire for the production and trade of fishery products in Iceland.

5 Findings and Conclusions

5.1 Legislation and implementing measures

Legal requirements

Article 7 of the EEA Agreement states that acts referred to or contained in the Annexes to the Agreement are binding upon the Contracting Parties and shall be, or be made, part of their internal legal order.

Findings

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, the Ministry of Fisheries and Agriculture is responsible for Icelandic legislation and implementation and application of EEA acts related to the production of fishery products.

The list of Icelandic laws, regulations and administrative provisions related to fishery products is given in Annex 4 to this report.

According to information provided by the Ministry of Fisheries and Agriculture in a letter addressed to the Authority on 10 November 2010, with the passage of Act No 143/2009, the Icelandic Parliament postponed the entry into force of Article 5 of Regulation (EC) No 882/2004 until 1 March 2011 (Delegation of specific tasks related to official controls).

Conclusions

The national legislation in place mostly fulfilled the relevant EEA requirements in the field of the production and the placing on the market of fishery products. However, the postponement of the entry into force of Article 5 of Regulation (EC) No 882/2004 leads to an incorrect application of Regulation (EC) No 882/2004.

5.2 Competent Authorities

5.2.1 Organisation and responsibilities

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for official controls, provides for efficient and effective co-ordination and cooperation between and within competent authorities.

Findings

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, Act No 80/2005, with amendments made by the Icelandic Parliament on 14 December 2007, No 167/2007, provides for the establishment of MAST. The head office of MAST is located in Selfoss, about 50 km east of Reykjavík. MAST has 14 district offices. MAST is the designated competent authority for official controls related to fishery products, except for controls at retail level which the local competent authorities are responsible for. The local competent authorities, organized under the respective municipalities, also carry out controls related to environmental issues and potable water in the municipalities. There are ten local competent authorities in Iceland.

The Directorate of Fisheries is the designated competent authority issuing licences for production areas for aquaculture.

At the opening meeting, MAST confirmed that an agreement would be signed with nine out of ten local competent authorities transferring the competence for official controls for approximately 30 small establishments (10% of the food business operators processing and placing fishery products on the market). At the final meeting, MAST presented a copy of one of these agreements to the mission team.

The mission team noted that MAST was not aware of the existence of one of the visited establishments. According to documentation presented to the mission team on-the-spot, only the relevant local competent authority had carried out official controls in the establishment, although it was not acting at retail level. Furthermore, another local competent authority, had issued an approval for processing fishery products to one establishment visited. MAST had later issued an approval for the same establishment.

Conclusions

Competent authorities had been designated. However, full compliance with Article 4 of Regulation (EC) No 882/2004 could not be ensured since the competent authorities did not

always carry out official controls in accordance with the designated competencies. Furthermore, efficient and effective coordination between competent authorities could not always be demonstrated.

5.2.2 Audits

Legal requirements

Article 4(6) of Regulation (EC) No 882/2004 requires that the competent authorities shall carry out internal audits, or may have external audits carried out.

Findings

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, an audit team composed of ten MAST officials was appointed in 2009 and its first task was to audit the documented procedures in place. The procedures audited until the time of the mission were related to the registration and approval of feed establishments, procedures on implementation of EEA acts, some procedures of the internal quality system etc. However, the inspection manual establishing procedures for controls carried out by MAST and/or by inspection bodies had, at the time of the mission, not been audited. The personnel of the appointed team received one day training on how to perform audits and half a day training on useful tools to perform audits e.g. the use of a database on how to manage the follow-up.

Conclusions

MAST has established an audit team that carries out internal audits according to Article 4(6) of Regulation (EC) No 882/2004.

5.2.3 Delegation of specific tasks related to official controls

Legal requirements

Article 5 of Regulation (EC) No 882/2004 sets out the scope of the possible delegation of specific tasks by the competent authority to control bodies, the criteria for delegation, and the minimum criteria which must be met by control bodies. Where such delegation takes place, the delegating competent authority must organise audits or inspections of the control bodies as necessary. The Authority must be notified of any such wish to delegate specific tasks to control bodies.

Findings

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, two accredited inspection bodies carry out controls on behalf of MAST of factory vessels, certain fishing vessels, auction halls and fishery processing establishments. The legal basis for the inspection bodies is Article 16 of Act No 55/1998 on Marine Products.

According to information provided by the Ministry of Fisheries and Agriculture to the Authority in a letter dated 10 November 2010, no tasks have been delegated to control bodies in Iceland. According to the same letter MAST monitors the activities of the inspection bodies and verifies that they carry out their duties in a satisfactory manner. All food business operators in the seafood sector that need approval from MAST shall draw up a contract with an inspection body. The inspection body charges its clients; i.e.

approved producers, an inspection fee. MAST has established certain procedures for supervision of the inspection bodies (see also Chapter 5.2.5). However, according to representatives of MAST no audits of the inspection bodies had, at the time of the mission, been organised by MAST

At the final meeting MAST informed the mission team that, official controls will not be delegated to inspection bodies in the future. The inspection bodies will continue to work as today until 1 February 2011.

Conclusions

No specific tasks have been delegated to control bodies within the meaning of Article 5 of Regulation (EC) No 882/2004. Furthermore, the inspection bodies acting on behalf of MAST at the time of the mission can not be said to be impartial and free from any conflict of interest since the establishments pay directly for their services. This is not in conformity with the requirements established in Article 5(2) of Regulation (EC) No 882/2004.

No audits have been organised by MAST in conformity with the requirement stated in Article 5(3) of Regulation (EC) No 882/2004.

5.2.4 Staff performing official controls

Legal requirements

Article 6 of Regulation (EC) No 882/2004 requires the competent authorities to ensure that staff performing official controls receive appropriate training, and are kept up-to-date in their areas of competence.

Findings

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, the main work of inspection and administrative work regarding fishery products is carried out within the division of Food Safety and Consumer Affairs of MAST. Three senior officers with university degrees in food science and engineering work on control of fish and fishery products. In addition MAST employs two fish inspectors. A number of specialists with university degrees in food science are involved in various special fields such as labelling, additives, contaminants, food contact materials etc. MAST's staff has also participated in several courses concerning legislation and official controls which should be carried out in the context of the production and placing on the market of fishery products.

According to representatives of MAST, a training programme for MAST's inspectors will be drawn up for 2011, taking into account the requirements laid down in Article 6 of Regulation (EC) No 882/2004.

The inspection bodies acting on behalf of MAST are responsible for their training programmes and these should, according to the accreditation standard, be part of their quality system.

MAST has organised two training seminars for the inspection bodies in 2010. One covered the general requirements and another the specific requirements for fish and fishery products laid down in the Food Hygiene Package.

In all the visited establishments, the mission team made several observations not reported by the inspection bodies in their reports. On several occasions, the inspection bodies did not point out non-compliances with regards to the requirements of the Food Hygiene Package. The findings described in the reports issued by the inspection bodies were not the same as the ones observed on-the-spot by MAST and the mission team.

The mission team noted several shortcomings in an establishment visited under the control of the local competent authority. The local competent authority had not pointed out any deficiencies in the establishment in the inspection report examined by the mission team. Furthermore, the representative of the local competent authority was not aware of several of the requirements laid down in the Food Hygiene Package.

Conclusions

Personnel of MAST and the inspection bodies met by the mission team were suitably qualified. However, personnel of the inspection bodies and the local competent authorities had limited knowledge of the requirements laid down in the Food Hygiene Package which is not in line with the requirement of keeping up to date in their area of competence as laid down in Article 6 of Regulation (EC) No 882/2004.

5.2.5 Control and verification procedures

Legal requirements

Article 8(1) of Regulation (EC) No 882/2004 requires competent authorities to carry out official controls in accordance with documented procedures. These procedures must contain information and instructions for staff performing official controls.

Article 13 of Regulation (EC) No 882/2004 requires Member States to draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to pose a serious risk to humans or animals either directly or through the environment.

Findings

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, the procedures for official control are described in the inspection manual which is available on MAST's website. The manual was last revised 1 May 2010 in order to take into account the requirements laid down in Regulations (EC) No 852/2004 and 853/2004. Inspections should be performed according to the inspection manual which is in the form of a check list, including a list of items which should be inspected. For each inspection the inspection body shall draw up a report. At the end of the visit the report is reviewed by the inspector and a responsible person from the establishment, including the given time period for corrective actions. The owner or the responsible person signs the inspection report and a copy is left with the establishment.

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, in addition to the inspection manual, procedures have been established in order to ensure common understanding of legal requirements by the inspectors of MAST and the inspection bodies. MAST accompanies the inspection bodies on joint inspections and prepares annual statistics to evaluate the harmonisation between MAST and the inspection bodies. The statistics are presented and discussed in a seminar for the inspectors.

During the visits on-the-spot the mission team observed that inspections were performed by the inspection bodies and by MAST according to the documented procedures mentioned above and the reports were available in the establishments.

At the initial meeting, a representative of MAST informed the mission team that operational contingency plans for crisis management when food poses a serious risk to human health were still under preparation at the time of the mission and should be available from March 2011.

Conclusions

Competent authorities carried out official controls in accordance with documented procedures as laid down in Article 8 of Regulation (EC) No 882/2004.

Operational contingency plans for crisis management were not available as required by Article 13 of Regulation (EC) 882/2004.

5.2.6 Follow up of Rapid Alert System for Food and Feed (RASFF) notifications

Legal requirements

Regulation (EC) No 178/2002 lays down the general principles and requirements of food law, establishing the European Food Safety Authority and procedures in matters of food safety. Articles 50, 51 and 52 of the Regulation lays down the scope and procedures of the RASFF.

Findings

RASFF notifications since 2001 concerning fishery products in Iceland or of Icelandic origin are listed in Annex 5. As an example of follow up action in case of RASFF notifications, the mission team received the documentation concerning the last notification dated 2008. The file contained evidence of the competent authority's investigation and further follow up.

Conclusions

MAST has a system in place to investigate notifications related to the rapid alert system for food and feed and to take action in line with the requirements.

5.3 Approval of establishments

Legal requirements

Article 31 of Regulation (EC) No 882/2004 and Article 3 of Regulation (EC) No 854/2004 require Member States to establish procedures for the registration/approval of food and feed business operators, for reviewing compliance with conditions of approval, for granting conditional approval and for the withdrawal of approvals.

Findings

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, the food business operators submit an application to MAST. After an on-site inspection of facilities and evaluation of the own check systems and compliance with the requirements in the relevant EEA legislation, MAST issues an approval. A conditional approval may be given if only minor corrective actions are needed to rectify non compliances identified, in other cases the application is rejected by MAST. Before the

approval is issued, the food business operator also has to comply with other relevant legislation e.g. environmental requirements. The list of approved establishments in Iceland is available on MAST's website. The list includes codes to identify the type of fishery products manufactured.

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, an approval may be suspended or withdrawn based on a notification from an inspection body of serious non-compliances, a notification from an inspector of MAST or based on a notice from the establishment itself.

During the missions, the mission team visited an establishment that was not approved by MAST. According to representatives of MAST, the local competent authority should carry out controls in this establishment, even though MAST is the designated competent authority (see also Chapter 5.2.1). The establishment was authorised by the local competent authority on 17 December 2008 for "other fishery products" without specifying the activities carried out. According to information provided to the mission team prior to the visit, the establishment was authorised to process smoked fish. However, during the visit the mission team noted that in addition to hot and cold smoking, also filleting, preparation of pate and freezing were carried out. Furthermore, the mission team noted several non-conformities in the establishment related to the general requirements for food premises.

In another establishment the mission team was informed by the representatives of MAST that they had not been aware of the existence of the establishment. Again the mission team noted several non-conformities in the establishment related to the general requirements for food premises.

None of these two establishments appeared on the list of approved establishments in Iceland.

In the establishments visited that were approved by MAST, the mission team noted that the codes indicated in the approvals issued did not identify the activities carried out. Some establishments carried out activities for which the relevant codes were not included in the approvals, others did not carry out all the activities indicated by codes in the approvals. According to representatives of MAST, new approval documents were issued for all establishments approved at the time of the entry into force of the Food Hygiene Package in Iceland. These approvals were based on the existing approvals of the establishments, and no on-site visits were carried out by MAST prior to issuing them.

In one establishment visited, approved for code 1 (fresh and frozen products) and 2 (salted fish), the mission team noted that mechanical separation of fish was also being carried out. The establishment had not informed MAST of the additional activity and it was not included in the hazard analysis and critical control point (HACCP) manual. According to representatives of MAST, this was not considered to be a significant change of the activities in the establishment, however, mechanical separation of fish is one of the codes that MAST uses to identify type of products manufactured in the list of approved establishments.

Conclusions

Compliance with Article 31 of Regulation (EC) No 882/2004 and Article 3 of Regulation (EC) No 854/2004 was not fully ensured since not all establishments processing fishery products were approved by the competent authority, and the list of approved food business operators is not kept up to date.

5.4 Official controls and action taken in case of non-compliances concerning production and placing on the market of fishery products

General legal requirements

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency and that official controls shall be carried out without prior warning.

Article 4 of Regulation (EC) No 854/2004 requires that the competent authority shall carry out official controls to verify food business operators' compliance with the requirements laid down in Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004. Official controls shall include audits and verification of good hygiene practices and HACCP-based procedures.

Article 7 of Regulation (EC) No 854/2004 requires official controls with respect to fishery products to take place in accordance with Annex III of the said regulation.

Article 5 of Regulation (EC) No 852/2004 requires food business operators carrying out any stage of production, processing and distribution of food after primary production to put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

Findings

The mission team noted that MAST did not carry out official controls regularly. According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, the inspection bodies carry out regular inspections of fish establishments on behalf of MAST. The frequency is four times a year for land based establishments operating all year and less frequent (one to three times) for establishments operating only part of the year. According to representatives of MAST, a risk based approach was not used for establishing the frequency of inspections. MAST was planning to establish procedures were factors like the food business operators' past records of compliance, identified risks and the reliability of own checks were taken into account when deciding the inspection frequency.

According to the information provided in the reply to the pre-mission questionnaire of the Authority, MAST had instructed the inspection bodies to carry out inspections without prior warning. However the mission team noted that the establishments were as a general rule informed of upcoming inspections prior to them.

According to representatives of MAST, food business operators' HACCP manuals will be audited prior to approval of new establishments. However, audits of HACCP manuals to verify that the food business operators apply procedures continuously and properly and comply with relevant legal requirements, e.g. microbiological criteria, residues, contaminants and prohibited substances etc. were not carried out by MAST or the inspection bodies. The mission team noted several shortcomings in the implementation of HACCP manuals and working procedures of the food business operators. HACCP manuals were not always updated with regard to the layout and machineries and the flow chart for the processes did not always reflect all the activities in the establishments, not all relevant hazards were taken into account (e.g. histamine, contaminants, etc.) and critical limits were not always defined and corrective actions not described.

In an auction hall visited, the mission team noted that the inspection body considered this to be a primary production. No HACCP manual could be presented to the mission team in this establishment.

Conclusions

Compliance with Article 3 of Regulation (EC) No 882/2004 was not fully ensured since the competent authority did not carry out official controls regularly, on a risk basis, with appropriate frequency and without prior notice.

Compliance with Article 4 of Regulation (EC) No 854/2004 was not fully ensured since official controls did not include audits of good hygiene practices and HACCP-based procedures.

Full compliance with Article 5 of Regulation (EC) No 852/2004 could not be ensured since the competent authority did not require all food business operators carrying out any stage of production, processing and distribution of food after primary production to put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

5.4.1 Primary production (aquaculture farms, fishing vessels)

Specific legal requirements

Article 4 of Regulation (EC) No 854/2004 states that the competent authorities shall carry out official controls to verify food business operators' compliance with the requirements of Regulation (EC) No 852/2004 and in particular its Annex I.

Article 7 of Regulation (EC) No 854/2004 requires official controls with respect to fishery products to take place in accordance with Annex III of the said regulation.

Chapter I of Annex III of Regulation (EC) No 854/2004 states that official controls are to include inspections at regular interval of vessels.

Findings

According to information provided by MAST at the initial meeting, the Directorate of Fisheries is the designated competent authority to grant permits to farmers involved in aquaculture activities according to the Icelandic Act No 71/2008 on Aquaculture and following this, permits for aquaculture farms are issued by the Directorate of Fisheries.

The application for an aquaculture permit is submitted to the Directorate of Fisheries. Other authorities are consulted in relation to the respective field of competence, including MAST, the Environmental Impact Assessment Authority, the Institute of Freshwater Fisheries, the Icelandic Coast Guard etc. The validity of a permit issued by the Directorate of Fisheries is normally five years. Permits may be withdrawn after inactivity for a period of 24 months or violation of the permit.

According to a representative of MAST, aquaculture farms are inspected annually by a fish health inspector of MAST for aspects related to fish health and welfare. According to additional information provided at the final meeting, these annual inspections carried out by MAST cover some hygiene requirements.

An aquaculture farm was visited by the mission team. This farm was included in the residues plan 2009, and the mission team noted that samples had been collected by MAST according to the plan. The mission team noted that records including concerning feed and medication. The last time antibiotics had been used on the farm was in 2002.

The official list of approved fishing vessels available on MAST's website, dated 10 November 2010 included 38 factory vessels and eight freezing vessels. These and registered fishing vessels with a capacity of more than 15 gross registered tonnage should, like processing establishments on land, have a contract with an inspection body. Vessels, other than factory vessels are inspected twice a year. However, according to information provided by MAST, the number of inspections did not correspond to the indicated frequency.

Fishing vessels with a capacity of less than 15 gross registered tonnage, 870 out of 1148 registered by the Directorate of Fisheries, were at the time of the mission not subject to official controls by MAST or controlled by the inspection bodies. These vessels land approximately 30 % of the total catch of demersal species from registered vessels in Iceland.

Conclusions

Compliance with Article 4 of Regulation (EC) No 854/2004 was not fully ensured since the competent authorities did not carry out official controls to verify food business operators' compliance with the requirements of Regulation (EC) No 852/2004 and in particular its Annex I in relation to aquaculture farms. Compliance with Chapter I of Annex III to Regulation (EC) No 854/2004 was not ensured since official controls did not include inspections at regular interval of all vessels.

5.4.2 Landing and first sale sites

Specific legal requirements

Article 7 of Regulation (EC) No 854/2004 requires official controls with respect to fishery products to take place in accordance with Annex III of the said regulation.

Point 1(a) of Chapter I of Annex III to Regulation (EC) No 854/2004 requires that official controls on the production and placing on the market of fishery products are to include, in particular, regular checks on the hygiene conditions of landing and first sale sites.

Article 3 of Regulation (EC) No 853/2004 requires food business operators to comply with the relevant provisions of Annex II and III of the said regulation.

Chapter II of Section VIII of Annex III to Regulation (EC) No 853/2004 lays down the structural, equipment, and hygiene requirements that should be followed by food business operators responsible for these premises.

Findings

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, regular inspections related to hygienic requirements of landing sites are not carried out. The mission team visited a landing site and observed that fish in tubs landed on the quay side was not placed, without delay, in a protected environment. The tubs were stored on the quay side for a prolonged time and the mission team noted that birds were picking on the fish.

The mission team visited two auction halls. Both had contracts with an inspection body and were inspected every three months. The mission team noted that there were no lockable facilities in the auction halls. In one case fish was not fully iced and temperature of the fish was in some parts up to 7,1°C. The mission team also noted that the practice at the premises could not exclude contamination of the products since e.g. carton boxes and dirty crates were placed on top of fish in tubs.

One of the auction hall visited used the reception area of an approved establishment for storing the fish awaiting auction. According to a representative of MAST the Ministry of Fisheries had accepted that the facilities for reception area and fish-markets could be shared. According to a representative of the auction hall, facilities for cleaning fish had previously been available in the production area of the establishment. A couple of months before the mission the equipment had been removed. The mission team noted unidentified large bags, tubs with technical equipment and canned chopped ocean clams stored in the auction hall/reception area of the establishment.

Conclusions

Compliance with Point 1 of Chapter I of Annex III to Regulation (EC) No 854/2004 was not ensured since regular checks on the hygiene conditions of landing are not carried out by MAST.

Compliance with Chapter II of Section VIII of Annex III to Regulation (EC) No 853/2004 was not ensured since lockable facilities to detain fish unfit for human consumption were not available in the auction halls visited and since one auction hall was used for other purposes at the time of display or storage of fishery products.

5.4.3 Facilities handling fishery products (land based establishments)

Specific legal requirements

Article 3 of Regulation (EC) No 853/2004 requires food business operators to comply with the relevant provisions of Annex II and III of the said regulation.

Chapter III of Section VIII of the Annex III to Regulation (EC) No 853/2004 lays down the structural and hygiene requirements for food business operators responsible for establishments on land.

Findings

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, the inspection bodies carry out regular inspections of fish establishments on behalf of MAST. Cold and refrigerated storages in establishments are integral part of the routine inspections.

The following was observed by the mission team in the different establishments visited, e.g.:

- in several establishments it was observed that the operational procedures and the design and lay out of the premises allowed cross flow of raw material, intermediate products for further processing, finished product and animal by-products not intended for human consumption;
- poor maintenance of the some of the facilities visited ;

- absence or limited numbers of hand-washing facilities in the processing areas, inadequate drainage;
- the size of one establishment did not allow for all the activities to be carried out inside the premises and, consequently activities were taking place outside;
- condensation and dripping of water on final products before being packed
- operators involved in several actions including manipulation of fishery products before and after packaging without washing hands in between the different operations;
- not all products in the cold stores were labeled and the traceability of products could not always be demonstrated;
- wooden pallets placed on top of unprotected fishery products in chilling room;
- fishery products were left on the worktables during the workers breaks;
- packaging materials were not always stored protected from the environment.

Conclusions

Compliance with Chapter III of Section VIII of the Annex III to Regulation (EC) No 853/2004 could not be ensured since food business operators responsible for establishments did not always fulfil structural and hygiene requirements.

5.4.4 Illegal use of food additives (polyphosphates and “Natural White”)

Legal requirements

Requirements for food additives other than colours and sweeteners are laid down in Directive 95/2/EC, in particular which substances may be used and for which purposes.

Findings

The mission team identified different chemical compounds in some of the visited establishments, including polyphosphates. In one establishment compounds were packed in unlabelled plastic bags. Other chemical compounds were only identified by the commercial name.

The itinerary included visits without prior warning to three establishments approved for production of salted fish. The mission team noted that all three establishments injected chemical compounds into the fish before salting.

In one establishment additives were used on individually quick frozen fish and fillets as allowed for in the legislation and in salted fish. The mission team noted that the labels of these products did not include information related to the use of food additives. The mission team noted that the food additives were not included on the label of packed products. In addition, relevant procedures in the HACCP manuals on the use of the additives were not established. Furthermore, according to representatives of the food business operators, the injection of polyphosphates is a common practice all over the country and that this is done to maintain the position in the market in certain EU Member States.

In one establishment visited, the mission team was informed that “*Natural White*” was used in the processing of smoked salmon. The mission team noted empty plastic bottles in the packaging area labeled “*NW smoked salmon*” only. No additional information related to the chemical composition of the “*Natural White*” could be presented to the mission team in this establishment. The representative of the company stated that he had not been

informed this was an unapproved substance but that he would, in light of the information given during the visit, stop to use it immediately.

Conclusions

Compliance with Article 2 of Council Directive 95/2/EC could not be ensured since polyphosphates were injected in fish fillets for salt-fish production, a product not included in Part C of Annex IV to that directive. In addition “*Natural White*”, which is not included in Annex I, III, IV or V of Directive 95/2/EC, was used in smoked salmon.

5.4.5 Action taken in case of non-compliance

Legal requirements

Article 54 of Regulation (EC) No 882/2004 requires the competent authority to take action when non-compliances have been identified and to ensure that the food business operator remedies the situation. When deciding which action to take, the competent authority shall take into account the nature of the non-compliance and the food business operators’ past record with regard to non-compliances.

Findings

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, the inspection bodies report their control result to MAST, which is responsible for enforcement measures in case of non-compliance. Inspection bodies are required to provide MAST with information on food business operators’ activities and conditions in a format determined by MAST. However, the mission team noted that the inspection bodies failed to inform MAST of their knowledge of illegal use of polyphosphates despite a specific and formal request from MAST to do so.

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, Regulation (EC) No 882/2004 and the Icelandic Act No 55/1998 on Fishery products and Act No 93/1995 on Foodstuffs establish legal basis for enforcement measures available to MAST in case of non-compliances related to food hygiene and safety.

Several non-compliances were observed by the mission team in the establishments visited during the mission and acknowledged by representatives of MAST (see findings under Chapters from 5.4.1 to 5.4.4). The mission team noted however, that MAST took action on-the-spot only in one case. In an establishment where the non-compliances were so many and severe, MAST suspended the approval of the establishment the following day. In addition, MAST stopped the distribution of the already made products and requested them to be destroyed.

Conclusions

Following identification of non compliance the competent authority did not always take appropriate immediate action to ensure that the food business operator remedied the situation as required by Article 54(1) of Regulation (EC) No 882/2004.

5.5 Official controls of fishery products

Legal requirements

Article 7 of Regulation (EC) No 854/2004 requires official controls with respect to fishery products to take place in accordance with Annex III of the said regulation.

Chapter II of Annex III to Regulation (EC) No 854/2004 requires that official controls of fishery products are to include at least certain parameters.

Article 11 of Regulation (EC) No 882/2004 requires that sampling and analysis methods, used in the context of official controls, comply with relevant Community rules or with internationally recognised rules or protocols or, in the absence of these, with other methods fit for the intended purpose or developed in accordance with scientific protocols.

Chapter I of Annex I to Regulation (EC) No 2073/2005 lays down certain microbiological criteria (including histamine).

Findings

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, a sampling plan to verify that the requirements of Chapter II of Annex III to Regulation (EC) No 854/2004 are met will be finalised before the end of 2010. At the time of the mission, the situation was the following:

a) Organoleptic examinations are not carried out by MAST. Food business operators (including vessels) are required to have a procedure in place for organoleptic checks of all raw materials. Iceland has included the organoleptic criteria laid down in Council Directive 91/493/EEC in the regulation incorporating Regulation (EC) No 853/2004;

b) freshness indicators are not checked by MAST. Freshness indicators, Total Volatile Basic Nitrogen (TVB-N), and Trimethylamine Nitrogen (TMA-N) will only be examined if the results from the organoleptic checks indicate spoilage;

c) histamine

With the increase in herring and mackerel catch in Iceland, the importance of temperature control and histamine analysis has been emphasised by MAST. A letter with instructions to the relevant food business operators, including vessels, to include histamine analysis in their sampling program has been issued. The mission team noted that some samples had been collected and analysed for histamine by the food business operators. However, none of the establishments collected nine samples per batch. MAST collected a total of nine samples in 2009 and in 2010, until the time of the mission, 27 samples for histamine analysis. To date all samples have been below the detection limit;

d) residues and contaminants

The fishing areas around Iceland are under surveillance by the AMSUM project (Monitoring of the marine biosphere around Iceland) and by the Ministry of Agriculture and Fisheries (Undesirable substances in seafood products). The reports are available on the website of Matis (an Icelandic Food and Biotech R&D institute);

e) microbiological checks are not routinely carried out by MAST. Food business operators are responsible for sampling as part of their own check system. MAST was, at the time of the mission, drawing up a sampling program for *Listeria monocytogenes* in smoked and gravad fish. According to the plan, sampling will be initiated in December 2010;

f) parasites are not checked by MAST. Screening for parasites is an integral part of the process in food business operators filleting fish (mainly demersal species);

g) poisonous fishery products

Fish of the following families: Tetradontiadae, Molidae, Diodontidae and Canthigasteridae are not commercial species in Iceland and fish species associated with ciguatera poison are not found in the Icelandic fishing grounds.

Conclusions

Full compliance with Chapter II of Annex III to Regulation (EC) No 854/2004 was not ensured since MAST did not carry out official controls of fishery products in line with the requirements therein.

Full compliance with Article 11 of Regulation (EC) No 882/2004 and Chapter I of Annex I to Regulation (EC) No 2073/2005 could not be fully ensured since samples for histamine analyses were not collected in line with the requirements laid down in Regulation (EC) No 2073/2005.

5.6 Other requirements

Legal requirements

Council Directive 98/83/EC lays down the requirements for the quality of water intended for human consumption. In particular, Article 5 of this directive provides that Member States shall set values applicable to water intended for human consumption for the parameters set out in Annex I. Chemical parameters are laid down in Part B of annex I.

Regulation (EC) No 1774/2002 lays down the requirements for the handling of animal by-products not intended for human consumption, in particular Article 7(1) states that animal by-products shall be collected, transported and identified in accordance with Annex II of the said Regulation.

Findings

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, the local competent authorities will collect samples with a frequency based on the number of people that the relevant water work supplies.

MAST requires the fish processing establishments to take samples of the drinking water (and ice) used in the establishment. The aim with this sampling is to supplement the official sampling taken by the local competent authorities. Establishments with their own water supply need an approval/registration of this from the local competent authorities. Furthermore, the local competent authorities should carry out official controls in such establishments to verify compliance with the legislation related to potable water.

The mission team noted in one establishment that no results of chemicals parameters in the water were available. The establishment was using water in provenance of its own water source. Representatives of the local competent authority informed the mission team at the final meeting that for smaller water sources, supplying less than 500 inhabitants, separate chemical analyses were not carried out. In these cases, satisfactory results from a larger water source, supplying more than 500 inhabitants, located in the same region would be sufficient for approving smaller sources.

The mission team noted that dead fish collected on the aquaculture farm visited, destined to be used as feed for minks, was stored in containers outside without labeling indicating that it was category 2 material. Furthermore, the mission team also noted in several of the visited establishments that animal by-products not intended for human consumption were

stored in tubs of the same type as products intended for human consumption were stored in. The tubs were not identified or designated for the different purposes. Finally, animal by-products were stored in the same chiller as fishery products fit for human consumption.

Conclusions

Compliance with article 5 of Council Directive 98/83/EC was not fully ensured since chemical parameters were not tested in one establishment visited.

Full compliance with the requirements laid down in Article 7 and in Chapter I and II of Annex II to Regulation (EC) No 1774/2002 could not be ensured since animal by-products not intended for human consumption since animal by-products were collected in tubs also used for products intended for human consumption and not kept separate and identifiable during collection.

5.7 Laboratories

Legal requirements

Article 12(1) of Regulation (EC) No 882/2004 states that the competent authority shall designate laboratories that may carry out the analysis of samples taken during official controls.

Findings

At the initial meeting, representatives of MAST informed the mission team that MAST had, at that time, not yet designated laboratories that may carry out the analysis of samples taken during official controls on fishery products. Laboratories have been designated for analysis of official samples in other fields (e.g. Salmonella in food and feed).

The mission team visited a laboratory analysing official samples. A representative of the laboratory provided information to the mission team related to the methods used. The methods used for microbiological analysis and TVB-N are accredited. Methods for analysing lead, cadmium and mercury are not accredited, however, the accreditation process and quality control schemes for these analyses have been initiated. The method used for histamine was, at the time of the mission, not accredited. However, there is an ongoing process to validate a method for analysing histamine in fish in cooperation with the Nordic Committee on Food Analysis. The laboratory uses standards and certified reference materials to ensure quality.

The mission team visited another laboratory which mainly analysed samples for the food business operators for microbiological and chemical parameters. In addition the laboratory carried out analyses on some official samples, mainly water samples. This laboratory forwarded samples to accredited laboratories in Europe for various analysis such as heavy metals, dioxins, polycyclic aromatic hydrocarbons (PAH), histamine etc. All the methods used by this laboratory for analysis of fishery products were accredited except the method for analysing TVB-N. In addition the method used for *Clostridium spp.* was accredited for the matrix food but not for water. According to information provided by a representative of the laboratory, they had not analysed any samples of surface water.

Conclusions

Compliance with Article 12(1) of Regulation (EC) No 882/2004 was not ensured since MAST had not designated laboratories that may carry out the analysis of samples taken during official controls on fishery products. The methods checked by the mission team

and used for the controls testing of fishery products are in compliance with EEA legislation.

6 Overall conclusion

The mission team found that the situation in Iceland concerning fishery products was not in conformity with several requirements laid down in the relevant EEA legislation. In particular, the limited number of inspections and audits carried out and few samples taken by the competent authority is not in line with the requirements of the EEA legislation. The competent authority relies on regular controls carried out by inspection bodies. However, several shortcomings of the establishments were not reported to the competent authority which thereby was not fully aware of the situation in the establishments. Furthermore, the mission team observed that enforcement actions were not always timely and appropriate.

Routine controls are carried out by inspection bodies which can not be seen as impartial as they collect fees directly from the establishments being controlled.

The situation concerning the implementation of the general and specific hygienic requirements by the food business operators was also found to not to be in conformity with several requirements laid down in the relevant European Economic Area legislation.

These observations made the mission team conclude that the official controls, and the use of enforcement measures, related to fishery products in place in Iceland at the time of the mission were inadequate.

7 Final meeting

A final meeting was held on 25 November 2010 at the Ministry of Fisheries and Agriculture in Reykjavik with representatives of the Ministry of Fisheries and Agriculture and MAST and one local competent authority. At this meeting, the mission team presented its main findings and some preliminary conclusions of the mission. At the meeting the mission team also explained that, based on a more detailed assessment of the information received during the mission, additional conclusions and recommendations could be included in the report.

The Icelandic representatives did not have any objections to the observations made and the preliminary conclusions presented.

8 Recommendations

Iceland should inform the Authority in its reply to the draft report, by way of written evidence, of the corrective actions taken and a plan for corrective measures and actions, including a timetable for completion of measures still outstanding, relevant to all the recommendations hereunder. This information will be annexed to the final report. The Authority should also be kept informed of the completion of the measures included in the timetable.

No	Recommendation
1	Iceland should ensure that its national legislation is in line with the EEA Agreement, in particular the entry into force of Article 5 of Regulation (EC) No 882/2004.
2	Iceland should ensure that all official controls are carried out by competent authorities designated in accordance with Article 4 of Regulation E(C) No 882/2004.
3	Iceland should ensure that control bodies operate only in line with the provisions provided for in Article 5 of Regulation (EC) No 882/2004.
4	The competent authority should ensure that staff carrying out official controls receive appropriate training related to the production and the placing on the market of fishery products in accordance with Article 6 of Regulation (EC) No 882/2004.
5	The competent authority should ensure that operational contingency plans for crisis management are available as required in Article 13 of Regulation (EC) No 882/2004.
6	The competent authority should ensure that approval of food business operators processing fishery products in Iceland is in line with the requirements laid down in Article 31 of Regulation (EC) No 882/2004 and Article 3 of Regulation (EC) No 854/2004.
7	The competent authority should ensure that official controls are carried out regularly, on a risk basis, with appropriate frequency and without prior notice as required by Article 3 of Regulation (EC) No 882/2004. Furthermore it should be ensured that official controls include audits of good hygiene practices and HACCP-based procedures as required by Article 4 of Regulation (EC) No 854/2004. Finally the competent authority should ensure that all food business operators carrying out any stage of production, processing and distribution of food after primary production put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles as required by Article 5 of Regulation (EC) No 852/2004.
8	The competent authority should ensure that official controls to aquaculture farms are carried out in compliance with Article 4 of Regulation (EC) No 854/2004 in order to verify that food business operators comply with the requirements of Regulation (EC) No 852/2004 and in particular its Annex I. The competent authority should ensure that official controls include inspections at regular interval of all vessels in line with the requirements laid down in Chapter I of Annex III to Regulation (EC) No 854/2004.
9	The competent authority should ensure that regular checks are carried out on the hygiene conditions of landing as required by Chapter I of Annex III to Regulation (EC) No 854/2004. The competent authority should also ensure that auction halls comply with the requirements laid down in Chapter II of Section VIII of Annex III to Regulation (EC) No 853/2004.
10	The competent authority should ensure that food business operators responsible

	for establishments handling fishery products fulfil structural and hygiene requirements in compliance with Chapter III of Section VIII of the Annex III to Regulation (EC) No 853/2004.
11	The competent authority should ensure that food additives used in fishery products are authorised and used in compliance with Part C of Annex IV of Council Directive No 95/2/EC.
12	The competent authority should ensure that, following identification of cases of non-compliance with legal requirements, action is taken to ensure that the food business operators remedy the situation as required by Article 54(1) of Regulation (EC) No 882/2004.
13	The competent authority should ensure that official controls of fishery products are carried out in line with the requirements laid down in Chapter II of Annex III to Regulation (EC) No 854/2004. The competent authority should also ensure that samples for histamine analyses are collected in line with the requirements laid down in Article 11 of Regulation (EC) No 882/2004 and Chapter I of Annex I to Regulation (EC) No 2073/2005.
14	The competent authority should ensure that potable water used by food business operators fulfil the requirements laid down in Council Directive 98/83/EC.
15	The competent authority should ensure that animal by-products are handled in line with the requirements laid down in Regulation (EC) No 1774/2002.
16	The competent authority should designate laboratories that may carry out the analysis of samples taken during official controls as laid down in Article 12 (1) of Regulation (EC) No 882/2004.

Annex 1 – List of abbreviations and terms used in the report

Authority	EFTA Surveillance Authority
Category 2 material.	Animal by-products not intended for human consumption as defined in Article 5 of Regulation (EC) No 1774/2002
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
Food Hygiene Package	<p>A term that refers to a group of European Regulations that represent a significant reorganisation of the regulatory framework for food and feed hygiene and safety. The package builds on general food law basis established by <i>Regulation (EC) No 178/2002 of the European Parliament and the Council laying down the general principles and the requirements of food law, establishing the European Food Safety Authority and laying down procedures for matters of food safety.</i></p> <p>The Food Hygiene package includes several Regulations, <i>inter alia</i>, Regulations (EC) No 852/2004, 853/2004 854/2004.</p>
HACCP	Hazard Analysis and Critical Control Point
MAST	<i>Matvælastofnun / Icelandic Food And Veterinary Authority</i>
RASFF	Rapid Alert System for Food and Feed
TMA-N	Trimethylamine Nitrogen
TVB-N	Total Volatile Basic Nitrogen

Annex 2 - Relevant legislation

The main EEA Acts regarding the production and placing on the market of fishery products and relevant for this mission are:

- a) The Act referred to at Point 7.1.2 of Chapter I of Annex I to the EEA Agreement, *Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC*, as amended;
- b) The Act referred to at Point 7.2.19 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results*, as corrected by OJ L 239, 6.9.2002, p. 66, as amended;
- c) The Act referred to at Point 6.2.52 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs*, as corrected by OJ L 278, 10.10.2006, p. 32 and OJ L 283, 14.10.2006, p. 62 and as amended;
- d) The Act referred to at Point 6.2.53 of Chapter I of Annex I to the EEA Agreement, *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*, as amended;
- e) The Act referred to at Point 6.2.55 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2005*, as amended;
- f) The Act referred to at Point 7.1.9b of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption*, as corrected and as amended;
- g) The Act referred to at Point 7a of Chapter II of Annex XX to the EEA Agreement, *Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption* as adapted to the EEA Agreement;
- h) The Act referred to at point 18 of Chapter XII of Annex II to the EEA Agreement, *Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs*, as corrected by

OJ L 124, 25.5.2000, p.66, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex II to that Agreement;

- i) The Act referred to at Point 54zb of Chapter XII of Annex II to the EEA Agreement, *European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners*, as amended;
- j) The Act referred to at Point 54zzzg of Chapter XII of Annex II to the EEA Agreement, *Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners*, as amended;
- k) The Act referred to at Point 54zzzn of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs*;
- l) The Act referred to at Point 54zzzp of Chapter XII of Annex II to the EEA Agreement, *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*; and
- m) The Act referred to at Point 54zzzz of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum level for certain contaminants in foodstuffs*, as amended and adapted to the EEA Agreement.

Annex 3 – Figures for the production and trade of fishery products in Iceland (in tonnes)¹

a) Total production in Iceland

Common name	Scientific name	2007	2008	2009
Herring	<i>Clupea harengus</i>	140.661	183.618	208.943
Capelin	<i>Mallotus villosus</i>	103.853	77.228	17.930
Blue Whiting	<i>Micromesistius poutassou</i>	38.552	45.847	32.154
Mackerel	<i>Scomber scombrus</i>	54	3.583	13.208
Cod	<i>Gadus morhua</i>	101.798	106.785	127.311
Haddock	<i>Melanogrammus aeglefinus</i>	47.509	53.092	41.978
Pollock	<i>Pollachius virens</i>	29.796	29.923	30.196
Redfish	<i>Sebastes marinus, Sebastes mentella</i>	43.918	47.382	45.394
Atlantic catfish	<i>Anarhichas lupus</i>	7.510	6.696	8.215
Greenland Halibut	<i>Reinhardtius hippoglossoides</i>	34.198	36.310	51.003

b) Total imports from third countries

Common name	Scientific name	2007	2008	2009
Redfish	<i>Sebastes marinus/ S. mentella</i>	2.015	5.750	6.020
Shrimp	<i>Pandalus borealis</i>	8.791	5.806	9.508
Fish oil	<i>Thunnus spp./ Sardinella spp.</i>	248	2.248	685
Squid	<i>Illex illecebrosus</i>	600	1.072	2.085
Greenland halibut	<i>Reinhardtius hippoglossoides</i>	1.162	811	2.037
Cod	<i>Gadus morhua</i>	89	520	183
Tuna (canned)	<i>Thunnus spp.</i>	160	160	175
Other*		614	548	285
	Total	13.679	16.915	20.978

¹As provided by MAST in its reply to the pre-mission questionnaire of the Authority.

c) Total traded with other EEA countries

Common name	Scientific name	2007	2008	2009
Herring	<i>Clupea harengus</i>	121.021	161.201	179.883
Capelin	<i>Mallotus villosus</i>	48.563	34.397	10.914
Blue Whiting	<i>Micromesistius poutassou</i>	34.842	37.335	22.617
Mackerel	<i>Scomber scombrus</i>	40	863	2.119
Cod	<i>Gadus morhua</i>	83.072	72.182	89.524
Haddock	<i>Melanogrammus aeglefinus</i>	36.647	44.581	34.753
Pollock	<i>Pollachius virens</i>	23.599	22.921	24.450
Redfish	<i>Sebastes marinus, Sebastes mentella</i>	30.634	30.872	31.942
Atlantic catfish	<i>Anarhichas lupus</i>	7.139	8.149	8.140
Greenland Halibut	<i>Reinhardtius hippoglossoides</i>	617	835	1.567

d) Direct landing of fishery products in Iceland by vessels flying the flag of a third country

Common name	Scientific name	2007	2008	2009
Greenland halibut	<i>Reinhardtius hippoglossoides</i>	1.162	811	2.037
Redfish	<i>Sebastes marinus/ S. mentella</i>	2.015	4.944	6.020
Shrimp	<i>Pandalus borealis</i>	1.349	162	1.534
	Total	4.525	6.427	9.750

Annex 4 – List of Icelandic laws, regulations and administrative provisions applicable to the control and monitoring of legislation related to fishery products²


- I. Act No 54/1990 on the Import of Animals.
 - Regulation No 448/2005 on veterinary checks applicable in EEA trade in certain aquaculture animals and products.
- II. The Foodstuffs Act, No 93/1995.
 - Regulation No 285/2002 on food additives authorised for use in foodstuffs.
 - Regulation No 503/2005 on the labelling of food, implementing Directive 2000/13/EC.
 - Regulation No 134/2010 incorporating EC Regulation No 1688/2005.
 - Regulation No 135/2010 incorporating EC Regulation No 2073/2005.
 - Regulation No 265/2010 incorporating EC Regulation No 1881/2006.
 - Regulation No 267/2010 incorporating EC Regulation No 1883/2006.
 - Regulation No 131/2010 incorporating Commission Decision 2006/677/EC.
 - Regulation No 103/2010 incorporating EC Regulation No 852/2004.
 - Regulation No 104/2010 incorporating EC Regulation No 853/2004, 2074/2005/2076/2005 1662/2006 1664/2006 and 1666/2006.
 - Regulation No 105/2010 incorporating EC Regulation No 854/2004 and 1663/2006.
 - Regulation No 106/2010, incorporating EC Regulation No 882/2004.
 - Regulation No 884/2010 incorporating EC Regulation No 333/2007
- III. Act No 7/1998 on Hygiene and Pollution Control.
 - Regulation No 536/2001 on the quality of water intended for human consumption.
- IV. Act No 55/1998 regarding Fishery Products.
 - Regulation No 450/1997 on practical procedures of accredited and independent inspection agencies in the fishery sector.
 - Regulation No 849/1999 on veterinary checks on imports of fish products.
 - Regulation No 1254/2004 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals.
 - Regulation No 512/2005 on veterinary checks of marine aquatic species and their products in intra-EEA trade.
 - Regulation No 835/2005 on the implementation of certain EU acts on establishing special health checks for the harvesting and processing of certain bivalve molluscs, amending Council Decision 225 and 226/2002/EEC.

² As provided by MAST in its reply to the pre-mission questionnaire of the Authority.

Annex 5 – RASFF notification of fishery products in Iceland or of Icelandic origin since 2001

1. Notification 2001/FN – Spoiled Redfish Fillets from Iceland notified by The Netherlands 4 May 2001 (inspection lead to seizure on 11 April 2001).
2. Notification 2002/206-add01: Salmonella Montevideo in dried squid with skin from Thailand (distribution to Iceland).
3. Notification 2004.637 – chloramphenicol in fishmeal from Iceland via Germany, notified by Hungary (first sale took place on 4/8/2004).
4. Notification 2004/065-add2 – Histamine in frozen tuna steaks from Indonesia via the Netherlands - also found in Iceland.
5. Notification 2004.CBG from Italy: Parasites – Anisakis in scorpion fish from Iceland.
6. Notification on 11/9/2007 from Iceland – Dioxin and PCB in Fishmeal (redfish) from Russia (remark : this is in the RASFF database without a notification number – just as a word doc).
7. Notification 2007.816 from Belgium regarding Salmonella in fishmeal from Iceland via France.
8. Notification 2008.877 from Malta: Prohibited substance chloramphenicol in cooked, peeled and quick frozen North Atlantic prawns from Iceland, via the United Kingdom.
9. Notification 2008.0877-: add 05 : Outcome of the investigations and measures taken in Denmark: In light of the additional testing undertaken in Iceland, which has shown negative results for chloramphenicol, the products have been released (outcome of investigations in Denmark).

Annex 6– Table of corrective actions provided by the Icelandic Food and Veterinary Authority in its reply to the draft report

No	Recommendation/Subject	Action	Time aspect	Enclosures
1	Iceland should ensure that its national legislation is in line with the EEA Agreement, in particular the entry into force of article 5 of Regulation EC No. 882/2001	<p>Article 5 of Regulation (EC) No 882/2004 will not apply in Iceland until 1 March 2011 and until that date the control bodies operate according to the legislation that has been notified to ESA prior to the implementation of the new EEA official control and hygiene legislation.</p> <p>MAST will from March 1st 2011 take over the tasks of official control that were formerly delegated to Inspection bodies</p> <p>Enclosed is a letter from Icelandic Authorities to ESA dated November 10 2010 regarding control of marine products (Case No 67907).</p>	Ongoing	 <p>Letter to ESA_882_2004 Art5.l</p>
2	Iceland should ensure that all official controls are carried out by competent authorities designated in accordance with Article 4 of Regulation (EC) No 882/2004.	<p>A decision has been taken on the delegation of tasks between the CCA and LCAs. Private control bodies will not be involved in official control as of March 1 2011. Contracts on delegations of tasks are being completed with all 10 LCAs.</p>	Completed	
3	Iceland should ensure that control bodies operate only in line with the provisions provided for in Article 5 of Regulation (EC) No 882/2004.	See answer provide to point 1 above.		
4	The competent authority should ensure that staff carrying out official controls receives appropriate training, related to	A training programme is under construction for 2011 which will take notice of article 6 of Regulation (EC) No 882/2004. The aim is to cover the items listed in Ch. I of Annex II of Regulation 882/2004.	01.03.2011	


	the production and the placing on the market of fishery products in accordance with Article 6 of Regulation (EC) No 882/2004.	MAST is in the process of employing inspectors. A training programme will be arranged for the new inspectors and the inspectors already working at MAST. It should be finalised before 1 st of March 2011.		
5	The competent authorities should ensure that the operational contingency plan for crisis management is available as required in Article 13 of Regulation (EC) 882/2004.	The contingency plan will be reviewed in the coming months in light of requirements of Article 13 of Regulation (EC) No 882/2004.	01.04.2011	
6	The competent authorities should ensure that approval of food business operators processing fishery products in Iceland is in line with requirements laid down in Article 31 of Regulation (EC) 882/2004 and Article 3 of Regulation (EC) No 854/2004.	<p>MAST has already taken steps towards improvements of the procedure for approving establishments. The conditions for approval will be the fulfilment of the general hygiene requirements laid down in 852/2004 and in Annex II of the same Regulation and the relevant specific requirements laid down in 853/2004 in Annex III section VII and Annex VIII.</p> <p>MAST will use the possibility of conditional approval in order to be able to verify that the HACCP system is implemented as planned and to verify that there is an understanding of HACCP before the issue of final approval. MAST's goal will be to issue final approval when the establishments have been operating for 3 months. However, a relatively large number of establishments operate only part of the year and on some occasions less than 3 months.</p> <p>The procedure for approval of establishments will be revised when MAST takes over the inspections of the establishments.. As soon as it has been issued it will be audited by MAST's audit team and a plan for regular audits will be made.</p>	01.04.2011	

		<p>MAST will during the first inspection after 1st of March verify the production activities performed in each establishment and correct the list and the approval documents accordingly. A policy regarding the maximum period an approval that is temporary not in use, can be regarded as valid, will be designed before 1st of March 2011.</p>	01.07.2011	
7	<p>The competent authorities should ensure that official controls are carried out regularly, on a risk basis, with appropriate frequency and without prior notice as required by Article 3 of Regulation (EC) 882/2004. Furthermore it should be ensured that that official controls include audits of good hygiene practice and HACCP based procedures as required by Article 4 of Regulation (EC) No 854/2004.</p>	<p>MAST is working on risk classification of establishments. The aim is to have the system in place when MAST takes over the regular inspection of establishments 01.03.2011</p> <p>A new inspection manual is under construction. The methods of inspections will be changed with a bigger emphasis on audits.</p>	01.03.2011 01.03.2011	

	<p>Finally the competent authority should ensure that all food business operators carrying out any stage of production, processing and distribution of food after primary production put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles as required by Article 5 of Regulation (EC) No 852/2004.</p>	<p>MAST has made a guidance on the requirements of the own checks system and HACCP. It will be issued as a brochure and published on MAST website before 1st of February. Guidelines on the prerequisite program are under preparation and will also be published on MAST's website in January. www.mast.innraeftirlit.</p> <p>According to this guidance fish auctions should work according to good hygiene practices (GHP) and a prerequisite program which should prevent hazards in the auction hall.</p>	01.02.2011	
8	<p>The competent authorities should ensure that official controls of aquaculture farms are carried out in compliance with Article 4 of Regulation (EC) No 854/2004 in order to verify that food business operators place comply with requirements of Regulation (EC) No 852/2004 and in particular its Annex I. The competent authorities should ensure that official controls include inspections at regular interval of all vessels in line</p>	<p>Aquaculture Farms:</p> <p>Not all requirements regarding official control of aquaculture in Regulation No 852/2004 are fulfilled. MAST will before include aquaculture farms in its control plan to insure that aquaculture farms comply with requirements of Regulation No 852/2004.</p> <p>Vessels.</p> <p>The Directorate of Fisheries (DoF) and MAST are discussing a formal participation of the first in control and follow-up actions regarding fishing vessels. MAST will however inspect the fishing vessels regarding hygiene, handling and documentation, according to a risk based frequency.</p>	<p>Aquaculture</p> <p>01.09.2011</p> <p>Vessels</p> <p>01.03.2011</p>	

	with the requirements as laid down in Chapter 1 of Annex III to Regulation(EC) No 854/2004			
9	<p>The competent authorities should ensure that regular checks are carried out on the hygiene conditions of landing as required by Chapter 1 of Annex III to Regulation (EC) No 854/2004. The competent authorities should ensure that auction halls comply with the requirements laid down in Chapter II of Section VIII of Annex III to Regulation (EC) No 853/2004.</p>	<p>Landing sites:</p> <p>A letter to the municipalities and companies that control the landing sites will be sent in February in order to clarify practical things like contact persons etc.</p> <p>The Directorate of Fisheries (DoF) and MAST are discussing a formal participation of the first in control and follow-up actions regarding landing sites. MAST will however inspect at regular intervals the landing sites regarding appropriate landing equipment, contamination hazards and facilities to allow proper handling of the landed fish.</p> <p>According to the discussions the DoF inspectors will measure temperature and the use of ice in landed fish and report to MAST. The DoF inspectors will also report to MAST the use of unclean fish tubs intended for fish going into the fish auctions.</p> <p>Auction halls:</p> <p>The recommendations regarding requirements laid down in Chapter II of Section VIII of Annex III to Regulation (EC) No 853/2004 concerning auction halls will be highlighted in a letter to the FBOs (auction halls) and a time limit for compliance will be given. (Correction plan).</p>	<p>Landing sites:</p> <p>01.05.2011</p> <p>Auction halls:</p> <p>01.06.2011</p>	

10	<p>The competent authorities should ensure that food business operators responsible for establishments handling fishery products fulfil structural and hygiene requirement in compliance Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004.</p>	<p>A new inspection manual is under construction. The requirements of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 will be taken into account.</p> <p>Guidance on handling of packaging materials has been published on MAST's website http://www.mast.is/Uploads/document/leidbeiningar/LeidbeiningarUmbudir.pdf The handling of packaging materials will be given a special emphasis in the inspections this year.</p> <p>Guidance on definition of clean and unclean areas is under preparation and will be placed on MAST's website.</p> <p>Guidance on handling of ABP and use of commercial documents will be prepared and placed on MAST's website.</p> <p>Higher emphasis will be on guidance on GHP.</p>	<p>01.03.2011</p> <p>Completed</p> <p>01.03.2011</p> <p>01.03.2011</p>	
11	<p>The competent authorities should ensure that food additives used in fishery products are authorised and used in compliance with part C of Annex IV of Council directive No 95/2/EC</p>	<p>MAST has for the past months been focusing on the use of polyphosphates in the salt fish industry. MAST will continue to inspect establishments producing salt fish in the next months to ensure that phosphate use has stopped. Regarding general use of additives MAST will revise the inspection manual for fish establishments. Special attention will be given to the use of additives. In addition, inspectors will be trained in the food additive legislation. MAST will also change inspection procedures so that experts working with the food additive legislation will be more involved in assisting and guiding on issues dealing with the use of food additives.</p>	<p>01.03.2011</p>	

12	The competent authorities should ensure that following an identification of non-compliance with legal requirements, action is taken to ensure that the food business operators remedy the situation as required by Article 54(1) of Regulation (EC) No 882/2004.	<p>MAST already has a system in place for follow-up inspections in cases of serious deficiencies or when the number of minor deficiencies exceeds a defined limit. MAST however, takes notice of the recommendation and all measures will be taken to analyse what has to be improved and how it will best be done</p> <p>The system for follow up of inspections will be revised when the new system for inspections will be implemented.</p> <p>The procedure will be described and be a part of MAST's quality manual. It will be audited as other procedures.</p>	March 2011	
13	The competent authorities should ensure that official control of fishery products is carried out in line with the requirements laid down Chapter II of Annex III to Regulation (EC) No 854/2004. The competent authorities should also ensure that samples for histamine analyses are collected in line with the requirements laid down in and Article 11 of Regulation (EC) No 882/2004 and Chapter I of Annex I to Regulation 2073/2005.	MAST has designed a sampling plan of final products which will take into account the requirements of 854/2004 chapter II of Annex II and relevant requirements in 2073/2005 are met. The sampling plan is attached.		 <p>Sýnatökuaæltun fjöldi syna og verð - f</p>
14	The competent authority should ensure that potable water used by food business operators fulfil the requirements laid	As stated at the final meeting of the LBM mission, MAST intends to carry out a survey in cooperation with the LCAs in order to document the monitoring and frequency of analysis of water supplied to FBOs.	Mast expects answers from the local authorities no	

	down in Council Directive 98/83/EC.		later than the 15th of February.	
15	The competent authority should ensure that animal by-products are handled in line with the requirements laid down in Regulation (EC) No 1774/2002.	<p>The CA is working on guidelines to be put on MAST's website explaining the general obligations regarding handling, categorizing and documentation each FBO has regarding ABP as laid down in the Regulation (EC) No 1774/2002.</p> <p>A form for commercial document for transport of ABPs inside Iceland has been placed on and can be filled in from the Mast's homepage: http://www.mast.is/Uploads/document/eydublod/Heilbrigdiseftirlit/Vidskiptaskjal.doc</p> <p>A special attention will be given to ABP handling in inspection visits in 2011.</p>	01.03.2011	
16	The competent authority should designate laboratories that may carry out analysis of samples taken during official controls as laid down in Article 12 of Regulation (EC) No 882/2004.	Designation of official laboratories in accordance with Regulation (EC) No 882/2004 has commenced. Official laboratories for salmonella in food and feed have been designated and can be found on MAST website.	Ongoing	