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The logo of the EFTA Surveillance Authority, featuring the text 'EFTA SURVEILLANCE AUTHORITY' in white on a dark blue background.

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AUTHORITY

## **Final report**

### **EFTA Surveillance Authority Mission to Iceland**

**from 19 to 23 October 2015**

**regarding the application of EEA legislation**

**related to the hygiene of fishery products**

Please note that comments from Iceland to factual errors in the draft report are referred to in foot notes in *underlined italic print* in this final report. Comments and information on the corrective actions already taken or planned by Iceland are included in Annex 3.

### *Executive Summary*

*This report describes the outcome of a mission carried out by the EFTA Surveillance Authority in Iceland from 19 to 23 October 2015*

*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 (EEA) legislation.*

*The competent authority has established a control system that is based on the EEA requirements and national legislation is supported by instructions, checklists and accredited laboratories. The control system is consistently and adequately implemented.*

*A considerable improvement from the last mission was evident and most of the recommendations issued in 2010 can be considered as addressed.*

*The main weaknesses of the control system seen in the recent mission were in following areas:*

- compliance with the requirements of Article 31(2) of Regulation (EC) No 882/2004 related to approval of establishments was not always ensured;*
- the use of traditional methods to dry fish outside has not been notified to the Authority.*
- an internal audit system has been developed with the view to adequately cover all relevant areas of activity and all relevant competent authorities within the sectors covered by Regulation (EC) No 882/2004. However the system was not operational at the time of the mission;*
- no official samples of potable water are taken from within the establishments. MAST relies on operators' own checks, and on inspectors to check the results of these during official controls;*
- official controls of fishery products do not cover all required elements (organoleptic checks, contaminants etc.). MAST relies on operators' own checks, and on inspectors to check the results of these during official controls.*

*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.*

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## 1 Introduction

The mission took place in Iceland from 19 to 23 October 2015. The mission team comprised three inspectors from the EFTA Surveillance Authority (the Authority) and an observer from the Food and Veterinary Office of the European Commission (FVO).

The opening meeting was held with representatives of the Icelandic Food and Veterinary Authority (MAST) and the Ministry of Industry and Innovation (MoII) on 19 October 2015 at MAST Head Office in Selfoss. At the meeting, the mission team confirmed the objectives and the itinerary of the mission and the Icelandic representatives provided additional information to that set out in the reply to the Authority's pre-mission document.

Throughout the mission, representatives of the Icelandic competent authority accompanied the mission team.

A final meeting was held at MAST office in Reykjavík on 23 October 2015, at which, the mission team presented its main findings and some preliminary conclusions from the mission.

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

## 2 Scope and objectives of the mission

### A) Objectives

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

In particular, the mission team focused on and assessed the application by the Icelandic competent authorities of:

- a) Regulation (EC) No 178/2002 laying down the general principles and requirements of food law;
- b) 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;
- c) Regulation (EC) No 852/2004 on the hygiene of foodstuffs;
- d) Regulation (EC) No 853/2004 laying down the specific hygienic rules for food of animal origin;
- e) Regulation (EC) No 854/2004 laying down specific rules for the organisation of official control on products of animal origin intended for human consumption;
- f) Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

This assessment was carried out based on, and related to, the legislation referred to in this chapter and Annex 2 to this document.

## B) Scope

A particular focus was paid to the following areas related to fishery products:

- a) Competent authorities
  - Resources for performance of official controls over the hygiene of fishery products;
  - Staffing provisions and facilities;
  - Staff qualification and training;
  - Organisation and implementation of official controls;
  - Registration / approval of food business operators;
  - Prioritisation and verification of official controls;
  - Control activities, methods and techniques;
  - Sampling and laboratory analyses.
  
- b) Food safety
  - Operation of establishments with regard to compliance with the EEA legislation on different issues such as the sourcing of raw material, equipment and procedures used by the food business operator and Hazard Analyses and Critical Control Point (HACCP) plans;
  - Traceability;
  - Official supervision of establishments, in particular regarding the above-mentioned.

The evaluation included the gathering of relevant information, and appropriate verifications, by means of interviews/discussions, review of documents and records, and on-the-spot inspections, to demonstrate the normal control procedures adopted and measures in place to ensure that necessary corrective actions are taken when necessary.

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

**Table 1: Competent authorities and establishments/sites visited during the mission**

	Number	Comments
Competent authorities	2	An initial meeting and a final meeting between the mission team and the Icelandic competent authorities, representatives of MAST and MoII were present at both meetings.
Fishing vessels	2	One factory vessel and one fishing vessels using refrigerated seawater.
Processing establishments	6	Three establishments were processing fresh and/or frozen fish. One establishment produced ready to eat products/pre-cooked products. One establishment was salting fish and one was drying fish (inside drying).
Auction hall	1	E-market
Cold store (stand-alone)	2	Two independant cold stores storing food of animal origin.

### 3 Legal basis for the mission

The legal basis for the mission was:

- 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;
- c) 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;
- d) 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.

Legislation referred to in this report is listed in Annex 2.

### 4 Background - Previous missions

A mission regarding fishery products was carried out in Iceland in 2010 (case no 68030). The report from that mission included several recommendations and the Authority used this mission to follow up on them in order to verify if indicated corrective actions had been implemented according to plan.

The final report from that mission can be found on the Authority's website ([www.eftasurv.int](http://www.eftasurv.int)).

### 5 Findings and conclusions

#### 5.1 Legislative and implementing measures

##### 5.1.1 *Transposing measures*

##### Legal Requirements

Article 7 of the EEA Agreement requires acts referred to or contained in the Annexes to the EEA Agreement to be made part of the Icelandic internal legal order.

##### Findings

According to information provided by the Icelandic competent authority in its reply to the pre-mission document of the Authority, within the Ministry of Industries and Innovation (MoII), the Department of food, agriculture and rural affairs is responsible for policy development/co-ordination and legislation (including the transposition of the EEA legislation).

MAST also provided in the reply to the pre-mission document a list of laws, regulations and administrative provisions implementing the EEA legislation included in Annex 2 to this report.

## Conclusions

The relevant EEA legislation as listed in Annex 2 to this report concerning the production and the placing on the market of fishery products had been made part of the Icelandic internal legal order in line with Article 7 of the EEA Agreement.

### *5.1.2 Traditional production methods*

#### Legal requirements

Article 13(3) and (4)(a)(i) of Regulation (EC) No 852/2004 provides that Member States may adopt national measures to adapt certain requirements of this regulation with the aim of enabling the continued use of traditional methods at any of the stages of production, processing and distribution of food. Member States may adopt such measures in accordance with Article 13, paragraphs 5 to 7 of the said regulation.

Article 10(3) and 10(4)(a)(i) of Regulation (EC) No 853/2004 states that Member States may adopt national measures to adapt certain requirements of this regulation with the aim of enabling the continued use of traditional methods at any of the stages of production, processing and distribution of food. Member States may adopt such measures in accordance with Article 10, paragraphs 5 to 7 of the said regulation.

According to Article 7 of Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under the Hygiene regulations, Member States may grant establishments producing foods with traditional characteristics derogations from certain requirements of Regulation (EC) No 852/2004, under certain conditions. They shall then notify these derogations in accordance with Article 7(3) of Regulation (EC) No 2074/2005.

#### Findings

Representatives of MAST informed the mission team that dried fish (hardfiskur/stockfish) is produced in Iceland using a traditional method, i.e. hanging the fish for drying outside using wooden racks. At the final meeting the competent authority informed the mission team that national legislation covering traditional methods used to dry fish outside was being drafted. However, Iceland has not notified to the Authority any adaptations or derogations for establishments producing food with traditional characteristics.

#### Conclusions

Although the outside drying of fish is practised, Iceland had, at the time of the mission, not notified to the Authority national measures concerning the use of traditional methods (neither on the basis of Article 13 of Regulation (EC) No 852/2004 or Article 10 of Regulation (EC) 853/2004, nor on the basis of Article 7 of Regulation (EC) No 2074/2005).

## 5.2 Competent authorities

### 5.2.1 Organisation of the competent authority, coordination and cooperation

#### Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for the official controls set out in the Regulation. It also lays down operational criteria for the competent authorities.

Article 4(4) of Regulation (EC) No 882/2004 requires competent authorities to ensure the impartiality, quality and consistency of official controls at all levels.

Article 4(2)(f) of the same article requires that the competent authority have contingency plans in place, and are prepared to operate such plans in the event of an emergency.

Article 4(5) of Regulation (EC) No 882/2004 requires competent authorities to ensure efficient and effective coordination and cooperation between the different units involved in the official controls.

#### Findings

##### **Structure and organisation**

According to information provided by the Icelandic competent authority in its reply to the pre-mission document of the Authority, MAST is the central competent authority for food and feed safety, animal health and animal welfare and operates under the auspices of MoII. The organisation and structure of MAST is based on provisions of the Icelandic Act No 80/2005 on the Food and Veterinary Authority.

The Icelandic Act No 93/1995 on Foodstuffs (the Foodstuffs Act) provides the legal basis for official controls of foodstuffs. According to Article 30 of the Foodstuffs Act, the staff of MAST have full access to all the premises and documentation of food business operators. The Foodstuffs Act also requires food business operators to undergo inspections and assist the competent authority in the process (Article 24 (1)).

The funding of MAST is dealt with in Regulation IS No. 567/2012. Inspection fees contribute to 30% of MAST operational costs. The remaining 70% is financed from the State budget. The fees are directly linked to the inspection activity and the level of fees is based on actual cost for each inspection.

Further and more detailed information regarding the structure and organisation of MAST can be found in the Icelandic country profile of April 2014.

##### **Coordination**

According to information provided by the Icelandic competent authority in its reply to the pre-mission document of the Authority, MAST is the only competent authority in Iceland responsible for official controls of fishery products along the whole chain from primary production until placing on the market, except for retail which is the responsibility of the local competent authorities (LCAs). There are six inspectors within MAST carrying out official controls related to the hygiene of fishery products. According to the Icelandic



country profile of April 2014, there are some mechanisms in place to ensure effective coordination within MAST.

At the opening meeting the mission team was informed that MAST regularly holds meetings and exchanges emails to organise and coordinate work related to official controls of fishery products, such as monthly interdepartmental meetings and coordination meetings within MAST. The mission team was presented with documented communication in relation to meetings held for this purpose:

- Email exchanges with inspection plan updated monthly<sup>1</sup> *E-mail exchanges with feed back data from the database Ísleyfur, used for monthly updating of the inspection plan;*
- Minutes of coordination meeting within MAST: meeting for fishery inspectors on inspection of registered fishing vessels in October 2015.

Individual annual meetings with staff had been planned however were only carried out in 2013.

The inspectors met during the mission were able to demonstrate that control activities carried out are coordinated with respect to frequency of controls, control methods and techniques.

### **Contingency plan**

The mission team was informed that the contingency plan had been drafted and the validation by the chief epidemiologist was pending.

### Conclusions

The competent authority responsible for the official controls of fishery products in Iceland has been designated as foreseen in Article 4 of Regulation (EC) No 882/2004.

The competent authority has developed measures to ensure that official controls are carried out consistently and in a uniform manner in accordance with Articles 4(4) and (5) of Regulation (EC) No 882/2004.

No contingency plan was available at the time of the mission which is not in line with Paragraph 2(f) of Article 4 of Regulation (EC) No 882/2004.

#### *5.2.2 Training and adequacy of staff*

### Legal requirements

Article 4(2)(b) of Regulation (EC) No 882/2004 requires the competent authority to ensure that staff carrying out official controls are free from any conflict of interest.

Article 4(2)(c) of Regulation (EC) No 882/2004 requires the competent authority to ensure that there is a sufficient number of suitably qualified and experienced staff.

Article 6 of Regulation (EC) No 882/2004 sets out general requirements for the training of the staff performing official controls.

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<sup>1</sup> See comments from Iceland in Annex 3

## Findings

According to information provided by the Icelandic competent authority in its reply to the pre-mission document of the Authority, Chapter II of Act No. 37/1993 on official administration includes provisions related to the absence of conflict of interest of staff. During an introductory training provided by a lawyer the relevant provisions of the act are introduced to new employees in one to one or group sessions. Further consultation of lawyers is encouraged in case of doubts.

With regard to training and qualification of staff, the competent authority provided in the reply to the pre-mission document an overview of Better Training for Safer Food (BTSF) training courses attended from 2008 to 2015. The content of the courses was mostly related to general food hygiene although some courses were specifically aimed at fishery products. At the opening meeting the mission team was informed that in general fish inspectors had a university education, such as food science, mechanical engineering and fish processing.

Further the mission team noted that:

- for newcomers, no formalised protocol or training program had been established. However representatives of MAST stated that the supervisors would carry out an assessment of training needs. No documents could be presented for such an assessment having been made, but, the mission team noted that training of a newcomer was documented, identifying topics covered. The training, inter alia covered Act No 37/93 and the public information Act No 140/2012.
- MAST was using different means to discuss and evaluate the training needs: the annual meeting between the supervisor and staff member could include discussions on needs for training; the same was said for the monthly interdepartmental meetings;
- according to representatives of MAST, training of staff is carried out on different topics according to needs. Documents listing participants for in-house training on e.g. new legislation, IT programs, quality systems etc. were provided.
- MAST confirmed that there was no harmonised approach for assessment of training needs for new or existing staff, and that the process depended on the supervisor.

The mission team noted that inspectors met during the on-the-spot visits were in general experienced and qualified.

## Conclusions

Measures were in place to ensure that staff was informed of rules concerning conflict of interest in line with Article 4(2)(b) of Regulation (EC) No 882/2004.

Although there is no formalised approach to assess training needs and train the staff responsible for the official controls of fishery products, training is provided and staff met was experienced, qualified and up-to-date with working instructions as required by Article 6 of Regulation (EC) No 882/2004.

### 5.2.3 *Verification and reporting procedures*

#### Legal requirements

Article 4 (2)(a) of Regulation (EC) No 882/2004 requires that the competent authority ensures the effectiveness and appropriateness of official controls on feed and food at all stages.

Article 8 of Regulation (EC) No 882/2004 requires the competent authority to carry out official controls in accordance with documented procedures, to have procedures in place to verify the effectiveness of official controls, to ensure that corrective action is taken when needed and that documented procedures on official controls are updated as appropriate.

Article 9 of the same regulation requires the competent authority to draw up reports on the official controls that it carries out, describing the purpose, the control methods and the results of the official controls and, where appropriate, the action that the food business operator is to take.

Article 10 of Regulation (EC) No 882/2004 requires the competent authority to use appropriate control methods and techniques during official controls.

#### Findings

According to information provided by the Icelandic competent authority in its reply to the pre-mission document of the Authority, the quality manual of MAST includes all written procedures used in relation to official controls. Inspections in processing plants and other establishments for fishery products are carried out according to an inspection handbook established for official controls of all food processing establishments falling within the scope of Regulation (EC) No 853/2004. The current version was published in March 2012 and has not been revised.

To support the handbook procedures, a database (ÍsLeyfur) has been established. The database includes important information such as: list of approved establishments, reports, inspection history, inspection hours, non-compliances etc.

In relation to reporting procedures, the mission team noted:

- all inspections were carried out using the handbook and the database;
- inspection points are indicated in the cover page of the report and in the inspections' overview generated by Ísleyfur;
- inspection reports were generated by the database and emailed to the operators. Copies of the reports were available in the establishments and could be accessed online by the inspectors;
- the reports indicate what was checked, describe findings, identify non-compliances and reflect the follow up of non-compliances in previous inspections.

With regard to the verification of effectiveness the mission team noted:

- strategical or operational objectives have not been set, however an internal audit system has been developed (see Chapter 5.2.4 internal and external audits);
- the number of establishments in performance category A has gone up. This was reflected by a reduction of inspection hours allocated to the individual inspectors;
- quantitative measurements/verification of planned arrangements were in place:

- It is possible to monitor the number of inspection hours used and left for each establishment and inspector;
- The frequency of inspections was monitored by supervisors at the Central Office and inspectors receive monthly overview of upcoming tasks;
- some qualitative measurements of planned arrangements were in place: The inspection manual and the set-up of Isleyfur are designed to cover all checkpoints of the inspection manual by maximum two inspections in an establishment.

Further the mission team noted that inspections were the only control method used in the establishments visited.

### Conclusions

Official controls related to the scope of the mission are carried out in accordance with documented procedures and non-compliances are recorded in the reports as required in Articles 8 and 9 of Regulation (EC) No 882/2004.

Certain elements are in place for the verification of effectiveness of official controls, in relation to verifying planned arrangements both quantitatively and qualitatively. However full compliance, with Articles 4 (2)(a) and 8 (3)(a) and (b) of Regulation (EC) No 882/2004 cannot be ensured since there are no procedures in place to verify the effectiveness of official controls. Furthermore, the absence of procedures as well as strategical or operational objectives, did not allow the assessment of the need for corrective actions to be taken, consequently it is not possible to ensure that corrective action is taken when needed.

#### *5.2.4 Internal and external audits*

##### Legal requirements

Article 4(6) of Regulation (EC) No 882/2004 states that competent authorities shall carry out internal audits, or may have external audits carried out and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of this Regulation. These audits must be subject to independent scrutiny and carried out in a transparent manner.

##### Findings

According to information provided by the Icelandic competent authority in its reply to the pre-mission document of the Authority, an internal audit system has been developed recently. It is based on the requirements of Decision 2006/677/EC setting out the guidelines and laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 and on the ISO 19011:2002 standard (Guidelines for quality and/or environmental management systems auditing). The system covers MAST and the local competent authority.

The auditing system is structured as follows:

- The audit committee shall approve an annual audit plan. The committee shall also evaluate the audit system and suggest changes based on their assessment to ensure an independent scrutiny of the audit process.
- The audit steering committee shall confirm a five-year audit program and is responsible for the internal audit system and follow-up of audit results. It receives consultation and assistance from the audit committee.
- The quality manager of MAST is responsible for the internal audit process as lead auditor, drafts the one-year audit plan and five-year audit program and appoints

auditors of the internal audit team. He is under the authority of the audit committee and the audit steering committee, and is independent of all other organisation units at MAST

- The internal audit teams consist of MAST specialists who have attended the BTSF “training on audit systems and internal auditing” and a TAIEX seminar on “internal audits of official controls”.

The mission team noted that no internal audits had been carried out according to this new system. A five-year internal audit program had been prepared to cover all areas of Regulation (EC) 882/2004 and all responsible authorities, i.e. MAST, LCAs, laboratories and the Ministry. An annual risk-based audit plan had also been drafted, however, at the time of the mission it had not been confirmed since the audit committee was not yet appointed. Furthermore, the mission team was informed by representatives of MAST that no internal audits would be carried out until the audit committee has approved the annual audit plan. Since the audit committee had not been appointed at the time of the mission, it is uncertain when the first internal audit under the new system will be carried out.

MAST carried out an audit in 2012 on the working procedures for regular inspections to fish processing establishments. According to the report shared with the mission team, no non-compliances were identified. However there were no evidence given on the measures taken following the audit.

### Conclusions

Although an internal audit system has been developed with a view to ensure coverage of all relevant areas of activity and all relevant competent authorities within the sectors covered by Regulation (EC) No 882/2004, full compliance with Article 4(6) in (EC) Regulation No 882/2004 is not ensured since the new system is not operational.

#### *5.2.5 Actions in case of non-compliance and enforcement measures*

### Legal requirements

Article 54 of Regulation (EC) No 882/2004 describes certain measures that the competent authority should have in place to ensure that the operator remedies the situation when non-compliances are identified. Furthermore the competent authority should provide the operator concerned with written notification of its decision concerning the action to be taken together with the reasons for the decision, and with information on rights to appeal such decisions and the applicable procedure and time-limits.

### Findings

According to information provided by the Icelandic competent authority in its reply to the pre-mission document of the Authority, the legal basis for competent authorities to carry out follow-up on non-compliances and impose sanctions is found in the Foodstuff Act No. 93/1995, Articles 30 and 30a.

According to the Foodstuff Act several measures can be taken to ensure compliance such as partial or full suspension of activities, decontamination, or destruction of products.

Further Article 30a provides for the use of financial penalties in the form of daily fines until operators take the necessary corrective actions. The competent authority can also order third

parties to take actions at the expense of the operators. Finally the act also foresees fines and prison sentences in case of serious infringements.

One example of enforcement measures and use of sanctions was presented in the pre-mission document: a fish processing establishment was closed and the approval was withdrawn by the competent authority due to violation of the general hygiene principles of Regulation (EC) No 852/2004. The competent authority, after finding out that the establishment was still operating, took measures and seized all the products. MAST brought official charges against the fish-processing establishment and the local Court sentenced the food business operator to a fine.

The case was well documented and all reports with findings and corrective actions requested were presented to the mission team. The documentation also included letters to the operator where he was informed about the decisions and his right to appeal within a certain timeframe.

Throughout the mission the team observed numerous instances where non-compliances were detected, recorded in reports and followed up by the inspectors.

### Conclusions

Legislation on measures to be taken in case of non-compliances were in place in Iceland in line with Article 54(2) of Regulation (EC) No 882/2004.

The competent authority identified non-compliances, took action and requested corrective actions as per Article 54(1) of Regulation (EC) No 882/2004.

## **5.3 Organisation/prioritisation of the official controls**

### 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. Official controls shall be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Furthermore official controls shall cover all of the stages of production, processing and distribution of food of animal origin.

Article 41 of Regulation (EC) No 882/2004 requires that each Member State prepares a single integrated multi-annual national control plan (MANCP).

### Findings

According to information provided in its reply to the pre-mission document of the Authority, MAST has established a system to set the control frequency in establishments dealing with and/or handling fishery products. The control frequency is based on a risk classification system and a performance evaluation system.

Each establishment is classified according to three risk indicators: the inherent risk of the product or the production method; the size or production volume of the establishment; and the targeted consumer. Each risk indicator gives the establishment a risk score, according to which the risk category is decided upon. The risk category corresponds to the minimum frequency of official controls calculated in hours/year. Additional time may be allocated to



the establishment based on: volume and nature of labelling and packaging activities and complexity of operations.

In addition establishments are also evaluated according to their performance history during official controls. The establishments are classified in three performance categories, A, B or C. All establishments start in category B, for which official control time is multiplied by the performance index 1. Establishments for which 2 audits where at least 80% of the criteria established in the inspection manual have been checked can be moved to performance category A. In this case the official control time allocated to the establishment is multiplied by the performance index 0,5. Establishments that have repeated non-compliances or a serious non-compliance are moved to performance category C and their official control time is multiplied by the performance index 1,5. The performance evaluation only affects the time for regular official controls.

The mission team was informed that additional controls due to non-compliances are not counted in the total hours allocated to the establishments for regular official controls.

The mission team noted that:

- the frequency of inspections was respected, and reports were available.
- findings in the reports reflected the current situation and included follow up of previous inspection.
- inspectors registered hours spent on-site; time spent for preparation and follow up activities are not included.
- a monthly overview of the inspections was shared among all inspectors indicating the status of establishment and the responsible inspector, with respect to:
  - total inspection hours allocated to each establishment
  - hours spent and hours left for each establishment
  - deadline by which hours need to be spent to fulfil the planned arrangements.
- inspectors were assigned responsibility for official controls of establishments, and measures were in place to ensure a rotation of inspectors/establishments. However, the approach by which the rotation took place had not been formalised.
- initially around 600 inspection hours were allocated to each inspector per year. According to an overview sheet, the amount of hours was in some cases reduced due to establishments moving to performance category A.
- the inspectors used checklists (E-Tables) referring to the chapters of the inspection handbook to ensure that all relevant points are checked within a certain timeframe. The E-tables are indicated in the cover page of the inspection report.
- inspection and audits were not distinguished by the competent authority as audit was considered to be part of the inspection. According to representatives of MAST most of the regular inspections were carried out with a short prior warning in order to ensure the relevant staff/documents of the operators were available.
- no regular official controls of landing activities had been carried out at the time of the mission.

Further the mission team was informed that the multi annual national control plan was still under construction with the aim to publish it in first half of 2016.

## Conclusions

Although a system had been established to ensure that official controls are carried out regularly, on risk basis and with appropriate frequency as required by paragraph 1 of Article 3 of Regulation (EC) No 882/2004, the system did not cover all stages of production as paragraph 3 of the same Article requires.

The requirement of Article 41 of Regulation (EC) No 882/2004 was not fulfilled since the multi annual national control plan had not been prepared.

## **5.4 Registration and approval of establishments**

### Legal Requirements

According to Article 31(1)(a) and (b) of Regulation (EC) No 882/2004, competent authorities shall establish procedures for feed and food business operators to follow when applying for the registration of their establishments, and shall draw up and keep up-to-date a list of feed and food business operators which have been registered.

According to Article 31(2)(a), (b), (c), (d) and (f) of Regulation (EC) No 882/2004, competent authorities:

- shall establish procedures for feed and food business operators to follow when applying for the approval;
- shall upon receipt of an application for approval from a feed and food business operator, make an on-site visit;
- shall grant an approval to an establishment only if the food business operator can demonstrate compliance with the relevant feed or food law;
- may grant conditional approval if it appears that the establishment meets all the infrastructure and equipment requirements;
- Shall maintain up-to-date lists of approved establishments.

Article 6(2) of Regulation (EC) No 852/2004 foresees that food business operators must ensure that the competent authority always has up-to-date information on establishments.

Article 4(2) of Regulation (EC) No 853/2004 provides that establishments handling those products of animal origin for which Annex III lays down requirements must be approved.

### Findings

According to information provided by the Icelandic competent authority in its reply to the pre-mission document of the Authority, the quality manual of MAST includes procedures to be followed for the granting of approval. Further the criteria for initial approval of establishments are described in the inspection handbook for inspectors. An online application form for food business operators has been established and can be found on MAST homepage ([www.mast.is](http://www.mast.is)).

The mission team noted that:

- MAST used the register from the Directorate of Fisheries to identify vessels that were not subject to approval<sup>2</sup>. *The list originates from the Directorate of Fisheries*

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<sup>2</sup> See comments from Iceland in Annex 3



*(Fiskistofa) which is the legal instance to create the list, containing vessels fulfilling all three conditions for being approved as fishing vessel with specified fishing rights. So the only reliable list is the one originated from Fiskistofa.*

- MAST's working instructions allows approval to be granted without prior visit, under specific circumstances (MAST explained in the opening meeting that this could be e.g. in cases where the sole change was the ownership). One of the establishments visited had been granted approval without prior visit.<sup>3</sup> *More precise is that when owners (one or more) of a fish processing establishment sell their shares, part of them or all, without visible changes of any kind regarding responsibility, production, staff or other parameters that can cause health risk for the consumer, there is no need to issue a new approval every time this happens. In the big companies on stock markets this happens every day. In general the working procedure for granting approvals to fish processors is according to the procedure described in Regulation 882/2004.*
- For one of the establishments visited two approval documents had been issued both with the same approval number, but for different activities; One for fresh fishery products and for minced fishery products. The other approval indicated the activity cold-store. The approval as cold store was not reflected in the list of approved establishments.
- In another establishment the activity codes included in the approval document and in the list of approved establishments did not correspond to the actual activities in the establishment as the freezing of fishery products was not included.
- Another visited establishment was approved for several activities in the same premises: processing plant fresh fishery products, processing plant dried traditional fishery products and pet food production. The activity code for the petfood production referred to the animal by-products regulation (Regulation (EC) No 1774/2002).
- One of the visited establishments was operating under a conditional approval (for one of the activities PP1A) until July 2015, an inspection report from June 2015 indicated that a full approval could be granted. However, the full approval was only issued in September 2015. In addition the mission team was presented with two approval documents for the same establishment: in the approval document available at the food business operator's premises the validity date for the activity PP1A was 01.01.2015 but according to the approval document sent to the mission team by the competent authority the validity date for the same activity was 26.07.2011.
- One establishment was operating in new facilities without a new approval. The establishment was still operating on the basis of the approval of the initial facilities. The representatives of MAST indicated that an inspection of the establishment was planned for the week after the mission<sup>4</sup>. *This is not correct since the establishment was inspected on 24 September, 2015 and an approval was issued on 22 October 2015. An error was found in the document so it had to be corrected and re-issued. See enclosed inspection reports and a copy of the approvals.*
- In one establishment a new building had been taken into use (cold store). The food business operator had not notified this to the competent authority. However the inspection report of March 2014 indicated that the new building was not included in the blue print of the establishment. In the report of the following regular inspection it was noted that the new building had been included in the blue print. No further

<sup>3</sup> See comments from Iceland in Annex 3

<sup>4</sup> See comments from Iceland in Annex 3

information was available concerning the assessment by MAST or the establishment of the potential consequences of the changes for internal procedures, HACCP etc.

### Conclusions

The competent authorities have established procedures for food business operators to follow when applying for the approval of their establishments as required by Article 31(2)(a) of Regulation (EC) No 882/2004.

However, compliance with the requirements of Article 31(2) of Regulation (EC) No 882/2004 was not ensured since: in some establishments neither the approval documents nor the list of approved establishments reflected the actual activities in the establishments; full approvals can be granted without prior visit; an establishment was operating in new facilities without an approval; and the time limits of conditional approvals were not respected; further an establishment was approved for the production of food and handling of animal by-products in relation to the same facilities, potentially allowing the use of raw material unfit for human consumption within the establishment.

## **5.5 Official controls concerning production and placing on the market of fishery products**

### *5.5.1 Primary production and landing operations*

#### Legal Requirements

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

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.

#### Findings

The mission team noted that official controls on fishing vessels was not part of MAST quality manual however it was informed that the competent authority planned to include fishing vessels not subject to approval in their control activities. A frequency of inspection of such vessels had been established based upon the size; once every three years for vessels of less than one tonne and once per year for bigger vessels.

The mission team visited one fishing vessel using refrigerated seawater to cool the catch on board. The vessel was in good hygienic condition. No written procedures were established, however, measures to ensure that seawater used was of good quality was described: only filling the tanks when at open sea and after flushing them, access to clean seawater from boreholes if more seawater was needed during landing. Care was also taken in cooling the water sufficiently before fish was taken in. A system was in place to record and monitor the temperature of the water in all the storing tanks, and registered data showed sufficient cooling capacity. Examples of reports exchanged between the vessels and the operators receiving the fish, in particular in relation to temperature monitoring, were provided.

The mission team noted that landing activities were not included in the official controls. The competent authority relies on the food business operators' own checks at the reception of fishery products in the establishments.

### Conclusions

Although the competent authority had established a control system that covered the primary production of fishery products, full 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.

#### *5.5.2 Facilities handling fishery products (vessels and land based facilities)*

### 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.

Annex II of Regulation (EC) No 852/2004 lays down general hygiene requirements for all food business operators.

Article 4(2) 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 of Regulation (EC) No 853/2004.

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.

Article 7 of the said directive provides that Member States shall take all measures necessary to ensure that regular monitoring of the quality of water intended for human consumption is carried out, and that competent authorities should establish monitoring programmes meeting the minimum requirements of its Annex II (Annex II, table B1 requires Member States in particular to take samples at the points of compliance).

### Findings

According to information provided by the Icelandic competent authority in its reply to the pre-mission document of the Authority, the local competent authorities are responsible within their respective regions for the surveillance of the waterworks distribution network.

MAST explained in the opening meeting that all food business operators are required to take samples of their own water and ice used in their facilities, to evaluate the results and take action if needed and that this is followed up during official controls. According to MAST, the minimum frequency of samples to be taken by the food business operators was set with one sample of potable water per year from the point of compliance and one sample of clean seawater per month.

The mission team noted that MAST was not taking any official samples of potable water in the establishments. MAST checks the food business operators' sampling plans for both potable and clean seawater, and that the samples are collected according to the plans as well as the analytical results during official controls. Furthermore, it was noted that the samples

of potable water collected by the food business operators were only analysed for microbiological parameters.

With regard to the establishments visited the mission team noted the following:

All establishments had in place quality manuals based on HACCP principles, which mirrored the layout from MAST inspection handbook. Systems for traceability had been implemented and were in general found to be functional. The monitoring and recording of temperature in products and cooling/freezing rooms was in general found to be sufficient.

Hygienic conditions were generally acceptable. The main shortcomings detected by the mission team were related to good manufacturing practices.

- Separation of animal by-products and food in coolers and working areas:
  - in one establishment a tub used for animal by-products was identified as CAT 3 and of different colour than the ones used for food, however the mention “not for human consumption” was not indicated. The tub was in close proximity with a tub with products for human consumption;
  - further the mission team noted also in other establishments that the physical separation between animal by-products and food in working areas and in coolers was not appropriate.
- In an establishment producing ready-to-eat products from fresh fish, the mission team noted that:
  - in the coolers there was raw material (fresh whole fish), packed final products and packaging material stored together;
  - in the storage room for ingredients, there were unlabelled packages on the shelves and on the floor;
  - boxes with liners intended for packing final cooked products, were stored in the working area after the end of the working hours.
- In one of the establishments processing fresh fish, staff walked away from the working station for the breaks, leaving raw material still on the conveyor belts.
- In two of the establishments visited the mission team noted tubs where fish was stored in stagnant water before entering the next step of processing.
- In one establishment the mission team noted that chilled products were labelled with packaging date of the next day.

The mission team noted that the inspectors identified non-compliances which were pointed out to the operators in order to take corrective actions.

### Conclusions

In general, hygiene conditions were acceptable in the establishments visited. In case of shortcomings, the competent authority demonstrated that the official controls were appropriate to verify compliance with requirements of Regulation (EC) No 852/2004 and of Regulation (EC) No 853/2004, as required by Article 4(2) of Regulation (EC) No 854/2004.

The competent authority does not take official samples at the point of compliance to ensure the quality of potable water used by the food business operators, which is not in line with Article 7 and Annex II (Table B1) of Council Directive 98/83/EC.

### 5.5.3 HACCP based systems

#### Legal requirements

Article 5 of Regulation (EC) No 852/2004 requires food business operators carrying out activities at 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.

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 4 of Regulation (EC) No 2073/2005 provides that food business operators shall perform testing as appropriate against the microbiological criteria set out in Annex I thereof, when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice.

Article 5(2) of Regulation (EC) No 2073/2005 provides that food business operators manufacturing ready-to-eat foods which may pose a *Listeria monocytogenes* risk for public health, shall take samples from the processing areas and equipment for *Listeria monocytogenes* as part of their sampling scheme.

#### Findings

All approved establishments visited had implemented an own control system based on the HACCP principles. In general the systems were correctly implemented, hazards and critical control points were identified, critical limits and monitoring procedures had been established as well as corrective actions when needed. Records of the relevant control points were in general available in the establishments. Most of the food business operators had a contracted consultant providing the HACCP system.

In one establishment producing ready-to-eat and pre-cooked products, the mission team noted some shortcomings in relation to critical control points (CCPs) in the HACCP system. Three critical control points were identified in the HACCP plan, however only one of them was monitored and recorded appropriately. The team noted that shortcomings related to the HACCP system (including the lack of recording and monitoring of the two CCPs) had been identified in inspection reports.

One operator had taken samples of smoked fish for *Listeria monocytogenes*, however it was noted in the last inspection report that the operator was not taking samples for histamine analyses of the mackerel. An inspection report for another operator included remarks regarding the HACCP system where histamine samples were not included in risk analyses.

#### Conclusions

Own control systems based on HACCP principles were in place and generally correctly implemented as required by Article 5 of Regulation (EC) No 852/2004.

The own control systems were regularly checked during official controls and the inspection reports included a number of remarks related thereto as required in Article 4 of Regulation (EC) No 854/2004.

#### 5.5.4 Official controls of special elements for 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 elements, in particular organoleptic examinations, freshness indicators, histamine, residues and contaminants, microbiological checks and parasites.

##### Findings

Organoleptic examinations and freshness indicators are not directly checked by MAST. MAST relies on the own checks carried out by the food business operators. Organoleptic examinations are carried out by the food business operator at the reception of the raw material. The competent authority checked that samples were collected according to plan as well as the results of the own checks during official controls.

Parasite and microbiological checks are not routinely carried out by MAST. Food business operators are responsible for sampling as part of their own check system. The competent authority checked the results of the own checks during official controls.

Additives have never been checked. The mission team was informed that the competent authority considered to include analyses of samples for additives for 2016.

Histamine had not been sampled according to the sampling plan of 2015. However, the mission team was informed that some samples had been taken and sampling will be continued with the start of the fishing season. In 2014 no samples for histamine analyses were taken.<sup>5</sup> *This is not correct. In 2014 7 samples of mackerel were analysed for histamine.*

Samples for analyses of residues and contaminants had not been taken in 2014. Results for 2015 samples were still pending at the time of the mission.

In relation to 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

Compliance with Article 7 of Regulation (EC) No 854/2004 and Chapter II of Annex III of the said regulation was not ensured, in particular concerning the official controls of the elements listed in Chapter II of Annex III to the said regulation.

## 5.6 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.

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<sup>5</sup> See comments from Iceland in Annex 3



Article 33(1) of Regulation (EC) No 882/2004 states that Member States shall arrange for the designation of one or more national reference laboratories for each EU reference laboratory referred to in Article 32.

### Findings

According to information provided by the Icelandic competent authority in its reply to the pre-mission document of the Authority, the procedure under which the laboratories are designated is still at draft stage. The legal bases for the designation is given in the national Regulation No 106/2010. The working procedures are based on the provisions of Article 12 of Regulation (EC) 882/2004 and all designated laboratories are accredited in accordance with standard EN ISO/IEC 17025.

According to the same information, six laboratories have been designated to carry out analyses of samples in relation to official controls of fishery products. Four of the laboratories are located in Iceland and two in other European countries.

Laboratories designated for official controls under the scope of the mission:

- for *Salmonella* and *Listeria monocytogenes* in fish and products thereof: three laboratories in Iceland;
- for histamine and heavy metals in fish: one laboratory in Iceland;
- for parasites in fish: one laboratory in Iceland;
- for PCBs, dioxin and PAH: a laboratory in Sweden;
- for all relevant analyses, a laboratory in Germany.

The mission team noted that some of the analytical methods used were not the reference methods. However these had been validated against the reference methods.

National reference laboratories for most of the parameters relevant for this mission had been designated at the time of the mission. For the parameters *Salmonella*, *Listeria monocytogenes*, parasites and heavy metals, national reference laboratories had already been designated. The mission team was informed that the designation process for PAH and dioxin was ongoing.

### Conclusions

Laboratories to analyse official samples for fishery products have been designated as required by Article 12(1) of Regulation (EC) No 882/2004.

Full compliance with Article 33(1) of Regulation (EC) No 882/2004 was not ensured since the designation of national reference laboratories for some of the parameters had not been finalised.

## **5.7 RASFF notifications**

### Legal basis

Article 50, paragraphs (2) and (3)(a) of Regulation (EC) No 178/2002 requires that where a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified under the rapid alert system together with any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the

market or the recall of food or feed in order to protect human health and requiring rapid action;

### Findings

Examples of RASFF notifications between 2012 and 2014 in relation to fishery products were presented to the mission team. The team was informed that there were no notifications for 2012 and 2013, and two notifications and one news had been issued for 2014. In particular :

- Notification of histamine found in tuna for which the product was already sold and no further action was taken.
- Notification on undeclared allergen substance in seafood mix, recalled from the market with news.
- There was no follow up notifications sent through RASFF in relation to these two cases.
- RASFF news concerning a suspicion of fraud in relation to canned cod roe from Iceland. A letter dated 05.02.2014 was sent to Danish authorities as a reply. Investigation was carried out on the use of other species labelled as Cod roe (*Gadus Morhua*). MAST contacted two of the producers: a factory trawler and a fish processing plant. Roes received from vessels were labelled as *Gadus Morhua*. MAST was informed that the producer trusted the label and that mixing between species could not be excluded on board vessels. MAST informed the mission team that it had not been possible to carry out sampling since the production from last year had been sold. However MAST intends to check the procedures on separation between species on board of the fishing boats, in fish markets and in establishments in the coming roe period. Furthermore MAST intends to publish news on the website on handling of roes and the importance of separation between species at the point of gutting.

### Conclusions

There is a system in place to adequately investigate problems that occur and to take action in response to RASFF notifications. However the limited number of notifications and follow up actions did not allow assessing the implementation of procedures.

## **6 Final meeting**

A final meeting was held on 23 October at MAST office in Reykjavík with representatives from MAST and the Ministry of Industry and Innovation. At this meeting, the mission team presented its main findings and some preliminary recommendations 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.



## 7 Recommendations

In order to facilitate the follow-up of the recommendations hereunder, Iceland should notify the Authority no later than 1 April 2016, of additional corrective actions planned or taken other than those already indicated in the reply to the draft report of the Authority. In case no additional corrective actions have been planned, the Authority should be kept continuously informed of all changes made to the already notified corrective actions and measures, including changes of the deadlines indicated for completion and also the completion of the measures included in the timetable.

No	Recommendation
1	Iceland should ensure that, if traditional production methods are used, national measures are adopted and notified to the Authority in accordance with, as relevant, Article 13 of Regulation (EC) No 852/2004, Article 10 of Regulation (EC) 853/2004 or Article 7 of Regulation (EC) No 2074/2005.
2	The competent authority should ensure that it has operational contingency plans for crisis management in place as required in Paragraph 2(f) of Article 4 of Regulation (EC) No 882/2004.
3	The competent authority should ensure they have procedures in place to verify the effectiveness of official controls as required by Article 8(3)(a) of Regulation (EC) No 882/2004.
4	The competent authority should ensure that internal audits are carried out in accordance with Article 4(6) of Regulation (EC) No 882/2004.
5	Iceland should prepare a single integrated multi-annual national control plan in accordance with Article 41 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(2) of Regulation (EC) No 882/2004.
7	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.
8	The competent authority should ensure that official samples and monitoring of the quality of potable water used by food business operators are carried out in accordance with requirements laid down in Article 7 and Annex II of Council Directive 98/83/EC.
9	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.

### Annex 1 - List of abbreviations and terms used in the report

Authority	EFTA Surveillance Authority
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
MANCP	Single integrated multi annual national control plan
EN/ISO	European standards/International Organization for Standardization
EU	European Union
EURL	EU Reference Laboratory
Food Hygiene Package	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 the 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> . The Food Hygiene package includes several Regulations; <i>inter alia</i> , Regulations (EC) No 852/2004, 853/2004 and 854/2004.
HACCP	Hazard Analysis and Critical Control Point
MANCP	Single integrated multi-annual national control plan
MAST	Matvælastofnun / Icelandic Food And Veterinary Authority
RASFF	Rapid Alert System for Food and Feed
TMA-N	Trimethylamine Nitrogen
TVB-N	Total Volatile Basic Nitrogen
RASFF	Rapid Alert System for Feed and Food
TAIEX	Technical Assistance and Information Exchange instrument of the European Commission.
LCA	The local competent authority
BTSF	Better Training for Safer Food is a Commission initiative aimed at organising a training strategy in the areas of food law.
ISO 19011:2002	Guidelines for quality and/or environmental management systems auditing

## Annex 2 - Relevant legislation

The following legislation has been taken into account in the context of this mission:

- a) 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*, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement.
- b) 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*.
- c) The Act referred to at Point 7.1.13 of Chapter I of Annex I to the EEA Agreement, *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*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement.
- d) 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 amended.
- e) The Act referred to at Point 6.1.18 of Chapter I of Annex I to the EEA Agreement, *Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption*, as amended.
- f) The Act referred to at Point 1.1.11 of Chapter I of Annex I to the EEA Agreement, *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*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement.
- g) The Act referred to at Point 1.1.12 of Chapter I of Annex I to the EEA Agreement, *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*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement.
- h) The Act referred to at Point 6.1.16 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs*, as amended.

- i) The Act referred to at Point 6.1.17 of Chapter I of Annex I to the EEA Agreement, *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*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement.
- j) 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 5 December 2005 on microbiological criteria for foodstuffs*, as amended.
- k) 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) 854/2004*, as amended.
- l) 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 levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5)*, as amended and as adapted to the EEA Agreement by the adaptations referred to in Annex II to that Agreement.
- m) 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*, as amended.
- n) The Act referred to at Point 6.1.20 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EU) No 1079/2013 of 31 October 2013 laying down transitional measures for the application of Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council*.

### Annex 3 –Comments and proposed corrective actions from Iceland

EFTA Surveillance Authority  
Rue Belliard 35  
B-1040 Brussel  
Belgium



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Telephone: 530 4800 - Fax: 530  
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mast@mast.is www.mast.is

Selfoss, January 8, 2016  
Reference: Mast15030256/10.1.1

**Subject: Iceland's respond to a draft report from the Efta Surveillance Authority from a Mission in Iceland in October 2015 regarding fishery products.**

Please find attached documents from The Icelandic Food and Veterinary Authority in response to the draft report of the above mentioned mission. The documents include a Table of Corrective Actions, general remarks and attachments referred to in the latter document. The Case No of the mission is 76532 and the Document No is 775219. Team leader was Egill Steingrímsson.

On behalf of the Icelandic Food and Veterinary Authority,

  
Ástfríður Sigurðardóttir

## **Response to the draft report of the EFTA Surveillance Authority's mission to Iceland 19 to 23 October 2015 regarding the application of EEA legislation related to the hygiene of fishery products**

General remarks and further explanations

### **Page 9, first bullet point:**

The sentence 'E-mail exchanges with inspection plan updated monthly'

Should rather be:

E-mail exchanges with feed back data from the database Ísleyfur, used for monthly updating of the inspection plan.

### **Chapter 5.4, Page 17**

#### **Bullet point 1:**

The list originates from the Directorate of Fisheries (Fiskistofa) which is the legal instance to create the list, containing vessels fulfilling all three conditions for being approved as fishing vessel with specified fishingrights. So the only reliable list is the one originated from Fiskistofa.

#### **Bullet point 2:**

More precise is that when owners (one or more) of a fish processing establishment sell their shares, part of them or all, without visible changes of any kind regarding responsibility, production, staff or other parameters that can cause health risk for the consumer, there is no need to issue a new approval every time this happens. In the big companies on stock markets this happens every day.

In general the working procedure for granting approvals to fish processors is according to the procedure described in Regulation 882/2004.

#### **Bullet point 7:**

In the draft report is stated that one establishment had been allowed to start up operation without prior visit.

This is not correct since the establishment was inspected on 24 September, 2015 and an approval was issued on 22 October 2015. An error was found in the document so it had to be corrected and re-issued. See enclosed inspection reports and a copy of the approvals.

### **Page 22:**


Under findings, 4th paragraph, it is stated that in 2014 no samples for histamine analysis were taken. This is not correct. In 2014 7 samples of mackerel were analysed for histamine.


**Table of corrective action**


No	Recommendation	Reaction of Icelandic authorities	Date of Compliance	Comment/attachment
1	Iceland should ensure that, if traditional production methods are used, national measures are adopted and notified to the Authority in accordance with, as relevant, Article 13 of Regulation (EC) No 852/2004, Article 10 of Regulation (EC) 853/2004 or Article 7 of Regulation (EC) No 2074/2005.	<p>A draft to a national regulation on traditional productions methods and adaptation of certain requirements laid down in annex II of regulation 852/2004 and annex III of regulation 853/2004 is in place. Requirements for drying of fish in the open air are laid down in paragraph 12 of the regulation.</p> <p>The draft in attachment was sent to the ministry 30.12.2015. There are some comments in the draft from the Ministry and MAST's reply to the comments. The ministry will send the draft out for comments in the beginning of 2016.</p>	01.06.2016	<div data-bbox="1688 611 1760 676" data-label="Image"> </div> <p data-bbox="1626 683 1827 730">Reglugerð (drög) um aðlögun að kröfum fyr</p>
2	The competent authority should ensure that it has operational contingency plans for crisis management in place as required in Paragraph 2(f) of Article 4 of Regulation (EC) No 882/2004.	<p>A draft contingency plan has been written in cooperation with the Chief epidemiologist. It will be sent out for comments to the LCAs and the public health sector in the beginning of 2016 and then published on the authorities' websites. Presentation of the contingency plan will then follow.</p> <p>However, MAST would like to emphasize, that in cases of food borne outbreaks actions and cooperation</p>	01.04.2016	<p data-bbox="1568 1098 1886 1238"><i>(A copy of the contingency plan will be sent to ESA 11 January 2016)</i></p>

		between MAST the LCAs and the Chief epidemiologist are according the contingency plan from 2005.		
3	The competent authority should ensure they have procedures in place to verify the effectiveness of official controls as required by Article 8(3)(a) of Regulation (EC) No 882/2004.	<p>A formalized verification system is being developed that will describe the verification procedures and processes to identify the effectiveness of official controls. This project is closely connected with the development of the MANCP. Several verification procedures are already in place that will be further developed and implemented in 2016 and 2017.</p> <p>A working group will be established that will be responsible for describing the verification system and identifying indicators to measure the effectiveness of official controls and compliance with planned arrangements, the necessary procedures that need to be implemented and data that needs to be collected and analysed. The group will develop a project outline before 1.5.2016.</p>		
4	The competent authority should ensure that internal audits are carried out in accordance with Article 4(6) of Regulation (EC) No 882/2004.	The ministry plans to appoint the audit committee early 2016. A new Quality Manager has very recently started working at MAST. Further training of auditors will take place in 2016 and by the end of the year 2 audits will be completed.		



5	Iceland should prepare a single integrated multi-annual national control plan in accordance with Article 41 of Regulation (EC) No 882/2004.	<p>MAST is in the process of developing a MANCP. Work so far has been focused on the systematic changes to procedures and processes that make up the control system (risk classification systems, verification procedures, contingency planning, long-term objectives etc.) and are the necessary basis for the development of a strategic plan such as the MANCP as described in Article 41 of Regulation (EC) No 882/2004. A first draft will be finalised in 2016 with official publication expected in 2017.</p> <p>A working group will be established to work with the editor and directors on finalising the MANCP. A first draft will be finalised in 2016 with official publication expected in 2017.</p>		
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(2) of Regulation (EC) No 882/2004.	<p>From 2011 MAST has been working in accordance with a work procedure describing the steps taken by MAST to approve food business operators. <a href="#">Leyfisveitingar</a>.</p> <p>In line with the recommendation given by ESA, MAST will start a project of reviewing the procedure to ensure that the requirements of Article 31(2) of</p>	01.09.2016	 urbaedur_leyfisveitiga r_ESA rec.6.docx

		<p>Regulation (EC) No 882/2004 will be fully covered.</p> <p>The review project will be conducted according to a work procedure in MAST quality system. <a href="#">Úrbótaverkefni</a>.</p> <p>The main aspects of the review program are:</p> <ul style="list-style-type: none"> <li>• The importance of following working procedures</li> <li>• Formalizing the subjects which the procedure does not cover today</li> <li>• How sector and activity codes are used. Food v./Feed</li> <li>• Review the issue of license.</li> </ul>		
7	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.	MAST will consider how control with hygiene condition of landing could be organised. Improvement project will be organised according to work procedure in MAST quality system. In attachment there is a draft description of the project.	01.04.2016	 <p>EBL-007Urbaeturverk efnisblad_ESA_rec. 7.</p>
8	The competent authority should ensure that official samples and monitoring of the quality of potable water used by food business operators are carried out in accordance with requirements laid down in Article 7 and Annex II of Council Directive 98/83/EC.	<p>Water used by food businesses should come from water supplies that are under the control of LCAs. FBOs also take samples once per year.</p> <p>Seawater used in fish processing plant is not under the control of the LCAs. FBOs take samples once per month.</p>		

		<p>The FBO sampling is verified in MAST's inspection.</p> <p>MAST organised sampling of seawater for analysing of microbiological parameters last year and the sampling is ongoing will continue 2016. At the same time information on the origin of seawater and eventual treatment of seawater will be collected.</p> <p>Sampling plan for potable water used at point of compliance 2017-2020 will be made 2016. The sampling plan will be based on risk assessment.</p>	<p>01.10.2016</p> <p>01.10.2016</p>	
<p>9</p>	<p>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.</p>	<p>Samples for analysis of histamine in mackerel and herring were taken 2014 and 2015. Samples of capelin, herring and Greenland halibut were taken for analysis of heavy metals. Dioxins and Dioxin like PCBs were analysed in canned fish liver and cod liver oil. The results are in the attached excel document. Some results are not available by 8<sup>th</sup> of January. Updated table will be sent to ESA when all the results are available.</p> <p>Sampling plan for 2016 has been made. See attachment.</p> <p>Working group (MAST, MATIS, ANR and SFS (association of fish producers))</p>		 <p>Sampling_FP_results 2014_2015.xlsx</p>

was established 2015 by the ministry to reorganise the monitoring programs of contaminants in fish and fishery products. The group will submit recommendations on the subject to the minister by the end of January.

MAST has decided to make a control plan on organoleptic examinations and checks on parasites. The first step is to make a plan for corrective actions. The plan is expected to be finalised in February.

Guidelines on control of additives will be written in 2016 and the control will be implemented in June/ May. For your information 21 samples of meat products were analysed for nitrite and nitrate in 2015.



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2016-MÖN.xlsx



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