

Case No: 69584
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Final report
for the EFTA Surveillance Authority follow-up mission to Iceland
from 23 to 27 May 2011
regarding application of EEA legislation
related to control of live bivalve molluscs

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 3.

Executive Summary

This report describes the outcome of a follow up mission carried out by the EFTA Surveillance Authority (the Authority) in Iceland from 23 May to 27 May 2011 regarding application of EEA legislation related to control of live bivalve molluscs.

The Icelandic competent authority took into consideration the recommendations made by the Authority after the mission on live bivalve molluscs carried out in 2010. The implementation of appropriate corrective actions has been confirmed by this follow up mission.

Official controls and food business operators' procedures are in general in conformity with the requirements of the legislation.

Live bivalve molluscs produced in Iceland generally fulfil the legal requirements for harvesting and placing on the market of this commodity.

However, there is still a need for improvement in some areas such as:

- Official sampling of live and processed bivalve molluscs;*
- designation of laboratories for official controls of live bivalve molluscs;*
- general hygiene requirements at establishment level, and*
- controls on processed tunicates harvested outside classified areas.*

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1 Introduction

The mission took place in Iceland from 23 to 27 May 2011, as part of the EFTA Surveillance Authority's (the Authority) planned mission programme. The mission team comprised two inspectors from the Authority.

The opening meeting was held with representatives of *Matvælastofnun* (the Icelandic Food and Veterinary Authority-MAST) at MAST's office in Reykjavik. At the meeting, the representatives of MAST provided additional information to their reply to the Authority's pre-mission questionnaire.

Throughout the mission, two representatives of MAST's head office accompanied the mission team.

A final meeting was held at MAST's office in Reykjavik on 27 May 2011, where 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. 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 and a final meeting in Reykjavik with representatives of MAST. A representative of the Ministry of Fisheries and Agriculture was present at the final meeting.
Dispatch centres	1	A dispatch centre approved for blue mussels (<i>Mytilus edulis</i>).
Establishments processing live bivalve molluscs	1	An establishment processing live echinoderms (sea urchins).
Establishments processing bivalve molluscs	2	One establishment processing tunicates (sea cucumber) and one establishment processing marine gastropods (whelk).
Laboratories	2	A private laboratory taking and preparing net and sea water samples for phytoplankton and an official laboratory analysing net and sea water samples for phytoplankton.

2 Objectives of the mission

The objective of the mission was to verify the status of implementation of corrective measures with respect to the previous mission carried out by the Authority from 22 June to 1 July 2010.

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 corrected and amended to 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 corrected, 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 corrected, 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 corrected and amended to the EEA Agreement.

This assessment was carried out based on, and related to, the legislation referred to under Chapter 3 and Annex 2 to this document.

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) Point 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); and
- 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*.
- 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*.

Other legislation relevant for the mission is listed in Annex 2.

4 Background

During the Authority's last mission to Iceland from 22 June to 1 July 2010 regarding the application of EEA legislation related to the production and the placing on the market of live bivalve molluscs, some serious shortcomings were identified. The report from that mission contained twenty recommendations to the Icelandic competent authorities. Furthermore it was decided that a follow-up mission would be carried out in 2011, concentrating on the corrective actions taken by the Icelandic competent authorities in response to the Authority's recommendations.

5 Recommendations, corrective action, findings and conclusions

In this part of the report the headings mean the following:

- **Recommendations** are numbered and correspond to recommendations given by the Authority in the previous report after the mission to Iceland in 2010 regarding live bivalve molluscs;
- corrective actions and explanations given by MAST are reported in *italic text*;
- findings are the findings of the mission team, and
- conclusions are drawn from the correlation between corrective actions and explanations given by MAST and findings of the mission team.

5.1 Transposition and application of relevant legislation

Recommendation 1

The competent authorities should ensure that all relevant legislation related to this mission are, or are made, part of the Icelandic internal legal order in accordance with Article 7 of the EEA Agreement.

Corrective action

In its response to the draft report MAST indicated that:

“The basic EU hygiene- and control package has been implemented as of March 1, 2010. Other relevant legislation is in the EEA-process and implemented as soon as translated. In certain cases the Ministry of Fisheries and Agriculture can call for express translation.”

Findings

The mission team confirmed that the Authority had been notified on 18 November 2010 of the implementation of Regulation (EC) No 333/2007 laying down the methods of sampling and analyses for the official controls of the levels of lead, cadmium, mercury inorganic tin, 3-MPCD and benzo(a)pyrene in foodstuffs. The mission team further confirmed that this legislation had been incorporated (see Recommendation 13).

Conclusion

The relevant legislation for the purpose of the mission has been made part of the Icelandic internal legal order in line with Article 7 of the EEA Agreement.

5.2 Competent Authorities

Recommendation 2

The competent authorities should ensure the efficient and effective coordination and cooperation between different units within MAST as required by Article 4(5) of Regulation (EC) No 882/2004.

Corrective action

In its response to the draft report MAST indicated that:

“Notice has been taken of this recommendation and taken care of by the competent authority.”

Findings

In the opening meeting the representatives of MAST informed the mission team that the part of the service responsible for the issuing of a harvesting licence for live bivalve molluscs conferred with the part of the service responsible for approval of the establishments.

The mission team did not identify any discrepancy between the different units of MAST dealing with live bivalve molluscs.

Conclusions

The competent authorities have ensured efficient and effective coordination and cooperation between different units within MAST as required by Article 4(5) of Regulation (EC) No 882/2004 as regards official controls of live bivalve molluscs.

Recommendation 3

The competent authorities should ensure that the delegation of specific tasks related to official controls to one or more control bodies is in accordance with the requirements laid down in Article 5 of Regulation (EC) No 882/2004.

Corrective action

In its response to the draft report MAST indicated that:

“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. Consequently, the competent authority has not delegated any tasks to the control bodies and has no authority to operate according to the provisions of Article 5 of Regulation (EC) No 882/2004.”

According to the reply to the Authority’s pre-mission questionnaire:

“MAST has taken over the official controls from 1 March 2011.”

Findings

The mission team confirmed that according to legislation notified by Iceland to the Authority there are no provisions for the operation of independent control bodies based on national legislation as part of Iceland’s internal legal order as of 1 March 2011.

Conclusions

As of 1 March 2011 there is no delegation of official tasks by the competent authority that relates to the purpose of this mission.

Recommendation 4

The competent authority should ensure that staff in charge of official controls receive appropriate training, and are kept up-to-date in their areas of competence in line with the requirements of Article 6 of Regulation (EC) No 882/2004.

Corrective action

In its response to the draft report MAST indicated that:

“In the sector of fish and fishery products and LBM, accredited private IBs carry out the regular inspections according to instructions from MAST. The IBs have, according to accreditation standards, their own quality assurance system that demands training programmes for the inspectors in the field of the body’s accreditation. The accreditation body performs an audit once a year of the IBs, where their quality system is assessed and an inspector is followed on an on-site inspection.”

In January 2011 MAST gave the following information:

“MAST is in the process of employing inspectors. A training program will be arranged for the new inspectors and the inspectors already working at MAST. It should be finalised

before 1 March 2011. Furthermore one of MAST's senior officers attended DG SANCO's special training course on live bivalve molluscs."

According to the reply to the Authority's pre-mission questionnaire:

"Three inspectors have been employed in addition to the two inspectors that were already employed. Training program has been designed for each inspector. A long term training program on aspects concerning the regulations and audits and inspection technique. As part of this program all inspectors attended a half day training on Regulations (EC) 852/2004 and 853/2004.

A senior officer attended DG SANCO's Better training for safer food course on Animal health prevention and control of aquaculture animals, Molluscs and crustaceans health, in Vigo 3-5 Nov. 2010."

Findings

The mission team confirmed by auditing written material that the staff had attended two training courses given by DG SANCO one on live bivalve molluscs and another on the health of live bivalve molluscs. Also, the training of inspectors was confirmed. Furthermore, the quality manual in a draft version was presented to the mission team as was the new inspection handbook

Conclusions

The competent authority has made an effort to train staff involved in official controls of live bivalve molluscs to ensure that training is in accordance with requirements.

Recommendation 5

The competent authority should ensure that action in case of non compliance is taken as required by Article 54(1) of Regulation (EC) No 882/2004.

Corrective action

In its response to the draft report MAST indicated that:

"MAST 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."

According to the reply to the Authority's pre-mission questionnaire:

"MAST is in the process of reviewing the system for follow up of inspections as a part of procedures in MAST's Quality Manual. It is scheduled to be issued in May / June when a new database IS lexfur (Information on approved establishments and results of official control) will be taken into use."

Findings

In the quality manual of MAST audited by the mission team it was confirmed that follow up instructions were laid down and in the Inspection handbook. Instructions for follow up in case of non compliance were included in the handbook.

The mission team did not identify, on-the-spot, examples of lack of action taken by the competent authority in case of non-compliances.

Conclusions

MAST is working to ensure that action in case of non compliance is taken.

Recommendation 6

The competent authorities should ensure that the operational contingency plan for crisis management is reviewed as required in Article 13 of Regulation (EC) No 882/2004.

Corrective action

In its response to the draft report MAST indicated that:

“The contingency plan will be reviewed in the coming months in light of requirements of Article 13 of Regulation (EC) No 882/2004.”

According to the reply to the Authority’s pre-mission questionnaire:

“The contingency plan from 2005 is still valid and is used in case of crisis and/or food borne diseases.”

Findings

According to information given in the opening meeting by the representatives of MAST the revision of the contingency plan had been delayed because of lack of human resources.

Conclusions

The competent authorities had not reviewed the operational contingency plan for crisis management.

5.3 Official controls concerning live bivalve molluscs from classified production areas

Recommendation 7

The competent authorities should ensure that the production and placing on the market of live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods undergo official controls as required in Article 6 and detailed in Annex II to Regulation (EC) No 854/2004.

Corrective action

In its response to the draft report MAST indicated that:

“The control programme for production and placing on the market of live bivalve molluscs according to A.6 Annex II of regulation 854/2004, is under construction and is attached as „Icelandic Shellfish Monitoring Programme“. This is a draft document.

MAST is discussing the methods used to analyse toxins with the Irish Marine Institute and will eventually make some changes on the methods.

The harvesting areas for sea urchin, gastropods and sea cucumber have not been classified since they are not filter feeding animals as mussels and ocean quahog. MAST has concluded that the only possible risk could be chemical contamination and toxin after a period with a bloom of toxic algae. However chemical contamination is not considered a risk in Icelandic waters as demonstrated by the yearly monitoring programs organised by the ministry. The reports are available on Matis website.

After a period when the number of toxic algae has been over the limit in a harvesting area for gastropods a sample is taken of gastropods for analysis of marine biotoxins before first harvesting. Sample is also taken if harvesting is ongoing when the number of toxic algae is over the limit.

All production areas that have been classified are near to the coast and they are A areas. The fishing of sea urchin, gastropods and sea cucumber is in the open sea where there is very little risk of microbiological contamination.

Live Ocean quahog has been released to the ocean again. This was a decision taken by the FBO. The confirmation is in attachment.

As pointed out under recommendation 11-12 the FBOs have been requested to set up a sampling plan and MAST will also set up a sampling plan for those species.”

In January 2011 MAST gave the following information:

“The finalisation of the document the „Icelandic Shellfish Monitoring Programme“ was delayed until 01/05/2011. The mouse bioassay has been used for analysis of DSP toxins since august 2010. See attached results for analysis of DSP in Sea urchin.

MAST is in the process of performing risk assessment in order to determine the frequency of toxin analysis, microbiological and chemical analysis for different species and different areas. The document is scheduled to be finalised before 15.03.2010 The frequency of analysis of biotoxins in mussels is now according to the risk assessment.

Sea urchins are caught in two areas; Breiðaffjörður that is monitored regularly for presence of toxic algae, biotoxins E. coli and chemical contaminants.

However samples will be taken for analysis of E. coli. In areas where there is no monitoring (Berufjörður), the sea urchin were analysed for presence of marine biotoxins, E. coli and salmonella.

The producer of gastropods has taken some samples for analysis of fecal coliforms, salmonella and heavy metals.

It was verified by MAST 18.08 2010 that no traces of live ocean quahog were at the establishment. No production of ocean quahog since June 2010 and therefore no sampling. A sampling plan for 2011 has been set up.”

According to the reply to the Authority’s pre-mission questionnaire:

“MAST has further delayed the finalisation of the „Icelandic Shellfish Monitoring Programme“. In MAST’s Quality Manual a draft to internal working procedures are available.

The marine institute in Ireland has stopped using the mouse bio-assay from 22.04.2011. They are working on validation of the LC- MS / MS method for analysis of YTX PTX. It is expected to be submitted to accreditation before July 2011. However all DSP toxins will be covered by the LC-MS /MS method. The part covering the other DSP toxins is accredited.”

Findings

The competent authority informed the mission team that live bivalve molluscs and live echinoderms are harvested from classified areas. From the results available and checked by the mission team these areas are classified as A. Furthermore the live bivalve molluscs taken from these areas met the health standards required. The sampling frequency for official controls of live bivalve molluscs during harvesting was once a week.

The competent authority considered that since live echinoderms and live tunicates are not filter feeding animals the requirements of Annex II to Regulation (EC) No 854/2004 did not apply to them.

During a visit to a food business operator placing on the market live bivalve molluscs the mission team was informed that samples of final products taken by producers for sending to the laboratory are considered as official samples.

Conclusions

The competent authorities ensured that the production and placing on the market of live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods undergo official controls in line with the requirements of Article 6 and detailed in Annex II to Regulation (EC) No 854/2004.

The consideration that live echinoderms and live tunicates are not filter feeding animals is not in line with the requirements laid down in Annex II to Regulation (EC) No 854/2004.

Samples of end products taken by producers cannot be considered as samples taken for official controls within the meaning of Regulation (EC) No 854/2004 and Regulation (EC) No 882/2004.

5.4 Approval of establishments

Recommendation 8

The competent authorities should ensure that establishments are only approved if they comply with the relevant requirements as laid down in Article 31(2)(c) of Regulation (EC) No 882/2004 and Article 3 of Regulation (EC) No 854/2004.

Corrective action

In its response to the draft report MAST indicated that:

“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.

In the reply to the Authority’s pre-mission questionnaire MAST gave the following information:

“The procedure has been drafted and discussed at MAST. It is scheduled to be issued in May / June when a new database IS leyfur (Information on approved establishments and results of official control) will be taken into use. In order to increase harmonisation of the approval of establishments, one inspector is specially assigned to lead the first inspection of establishments.”

Findings

In the opening meeting the representatives of MAST presented evidence to the mission team that the date for the extension of a conditional approval of an establishment had in one case not been met. However the total length of the conditional approval did not exceed six months and at the correct date the establishment had been visited and got a full approval.

The mission team looked at the approval documents of all the establishments visited and did not find any irregularities.

Conclusions

The approval of the establishments visited was found in line with the legislation.

5.5 General hygiene requirements for food business operators

Recommendation 9

The competent authorities should ensure that food business operators place on the market live bivalve molluscs produced in conformity with the requirements laid down in Article 5 of Regulation (EC) No 852/2004.

Corrective action

In its response to the draft report MAST indicated that:

“MAST has taken steps to encourage the food sector branches to make guides to Good hygiene practices and HACCP. MAST is currently preparing a guidance for the food business operators on how to fulfil the requirements on own checks with regard to 2073/2005 and the HACCP requirement taking the possible flexibility into account.”

In January 2011 MAST gave the following information:

“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. A group has been established to make guidelines for producers on 2073/2005. Should be finalised before 01.04.2011.”

In the reply to the Authority’s pre-mission questionnaire MAST gave the following information:

“The guidelines (HACCP) were presented at MAST’s monthly meetings 25.01.2011 and they are available on MAST’s website. A draft to the guidelines (2073/2005) is available. It will be discussed at MAST and followed by presentation for food business operators.”

Findings

The mission team inspected the HACCP manuals of a food business operator producing live sea urchins and another food business operator producing live mussels. The manuals detailed the outcome products, the different steps in the processing and identified the proper hazards.

Conclusions

The competent authorities had ensured that food business operators visited placed on the market live bivalve molluscs produced in conformity with the requirements laid down in Article 5 of Regulation (EC) No 852/2004.

Recommendation 10

The competent authorities should ensure that food business operators place on the market live bivalve molluscs produced in conformity with the general hygiene requirements laid down in Annex II to Regulation (EC) No 852/2004.

Corrective action

In January 2011 MAST gave the following information:

“The LBM plants were inspected in august and they accordingly made a plan for corrective actions that will be followed up by MAST and the IBs. Guidance on handling of packaging materials has been published on Mast’s website. The handling of packaging materials will be given a special attention in the inspections this year.”

In the reply to the Authority’s pre-mission questionnaire MAST gave the following information:

“The facts on the establishments producing LBM are presented in a document attached. As mentioned under point 4 a special focus is on handling of packaging material and cold stores in the inspections from March – July.”

Findings

The mission team visited a food business operator harvesting and packing live sea urchins and a dispatch centre for live mussels. The mission team did not identify discrepancies with general hygiene requirements.

Conclusions

The competent authorities had ensured that food business operators visited placed on the market live bivalve molluscs produced in conformity with the general hygiene requirements laid down in Annex II to Regulation (EC) No 852/2004.

5.6 Specific hygiene rules for live bivalve molluscs

Recommendation 11

The competent authorities should ensure that food business operators place on the market live bivalve molluscs produced in conformity with the specific requirements laid down in Section VII of Annex III to Regulation (EC) No 853/2004.

Corrective action

In its response to the draft report MAST indicated that:

“MAST has written a letter to all the producers (dispatch centres and processing plants) of mussels, sea urchins and whelks requiring them to set up sampling plans to monitor and document that the requirements laid down in chapter V, section VII of Annex III to Regulation 853/2004 and relevant requirements in 2073/2005 are fulfilled.

MAST will set up a sampling plan for final products to verify that the food safety criteria of chapter V, section VII of Annex III to Regulation 853/2004 and relevant requirements in 2073/2005 are met.”

In the reply to the Authority’s pre-mission questionnaire MAST gave the following information:

“According to our information the producers have taken samples for analysis of Cd, Pb, Hg, .E. coli and salmonella. Samples for analysing of benzo(a)pyrene have not been taken by them and this is done in cooperation with MAST.

According to the monitoring program there is no risk of PAH substances in fish around Iceland, see Matis report chapter 5.4.

According to our risk assessment samples will be taken in case of oil leakage from ships (accidents).

One sample of mussels has been taken for analysis of benzo(a)pyrene, see point 13.

No samples according to the sampling plan have been taken yet. This work will be organised in May.”

Findings

The food business operators the mission team inspected producing live sea urchins and live mussels could document that they had taken and had analysed samples of their product for *E. coli*, Salmonella and heavy metals. All the samples analysed fulfilled requirements. However, they had only taken one sample for Salmonella analyses instead of the five samples required by the legislation (see Recommendation 12).

Conclusions

The competent authorities have ensured that food business operators visited placed on the market live bivalve molluscs produced in conformity with the specific requirements laid down in Section VII of Annex III to Regulation (EC) No 853/2004.

Recommendation 12

The competent authorities should ensure that food safety criteria as listed in Chapter 1 of Annex I to Regulation (EC) No 2073/2005 concerning live bivalve molluscs are complied with during official controls and own checks.

Findings

The food business operators the mission team inspected during the mission producing live sea urchins and live mussels could document that samples of their product taken by the food business operator were analysed for Salmonella but only one sample instead of five was taken. For *E. coli* one sample was taken.

Conclusion

The competent authority has not ensured that the requirements of Regulation (EC) No 2073/2005 regarding sampling for Salmonella are complied with. Sampling regarding *E. coli* was carried out in conformity with the legislative requirements.

5.7 Laboratories

Recommendation 13

The competent authority should designate laboratories to support the official controls on live bivalve molluscs in accordance with Article 4(2)(c) and Article 12 of Regulation (EC) No 882/2004.

The competent authority should ensure that methods of analysis used in the context of official controls are in conformity with the requirements as laid down in Article 11 of Regulation (EC) No 882/2004.

The competent authority should ensure that benzo(a)pyrene is monitored as required in Section 6, point 6.1.6. of the Annex to Regulation (EC) No 1881/2006.

The competent authority should ensure that with relation to heavy metals, the requirements laid down in the Annex to Commission Regulation (EC) No 333/2007 are fulfilled.

Corrective action

In its response to the draft report MAST indicated that:

“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. Letters to laboratories informing them of their designation as official laboratories dated in March 2009 are attached.

Work has also started regarding agreements with laboratories in official control.

Regulation 1881/2006 was implemented by Regulation 268/2010. Benzo(a)pyrene will from August 1 be analysed as a part of a sanitary survey. The frequency of monitoring will be decided when some results are available. Samples will be taken from open production areas this autumn.

Commission Regulation (EC) No 333/2007 has not yet been implemented due to delays in translation. The laboratory concerned in heavy metals analysis has been informed of the Regulation and asked to adapt its work to its provisions in order to prepare for the implementation of this Regulation in coming months.”

Findings

In the opening meeting the mission team was informed that the designation of laboratories was in progress.

The mission team visited a private laboratory which is collecting net and sea samples in the contexts of MAST’s monitoring programme of production areas. The samples are not analysed by this laboratory but are forwarded to the Marine Research Institute. During the visit the mission team noted that working instructions and standard operating procedures had been developed.

The mission team visited the laboratory of the Marine Research Institute analysing for phytoplankton. Even though the laboratory is not accredited, standard operating procedures and internal records per sample were available. Internal quality checks were done among the staff dealing with the samples. Samples for phytoplankton analysis arrived in the laboratory with proper forms filled in.

The mission team noted that results of analysis on phytoplankton are now issued using a formal assay report by e-mail with not only the figures of *Alexandrium*, *Dinophysis* and *Pseudonitzschia* counting but also other species found.

A sample was analysed for benzo(a)pyrene with negative results.

Results of analyses for heavy metals presented to the mission team were in conformity with the requirements of Regulation (EC) No 333/2007.

Conclusions

The two laboratories visited by the mission team were found adequate for the tasks they are dealing with in the context of this mission, however the competent authority has not yet designated laboratories to support the official controls on live bivalve molluscs in accordance with Article 4(2)(c) and Article 12 of Regulation (EC) No 882/2004.

5.8 Miscellaneous

Recommendation 14

The competent authority should ensure that the quality of water intended for human consumption is regularly monitored in accordance with Article 7 of Directive 98/83/EC and that the minimum requirements set out in Annex II (audit monitoring) are fulfilled.

Corrective action

In its response to the draft report MAST indicated that:

“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.

A report from 2007 on the results of chemical analysis of the municipal water supply in Þórshöfn was sent to ESA on July 8, 2010.”

Findings

In the opening meeting the mission team was informed that the Icelandic authorities use the number of inhabitants in a supply zone instead of the volume of water to determine the minimum frequency, assuming a water consumption of 200l/day/capita. They are also considering for small communities the possibility of using analyses of water originating from the same aquifer. They are still considering the use of water by the food industry.

The frequency of audit monitoring in small communities with inhabitants less than 500 but with food producing establishments where water is a part of the final product has not yet been established.

Conclusions

The absence of audit monitoring to check the quality of water in establishments processing fishery products is not in conformity with the requirements laid down in Article 7 of Directive 98/83/EC.

Recommendation 15

The competent authorities should ensure that food business operators place on the market fishery products (including processed bivalve molluscs) produced in conformity with the requirements laid down in Article 5 of Regulation (EC) No 852/2004.

Findings

The mission team visited two establishments processing bivalve molluscs. Both of them had HACCP manuals evaluated by the competent authorities and implemented by the food business operators; only minor remarks were observed by the mission team.

Conclusions

The competent authorities had ensured that food business operators visited place on the market fishery products (including processed bivalve molluscs) produced in conformity with the requirements laid down in Article 5 of Regulation (EC) No 852/2004.

Recommendation 16

The competent authorities should ensure that food business operators place on the market fishery products (including processed bivalve molluscs) produced in conformity with the general hygiene requirements laid down in Annex II to Regulation (EC) No 852/2004.

Findings

The mission team visited two establishments processing bivalve molluscs. One of them was generally in conformity with the requirements of the legislation but with minor remarks concerning the layout.

The other establishment was in poor condition regarding general hygiene requirements. The mission team noted e.g.:

- Wooden surfaces in areas where food were handled and in particular those in contact with food;
- absence of adequate facilities for the cleaning and disinfecting of knives and aprons;
- not all wall surfaces were in a sound condition;
- insufficient cleaning of overhead structures allowing contamination between and during operation, and

- wrapping and packaging materials stored in such a manner that they were exposed to a risk of contamination.

Conclusions

The competent authorities had not ensured that food business operators place on the market fishery products (including processed bivalve molluscs) produced in conformity with the general hygiene requirements laid down in Annex II to Regulation (EC) No 853/2004.

Recommendation 17

The competent authorities should ensure that the requirements laid down in Part A of Chapter IV of Section VIII (Fishery products) of Annex III to Regulation (EC) No 853/2004 are complied with.

Corrective action

In its response to the draft report MAST indicated that:

“Cooling should be incorporated as a step in a flow chart and HACCP analysis. A letter will be written to the relevant FBOs, where requested to send the revised flowchart and HACCP analysis to MAST before the production starts in September.”

In January 2011 MAST gave the following information:

“The establishments concerned will be visited in January and the flow chart will be verified.”

In the reply to the Authority’s pre-mission questionnaire MAST gave the following information:

“No remarks were made in January regarding the flow chart”

Findings

The mission team visited an establishment processing cooked mollusc shellfish and observed that in the relevant flow charts of HACCP systems rapid cooling following cooking was indicated as a process step.

Conclusions

MAST has ensured that, in the establishment visited, the requirements laid down in Part A of Chapter IV of Section VIII (Fishery products) of Annex III to Regulation (EC) No 853/2004 are complied with.

Recommendation 18

The competent authorities should ensure that the requirements mentioned in Chapter V point E.2 (Toxins harmful to human health) of Section VIII (Fishery products) of Annex III to Regulation (EC) No 853/2004 are complied with.

Corrective action

In its response to the draft report MAST indicated that:

“Ocean quahog was sampled at the time of landing 2008. There were 12 landings (batches) of ocean quahog in 2008. The broth was produced from those batches. All landings were tested for bio-toxins so there should be no risk of marine bio-toxins in the broth.”

Findings

The mission team audited the test results for bio-toxins and found that the relevant toxins had been analysed.

The mission team visited an establishment processing sea cucumbers that the competent authority informed the mission team were all originating from a classified area. However, the manager of the establishment informed the mission team that the sea cucumbers were harvested in two areas that were outside the classified area.

In the establishment's HACCP plan toxins were not taken into consideration as a hazard. The last results concerning bio-toxins were from the year 2003.

Conclusions

The competent authorities did not ensure that the requirements mentioned in Chapter V point E.2 (Toxins harmful to human health) of Section VIII (Fishery products) of Annex III to Regulation (EC) No 853/2004 were complied with.

Recommendation 19

The competent authorities should ensure that official controls of fishery products are carried out in conformity with the requirements laid down in Chapter II of Annex III to Regulation (EC) No 854/2004.

Corrective action

In its response to the draft report MAST indicated that:

“The producer has been requested in a letter to take some samples of broth to demonstrate that the levels of heavy metals are according to 1881/2006. The samples have been taken and a letter was sent to the producer allowing him to put the product on the market.”

MAST will set up a sampling plan of final products which will take into account the requirements of 854/2004 chapter II of Annex III.”

Findings

In the opening meeting the competent authority confirmed that a sampling plan was ready but no samples had yet been taken according to the plan.

The mission team visited an establishment processing sea cucumbers that the competent authority informed the mission team were all originating from a classified area. However, the manager of the establishment informed the mission team that the sea cucumbers were harvested in two areas that were outside the classified area.

The mission team was informed by the competent authority that they did not take samples for the presence of bio-toxins in fishery products derived from tunicates basing their risk assessment on United States' Food and Drug Administration information and literature.

Conclusions

The competent authorities did not ensure that official controls of fishery products, toxins harmful to human health, are carried out in conformity with the requirements laid down in Chapter II of Annex III to Regulation (EC) No 854/2004.

Recommendation 20

The competent authorities should ensure that food safety criteria as listed in Chapter 1 of Annex I to Regulation (EC) No 2073/2005 concerning cooked bivalve molluscs is complied with during official controls and own checks.

Corrective action

In its response to the draft report MAST indicated that:

“The producer has been requested in a letter to take some samples of broth to demonstrate that it meets the food safety criteria listed in chapter 1 (1.16) of Annex 1 to Regulation 2073/2005. The samples have been taken and a letter was sent to the producer allowing him to put the product on the market.”

Findings

In the opening meeting the competent authority confirmed that a sampling plan was ready but no samples had yet been taken according to the plan.

During the visits to the food business operators producing cooked bivalve molluscs, the mission team noted that when samples for Salmonella were taken for analyses only one sample was taken instead of five and at one establishment, sampling final product in October 2010, Salmonella was omitted.

Conclusion

The competent authorities did not ensure that food safety criteria as listed in Chapter 1 of Annex I to Regulation (EC) No 2073/2005 concerning cooked mollusc shellfish was complied with during official controls and own checks.

6 Overall conclusion

The Icelandic competent authority took into consideration the recommendations made by the Authority after the mission on live bivalve molluscs carried out in 2010. The implementation of appropriate corrective actions to a number of the recommendations from that report was confirmed by this follow-up mission.

Official controls and food business operators' procedures in the establishments visited are in general in conformity with the requirements of the legislation.

Live bivalve molluscs produced in Iceland generally fulfil the legal requirements for harvesting and placing on the market of this commodity.

However, there is still a need for improvement in some areas such as:

- Official sampling of live and processed bivalve molluscs;
- designation of laboratories for official controls of live bivalve molluscs;
- general hygiene requirements at establishment level, and
- controls on processed tunicates harvested outside classified areas.

7 Final meeting

A final meeting was held on 27 May 2011 at MAST's office in Reykjavik with representatives from the Ministry of Fisheries and Agriculture and MAST. 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 could be included in the report.

8 Recommendations to the Icelandic competent authority

No	Recommendation
1	The competent authorities should ensure that the operational contingency plan for crisis management is reviewed as required in Article 13 of Regulation (EC) No 882/2004.
2	The competent authorities should ensure that the requirements in Annex II to Regulation (EC) No 854/2004 are also applied to live echinoderms and live tunicates.
3	The competent authorities should ensure that samples of end-products taken for official controls comply with the requirements laid down in Article 4 of Regulation (EC) No 854/2004 and Regulation (EC) No 882/2004.
4	The competent authorities should ensure that food safety criteria as listed in Chapter 1 of Annex I to Regulation (EC) No 2073/2005 concerning live bivalve molluscs are complied with during official controls and own checks.
5	The competent authority should designate laboratories to support the official controls on live bivalve molluscs in accordance with Article 4(2)(c) and Article 12 of Regulation (EC) No 882/2004.
6	The competent authority should ensure that the quality of water intended for human consumption is regularly monitored in accordance with Article 7 of Directive 98/83/EC and that the minimum requirements set out in Annex II (audit monitoring) are fulfilled.
7	The competent authorities should ensure that food business operators place on the market fishery products (including processed bivalve molluscs) produced in conformity with the general hygiene requirements laid down in Annex II to Regulation (EC) No 852/2004.
8	The competent authorities should ensure that the requirements mentioned in Chapter V point E.2 (Toxins harmful to human health) of Section VIII (Fishery products) of Annex III to Regulation (EC) No 853/2004 are complied with.
9	The competent authorities should ensure that official controls of fishery products are carried out in conformity with the requirements laid down in Chapter II of Annex III to Regulation (EC) No 854/2004.
10	The competent authorities should ensure that food safety criteria as listed in Chapter 1 of Annex I to Regulation (EC) No 2073/2005 concerning cooked mollusc shellfish is complied with during official controls and own checks.

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

Authority	EFTA Surveillance Authority
DG SANCO	Directorate General for Health and Consumers of the European Commission
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
HACCP	Hazard Analysis and Critical Control Point
MAST	<i>Matvælastofnun / Icelandic Food And Veterinary Authority</i>

Annex 2 - Other relevant legislation

The main EEA Acts regarding relevant for this mission are:

- a) 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 and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC*, as corrected by OJ L 195, 2.6.2004, p. 12.
- 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* as adapted to the EEA Agreement.
- c) 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.
- d) 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.
- e) 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 to the EEA Agreement.
- f) 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 to the EEA Agreement.
- g) 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.

- h) 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*.
- i) 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*.
- j) The Act referred to at point 6.2.43 of Chapter I of Annex I to the EEA Agreement *Commission Decision 2002/226/EC of 15 March 2002 establishing special health checks for the harvesting and processing of certain bivalve molluscs with a level of amnesic shellfish poison (ASP) exceeding the limit laid down by Council Directive 91/492/EEC*.

Annex 3 – Comments to the draft report: Actions planned by the Icelandic Food and Veterinary Authority

ESA follow-up mission on LBMs in 2011				
No	Recommendation	Proposed Action	Date of compliance	Comment/attachment
1	The competent authorities should ensure that the operational contingency plan for crisis management is reviewed as required in Article 13 of Regulation (EC) No 882/2004.	Delayed until 01.01.2012	01.01.2012	
2	The competent authorities should ensure that the requirements in Annex II to Regulation (EC) No 854/2004 are also applied to live echinoderms and live tunicates.	The definition of catching areas will be discussed with the ministry with the aim of finding a way to secure that catching of echinoderms and tunicates will only take place in classified areas.	01.01.2012	
3	The competent authorities should ensure that samples of end-products taken for official controls comply with the requirements laid down in Article 4 of Regulation (EC) No 854/2004 and Regulation (EC) No 882/2004.	Samples of end products will be taken according to the sampling plan by Mast's inspectors. See recommendation 11 from 2010.	01.01.2012	
4	The competent authorities should ensure that food safety criteria as listed in Chapter of Annex I to Regulation (EC) No 2073/2005 concerning live bivalve molluscs are complied with during official	As already presented MAST is working on guidelines for FBOs on sampling according to 2073/2005. This work is ongoing and is expected to be finalised during the autumn.	01.01.2012	

	controls and own checks.			
5	The competent authority should designate laboratories to support the official controls on live bivalve molluscs in accordance with Article 4(2)(c) and Article 12 of Regulation (EC) No 882/2004.	Ongoing	01.01.2012	
6	The competent authority should ensure that the quality of water intended for human consumption is regularly monitored in accordance with Article 7 of Directive 98/83/EC and that the minimum requirements set out in Annex II (audit monitoring) are fulfilled.	The situation and the status of the survey were presented during ESA's mission on LBMs in May. MAST will meet with the LCAs and other stakeholders to gather information available for potable water and the water sources. The aim is to get a clearer picture of the water sources and to determine if there are common aquifers.	01.01.2012	
7	The competent authorities should ensure that food business operators place on the market fishery products (including processed bivalve molluscs) produced in conformity with the general hygiene requirements laid down in Annex II to Regulation (EC) No 852/2004.	Letter was sent to the establishments concerned. The letter and corrective actions are in attachments. No production from 1st of June to August. The corrective action will be followed up in the next inspection in August- September. Mast inspectors were informed that they should in each inspection make comments on insufficient cleaning of equipment, facilities, working clothes and bad housekeeping. They will receive written instructions on which inspection items in the inspection manual should always be evaluated.	01.09.2011	Attachment sent to the Authority
8	The competent authorities should ensure that the requirements	See point 2. According to MAST's risk assessment,		

	mentioned in Chapter V point E.2 (Toxins harmful to human health) of Section VIII (Fishery products) of Annex III to Regulation (EC) No 853/2004 are complied with.	toxins are not a Hazard in sea cucumber		
9	The competent authorities should ensure that official controls of fishery products are carried out in conformity with the requirements laid down in Chapter II of Annex III to Regulation (EC) No 854/2004.	Samples will be taken see point 3. Catching of sea cucumber outside classified area see point 2. Samples will be taken to verify Mast's conclusion on risk assessment. Furthermore sea cucumbers are not caught during the period when highest risk for toxic algae..	01.01.2012	
10	The competent authorities should ensure that food safety criteria as listed in Chapter 1 of Annex I to Regulation (EC) No 2073/2005 concerning cooked mollusc shellfish is complied with during official controls and own checks.	See point 3 and 4.		