

Case No: 67735
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Final report

EFTA Surveillance Authority 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

Please note that the comments from the Icelandic competent authorities to the factual content of the report, if any, have been included in the body of the report in italic print. Comments and information on the corrective actions taken and planned are included in Annexes 3 and 4 and referred to in footnotes in italic print.

Executive Summary

This report describes the outcome of a mission carried out by the Authority in Iceland from 22 June to 1 July 2010.

The objective of the mission was to verify that official controls related to live bivalve molluscs were carried out in compliance with the European Economic Area legislation.

The mission team found that the production and the placing on the market of live bivalve molluscs harvested in Iceland was not in conformity with several of the requirements listed in Regulations (EC) 852/2004, 853/2004, 854/2004 and 882/2004.

In the light of the serious weaknesses identified by the mission team in the official controls implemented by the Icelandic competent authority and the severe shortcomings at food business operators' level, there is a significant risk to the health of the final consumer as a result of being exposed to biotoxins, microbiological and chemical contaminants.

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 22 June to 1 July 2010, as part of the EFTA Surveillance Authority's (the Authority) planned mission programme. The mission team comprised two inspectors from the Authority and a national expert (who joined the mission team from 28 June to 1 July 2010).

The opening meeting was held with representatives of *Matvælastofnun* (the Icelandic Food and Veterinary Authority-MAST) and of the Ministry of Fisheries and Agriculture on 22 June at MAST's head office in Selfoss. At the meeting, the representatives of MAST added information to their reply to the Authority's pre-mission questionnaire.

Throughout the mission, a representative of the head office accompanied the mission team. In addition, inspectors of the control bodies in charge of official controls were usually present during visits to the different establishments under their control (except one establishment).

A final meeting was held at MAST head office in Reykjavik on 1 July 2010, 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	4	An opening meeting in Selfoss and a final meeting in Reykjavik with representatives of MAST, a meeting with <i>Fiskistofa</i> (the Directorate of Fisheries) and a meeting with the local competent authorities in charge of potable water control in a municipality.
Control bodies	2	The control bodies were met at the establishments.
Production areas	2	Production areas for blue mussels (<i>Mytilus edulis</i>)
Boats for transport	2	Transporting live bivalve molluscs from the production areas to the establishments for further processing (the boats were not inspected in details).
Dispatch centres	3	Two dispatch centres approved for blue mussels (<i>Mytilus edulis</i>) and one dispatch centre for ocean quahog (<i>Arctica islandica</i>) with an approval number withdrawn by MAST on 21 June 2010.
Establishments processing live bivalve molluscs	1	One establishment processing live echinoderms
Establishments processing bivalve molluscs	3	One establishment processing tunicates and one establishment processing marine gastropods (neither establishment was processing bivalve molluscs at the time of the visit). Another establishment approved for processing ocean quahog (in operation at the time of the visit but processing only fishery products).
Laboratories	4	A private laboratory analysing samples for microbiological parameters, a private laboratory analysing sea water samples for phytoplankton and two official laboratories.

2 Scope and objective of the mission

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

- a) The Act referred to at Point 7.1.13 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety* as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that 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;
- 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 by the sectoral adaptations referred to in Annex I to that 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 by the sectoral adaptations referred to in Annex I to that 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.

Other relevant legislation is listed in Annex 2.

The main objective of the mission was to evaluate the Icelandic systems in place for official controls of food business operators' compliance with general and specific rules on the hygiene of live bivalve molluscs and the implementation of these rules by food business operators

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*.

4 Background

4.1 Background

The previous mission concerning live bivalve molluscs was carried out in Iceland from 1 to 5 March 2004. The final report from that mission is accessible on the website of the Authority, www.eftasurv.int. The Authority concluded on a number of issues in the report from the mission in 2004 and subsequently the Icelandic competent authorities informed the Authority of corrective measures taken, or to be taken.

4.2 Information on production and trade

According to information provided by MAST in its reply to the Authority's pre-mission questionnaire, the figures for the production and trade of bivalve molluscs in Iceland are given in the tables below:

Table 2: Total production in Iceland (in kg)

Common name	Scientific name	2007	2008	2009
Blue mussels	<i>Mytilus edulis</i>			12000
Whelk	<i>Buccinum undatum</i>			
Ocean quahog	<i>Arctica islandica</i>	376000	600000	0
Sea cucumbers	<i>Holothuroidea</i>	66000	340000	398000

No information on the production of sea urchins was available from MAST, however they can be found in the following table 3.

Table 3: Amount of landed raw material (in kg, according to information provided by the Directorate of Fisheries - Fishing year from 1 September to 31 August)

Common name	Scientific name	2006-2007	2007-2008	2008-2009	2009-2010
Blue mussels	<i>Mytilus edulis</i>				
Whelk	<i>Buccinum undatum</i>	627327	612664	67328	129150
Ocean quahog	<i>Arctica islandica</i>	4259402	6411386	1808239	
Sea cucumbers	<i>Holothuroidea</i>	192	555775	1340862	1963376
Sea urchin	<i>Echinus esculentus</i>	130668	114841	128997	152105

According to additional information provided by the representatives of MAST in relation to Icelandic scallops (*Chlamys islandica*), the mission team was informed that it has been harvested since 1969; the population size decreased in all major subpopulations in Icelandic waters towards the end of the 1990s. The stock size index of the largest scallop population in Iceland, in *Breiðafjörður*, declined by 70% during the period 2000–2003. As a result, and in order to allow the stock to re-establish itself, the representatives of MAST informed the mission team that no quota for harvesting has been issued since 2003.

According to information available from the website of Statistics Iceland (www.statice.is/), the exports from Iceland of ocean quahog (*Arctica islandica*) were 163.000 kg in 2009 and 3.300 kg in the period from January to April 2010. The exports of blue mussels (*Mytilus edulis*) were 8.600 kg in the first quarter of 2010.

5 Findings and Conclusions

5.1 Legislation and implementing measures

Legal requirements

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

Findings

According to information provided by MAST in its reply to the Authority's pre-mission questionnaire, the relevant legislation regarding the application of EEA legislation related to the production and the placing on the market of live bivalve molluscs is implemented in Iceland.

However, in the same reply MAST informed the Authority that Regulation (EC) No 333/2007 has not been incorporated into the Icelandic legal order. During the initial meeting representatives of MAST explained that the main reason was due to delays in translation and the amount of relevant documents to be translated.

During the visit at an official laboratory, the mission team noted that the methods of analysis for heavy metals were not yet validated (limits of detection and limit of quantification were not yet established) and that the performance criteria of sampling (sealing and labelling) and reporting of results (expression of results and number of significant figures) were not detailed.

Conclusions

The national legislation in place fulfilled the relevant EEA requirements in the field of the production and the placing on the market of live bivalve molluscs. However, Regulation (EC) No 333/2007 has not been incorporated into the Icelandic legal order. This is not in conformity with the requirements set out in Article 7 of the EEA Agreement.

5.2 Competent Authorities

5.2.1 Organisation and responsibilities

Legal requirements

Article 4(1) of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for official controls. Article 4(5) of the same Regulation states that when, within a competent authority more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Findings

According to information provided by MAST in its reply to the Authority's pre-mission questionnaire, MAST is the competent authority in charge of the official controls of live bivalve molluscs in Iceland. MAST is also responsible for the enforcement of related legislation adopted by the Ministry of Fisheries.

The Directorate of Fisheries is the competent authority for the issuing of licences for the production areas for live bivalve molluscs.

The mission team noted inconsistencies by MAST in the procedures to grant conditional approval to establishments and harvesting licences. The mission team visited a dispatch centre for blue mussels (*Mytilus edulis*) approved by MAST. The certificate of approval issued by MAST on 1/3/2010 reported as valid until 28/02/2022. The establishment had been granted a conditional approval until 1 June 2010 but the letter was not found available on the spot. MAST

carried out an inspection on 9 June 2010 and extended the former conditional approval to 1 September 2010. However, the establishment operated and processed blue mussels from 1 to 8 of June 2010 on the base of a harvesting licence issued by MAST but without an approval as a dispatch centre. In another establishment dispatching live ocean quahog (*Arctica islandica*) a temporary licence was issued in June 2009 for three months and renewed until the withdrawal of approval, valid from 21 June 2010, was issued by a letter dated 3 June 2010. The dispatch centre appeared as approved without having any harvesting licence issued for live ocean quahog (*Arctica islandica*) since 2009. The responsible officers of the procedures for approval of establishments and release of harvesting licences are based in two different offices of MAST.

Conclusions

During the meetings with the different levels of the competent authorities involved in the control of the production and the placing on the market of live bivalve molluscs, the mission team confirmed that responsibilities were well defined, as required by Art. 4(1) of Regulation (EC) No 882/2004. However, efficient and effective coordination and cooperation between different units within MAST was not always ensured as required by Article 4(5) of Regulation (EC) No 882/2004

5.2.2 *Delegation of specific tasks related to official controls*¹

Legal requirements

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

Findings

According to information provided by MAST in the reply to the Authority's pre-mission questionnaire, two accredited control bodies are involved in official control based on national legal provisions which will be in force until 1 March 2011². The role of the control bodies is at establishment level only and they do not take part in the classification or opening and closing of production areas for live bivalve molluscs.

The control bodies are accredited according to EN 45004 (ISO/IEC 17020). They are acting on behalf of MAST performing inspections of processing establishments and dispatch centers. The control bodies regularly submit the results of their inspections to MAST, which handles actions that need to be taken in consequence of their results. According to Icelandic Act No 55/1998 all food business operators in the seafood sector that need approval from MAST shall draw up a contract with an accredited control body. Private control bodies and their employees have to be independent and may not participate in activities which could affect their judgement. The mission team was informed in the opening meeting that there is no knowledge of who owns the control bodies as they are private companies. According to the legislation the control bodies are paid directly by the establishment³. This legislation will be amended 1 March 2011.

A senior officer of MAST informed the mission team there had been no real audit by MAST of the control bodies. However, there had been coordination visits and statistical evaluation of the

¹ See comments from Iceland and MAST's view on application of the EEA legislation.

² The sentence "MAST has delegated inspections of processing plants and dispatch centres to two accredited control bodies." From MAST's reply to the pre-mission questionnaire was corrected as indicated by MAST.

³ The Authority deleted a sentence on the integration of the control bodies as MAST stated in its reply to the draft report that there were no intentions to integrate the control bodies.

control bodies. Also there were meetings with the control bodies to discuss issues relating to dispatch centres and processing plants and two-three meetings every year on inspection matters. MAST receives the information from the control bodies weekly.

MAST decided that during conditional approval of processing establishments the control bodies should not be involved in live bivalve molluscs' activities before having a meeting with MAST.

In order to ensure cooperation and coordination between MAST and the control bodies, MAST issued an inspection manual which is reviewed and discussed in order to ensure common understanding by all the inspectors of MAST and of the control bodies. Common inspections are carried out and an evaluation of the harmonisation between MAST and the control body and between the individual inspectors is prepared once a year based on statistics from the inspection reports. A seminar is held where the statistics are presented in forms of graphs and diagrams. The frequency of the most used inspection items is compared between the individual control bodies and between MAST's inspectors. If there is significant difference in some of the items, they are discussed and the interpretation of MAST is explained and clarified.

The mission team observed that MAST had made a follow up visit to an establishment. The inspector of MAST only took notice of the control body's last report and did not address the problems of the HACCP system in the previous report of the control body. The mission team observed that inspectors of the same control body did not always address all the problems presented in the previous report. The mission team also observed that despite a control body reported in writing that one of the activities an establishment was approved for was not on-going anymore, MAST issued an approval still including the activity mentioned above.

In another establishment approved as dispatch centre for Ocean quahog (*Arctica islandica*) in October 2009 the control body made a report that the activity was no longer carried out. Despite that on 1 March 2010 MAST approved this activity.

Conclusions

The control bodies can not be said to be impartial and free from any conflict of interest as regards the exercise of tasks delegated to them since the establishments pay directly for their services. This is not in conformity with the requirements established in Article 5(2)(b)(iii) of Regulation (EC) No 882/2004.

The mission team observed some problems in the effective coordination between the competent authorities and the control bodies involved in the control of the production and the placing on the market of live bivalve molluscs. This is not in compliance with Article 5(2)(f) of Regulation (EC) No 882/2004.

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

The requirements stated in Article 5(4) of Regulation (EC) No 882/2004 relating to the notification have not been fulfilled.

5.2.3 Staff performing official controls

Legal requirements

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

Article 54(1) of Regulation (EC) No 882/2004 states that when the competent authority has identified non compliance, it shall take action to ensure that the food business operator remedies the situation.

Findings

According to information provided by MAST in its reply to the Authority's pre-mission questionnaire, its staff took part in several courses concerning legislation which should be implemented and official controls which should be carried out in the context of the production and placing on the market of live bivalve molluscs. This was also confirmed to the mission team during the visits on the spot.

However, the mission team noted that limited training was provided by MAST to the control bodies in charge of official controls at processing establishments' level. However, MAST organised a training seminar for the control bodies on the general requirements of the food hygiene package in February 2010 and another training seminar concerning the specific requirements of the food hygiene package related to live bivalve molluscs in June 2010.

During all the visits the mission team made several observations not reported by the control body's inspectors in their reports.

Lack of experience in the requirements set down in the food hygiene package was noted by the mission team for both MAST and control bodies' inspectors during the visits on the spot. The mission team observed in one establishment that the last visit of MAST was the 9 June 2010 when the competent authority followed up the last report of the control body dated 16 February 2010 but did not take into consideration the previous report from December 2009 where several deviations were found in the HACCP system. Comparing this last report from MAST and the HACCP manual of the company the mission team found that the problems had not been addressed. The mission team found inconsistencies between the observations made by the two different inspectors of the control body concerned and the accuracy of the follow up in different inspection reports. A form from MAST on maintenance in the establishments has been distributed but it was not filled out in this establishment. In another establishment the mission team noted that deadlines given by MAST on the HACCP system in 2009 and 2010 were not respected and have not been followed up by MAST.

Conclusions

Personnel of MAST and of the control bodies met by the mission team were suitably qualified, but partially trained and experienced to carry out official controls related to the production and the placing on the market of live bivalve molluscs which is not in line with the requirements of Article 6 of Regulation (EC) No 882/2004.

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

5.2.4 Audits

Legal requirements

Under Article 4 (6) of Regulation (EC) No 882/2004 competent authorities are required to carry out internal audits, or may have external audits carried out.

Findings

MAST is in the process of making procedures for auditing. MAST is the body responsible for auditing within the food control field (including local public health authorities not involved directly within the scope of this mission but responsible, for example to check the quality of

potable water within a municipality). Representatives of MAST informed the mission team that they hope to begin auditing local public health authorities this year. The director general of MAST informed the mission team at the initial meeting that a letter was sent by the Ministry of Fisheries and Agriculture to the Authority in the first quarter of 2010 stating that MAST will be responsible for the internal audits to be organized within the scope of the food hygiene package.

An audit team composed of ten MAST officials was appointed in 2009 and its first task was to audit the documented procedures in place. The procedures audited till now were related to the registration and approval of feed establishments, procedures on how to implement the EEA acts, some procedures of the internal quality system etc. However, the inspection manual which reports the procedures to be followed in the context of inspections carried out by MAST and/or by the control bodies has not yet been audited.

The personnel of the appointed team received one day training on how to perform audits and a half day training on useful tools to perform audits e.g. the use of a database on how to manage the follow-up.

By the end of the year the audit team should be able to audit some local health authorities in charge of the implementation of some of the requirements listed in the food hygiene package.

Conclusions

MAST has established an audit team which has begun to carry out internal audits in conformity with the requirements of Article 4(6) of Regulation (EC) No 882/2004.

5.2.5 Control and verification procedures

Legal requirements

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

Article 13 of Regulation (EC) No 882/2004 requires Member States to draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to pose a serious risk to humans or animals either directly or through the environment. Member States must review these contingency plans as appropriate, particularly in the light of changes in the organisation of the competent authority and of experience, including experience gained from simulation exercises.

Findings

According to information provided by MAST in its reply to the Authority's pre-mission questionnaire, the procedures for official control are described in the inspection manual. The manual was revised 01.05.2010 and is available on MAST's website. The revision was made to incorporate Regulations (EC) No 852/2004 and 853/2004. The control bodies got furthermore some special instruction on how to inspect a dispatch centre. Inspections should be performed according to the inspection manual. There is a list of items which should be inspected. The manual is a kind of a check list. The results of the inspections are written down in a report. According to the inspection manual the control bodies are required to report to MAST by e-mail, once a week the results of all scheduled inspections. If however the inspector finds one or more serious deficiencies or ten or more minor deficiencies, he/she is required to inform MAST immediately (within 24 hours). If the report has less than ten minor deficiencies, the inspector is supposed to write down the due time for corrections of each deficiency according to guidelines from MAST. MAST keeps all the information in a database for further evaluation.

During the visits on the spot the mission team observed that inspections were performed by the control bodies and by MAST according to the documented procedures mentioned above; the reports of inspections were available and in conformity with the frequency requested by the procedures.

A representative of MAST informed the mission team that the presentation of the requirements that should be checked during inspections and which are listed in the inspection manual available are not detailed enough.

A representative of MAST informed the mission team that the operational contingency plan for crisis management when food poses a serious risk to human health had not been reviewed since 2005 and that it was under revision at the time of the mission.

Conclusions

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

The operational contingency plan for crisis management was not reviewed in the light of changes in the organisation of the competent authority as required in Article 13 of Regulation (EC) 882/2004.

5.3 Official controls concerning live bivalve molluscs from classified production areas

Legal requirements

Article 6 of Regulation (EC) No 854/2004 requires Member States to 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 described in Annex II of this Regulation.

Findings

5.3.1 Classification of production and relaying areas

According to information provided by MAST in its reply to the Authority's pre-mission questionnaire, by the Icelandic Act 71/2008 on Aquaculture the Directorate of Fisheries is the competent authority to grant permits to farmers involved in aquaculture activities, including live bivalve molluscs production. During the initial meeting the mission team was informed by representatives of MAST that a new law could be implemented soon transferring all such responsibilities to MAST. The validity of a permit issued by the Directorate of Fisheries is normally ten years. Withdrawal of permits could be done if there is a period of inactivity of 24 months or violation of the permit. The application for an aquaculture permit is submitted to the Directorate of Fisheries who grant it after a positive opinion received by other authorities consulted in relation to the respective field of competence (e.g. the environmental impact assessment authority, the institute of freshwater fisheries, the Icelandic coast guard etc.). MAST also provides its evaluation which consist in the carrying out a sanitary survey concerning the assessment of the microbiology criteria, heavy metals and chemical contamination in shellfish, and a 12 month survey for *E.coli* in shellfish flesh and faecal coliforms in seawater. There are mollusc farms that have started producing and have applied for a licence which are still in the approval stage. They have not started harvesting. The representatives of the Directorate of Fisheries informed the mission team that an identification code will be given to each production area; at the production area there would be a radar reflector and the production areas are marked by buoys.

After the aquaculture permit is issued, the operators should ask MAST a specific authorisation to harvest live bivalve molluscs.

Representatives of MAST informed the mission team that at the time of the mission there were no relaying areas authorised in Iceland and that only two production areas were authorised from MAST for harvesting live bivalve molluscs and both the areas were authorised for blue mussels (*Mytilus edulis*) only. The two areas were classified as being of class A, from which live bivalve molluscs may be collected for direct human consumption. No reclassification of production areas classified as A occurred since the placing on the market of live bivalve molluscs started. To decide on classification, opening or closure of production areas, MAST relies on sampling carried out by the food business operators. In both the production areas for blue mussels (*Mytilus edulis*) the mission team pointed out that not all the parameters for biotoxins were analysed (total absence of analysis of pectenotoxins and yessotoxins and infrequent analysis for amnesic shellfish poisoning (ASP)).

One of the classified areas for blue mussels (*Mytilus edulis*) visited by the mission team was properly identified with buoys and boundaries able to identify its limits. In the other classified area, several production areas were present in each one of the two geographical zones involved in the production. The mission team visited one of those production areas and noted the absence of a clear system of delimitation of boundaries. The authorisation issued by MAST to harvest blue mussels (*Mytilus edulis*) was issued for a production area not reported in the map available and not identified with proper coordination limits; MAST representatives explained to the mission team that the authorisation was issued based on results from another area where monitoring was carried out as the distance was considered irrelevant (a few hundreds metres) and that the different areas were considered as a unique geographical zone and therefore as a unique production area.

In relation to the production of live ocean quahog (*Arctica islandica*) representatives of MAST informed the mission team that six areas are authorised by the Directorate of Fisheries but that no sanitary survey has been carried out since the production was stopped in 2009. Therefore no production areas were classified since 2009.

In the case of live echinoderms, live tunicates and live marine gastropods there are no production areas classified in Iceland. Despite that, the mission team visited an establishment placing several consignments of live chilled echinoderms (sea urchins- *Echinus esculentus*) on the market of the EEA.

Conclusions

The total absence of analysis of pectenotoxins and yessotoxins and infrequent analysis for ASP was not in conformity with the requirements mentioned in Chapter II, A, 3 of Annex II to Regulation (EC) No 854/2004.

The absence of classification of production areas concerning live echinoderms was not in conformity with Chapter I of Annex II to Regulation (EC) No 854/2004.

5.3.2 Monitoring of classified relaying and production areas

According to information provided by MAST in its reply to the Authority's pre-mission questionnaire, monitoring of classified production areas consists of checking microbiological parameters four times a year, phytoplankton parameters once a week, biotoxins parameters once a week in the period from June to September and once a month in the period between October to May, and for the presence of chemical contaminants once every five years. For some chemical contaminants (dioxins, pesticides etc) the results of the monitoring of the marine biosphere around Iceland which is yearly carried out by the Icelandic Food and Biotech Research and Development Institute (MATIS) are also taken into consideration.

Blue mussels (*Mytilus edulis*)

In one of the two classified areas authorised for harvesting blue mussels, monitoring for microbiological parameters of blue mussels (*Mytilus edulis*) was not carried out according to the sampling plan established by MAST.

With regard to the monitoring of phytoplankton and for both classified production areas, the samples analysed were not representative of the water column (only one sample is collected at a determined depth) and a discrepancy on the depth of the collection of the sea water sample in the instructions prepared by the Marine Institute of Iceland was pointed out by the mission team. The instructions available at a food business operator mentioned a depth between 1-2 meters while another instruction found in a private laboratory collecting samples on behalf of the Marine Institute mentioned a depth of between 3 to 5 meters. The personnel responsible at the Marine Institute explained to the mission team the latter example was the updated version.

The monitoring frequency concerning marine biotoxins established by MAST is based on the period of the year (monthly in the period between October to May and weekly from June to September), and is based on the research conducted by MAST in cooperation with the Marine Institute of Iceland and the conclusion that the presence of toxin-producing plankton in production areas is *highly unlikely* (as mentioned in the memo provided to the mission team) and the fact that they never found biotoxins in blue mussels without the presence of the corresponding phytoplankton. The monitoring frequency did not take into consideration the harvesting period. Representatives of MAST explained to the mission team that the cost of analysis had been taken into account in the process to take a decision based on the number and species of phytoplankton found⁴.

A very basic risk assessment on phytoplankton occurrence was presented as a memo to the mission team before the final meeting; however the mission team noted that the following was missing: identification of risk, characterization of risk, risk exposure and determination of the level of risk.

The mission team observed that incomplete results for marine biotoxins in blue mussels (*Mytilus edulis*) reporting only the paralytic shellfish poison (PSP) parameter were received after twelve days from sampling and in an harvesting season particularly intensive as confirmed by the food business operator. The products were placed on the market before the results were available.

Ocean quahog (*Arctica islandica*)

Representatives of MAST informed the mission team that no sanitary survey had been carried out in the production areas during the last two years 2009 and 2010 and therefore that the areas were not classified. The last sample for marine biotoxin analyses was dated June 2009⁵. However, several batches (around 100 in the last two years) had been placed on the market by this operator during the period the production areas were not classified and no harvesting licences were issued.

The last official control on heavy metals (Lead and Cadmium) was dated 2007 and was related to the production of processed clams (boiled and chopped). The only sampling for heavy metals on live clam that had been stored in tanks for two years was carried out in April 2010; only Cadmium was analysed revealing a value of 1,20 mg/kg (which is above the maximum level (1

⁴ See comments from Iceland in the reply to the draft report

⁵ "and only pectenotoxins were analysed at that time" was deleted from the report as MAST provided evidence that this was not correct.

mg/kg) set in Regulation 1881/2006). There have not been done any marine biotoxin or microbiological analyses of the ocean quahogs (around 1 ton) that the mission team found stored and kept alive by the company.

Echinoderms, tunicates and gastropods

Harvesting areas for live echinoderms, live tunicates and live gastropods were not classified or monitored.

Conclusions

A classified production area for blue mussels (*Mytilus edulis*) was not periodically monitored to check the microbiological quality of live bivalve molluscs as required in Chapter II, B.1(a) of Annex II to Regulation (EC) No 854/2004.

The sampling frequency for toxins analysis in the molluscs was not weekly during the period at which harvesting, as is the general rule, but was reduced following an incomplete risk assessment which was not periodically reviewed as required in Chapter II, B.5 of Annex II to Regulation (EC) No 854/2004.

With regard to the monitoring of plankton, the samples were not representative of the water column as required in Chapter II, B.7 of Annex II to Regulation (EC) No 854/2004.

5.3.3 Additional monitoring requirements and food business operators' own checks

The mission team observed that in addition to the monitoring of production areas as described in chapter 5.3.2 a control system had not been set up by MAST comprising laboratory tests to verify food business operators' compliance with the requirements for the end products at all stages of production, processing and distribution. In particular MAST did not verify that the levels of all marine biotoxins and contaminants to be analysed did not exceed safety limits and that the microbiological quality of the molluscs did not constitute a hazard to human health.

To decide on opening or closure of production areas for blue mussels (*Mytilus edulis*) MAST only took into account the results of samples the food business operator had taken considering them as official samples. However, MAST did not designate the laboratories carrying out the analyses and samples had been taken according to instructions revealing the discrepancies already mentioned at point 5.3.2.

Conclusions

The absence of a control system set up by MAST comprising of laboratory tests to verify food business operators' compliance with the requirements for the end products at all stage of production, processing and distribution of live bivalve molluscs is not in compliance with the requirement stated in Chapter II, D.2 of Annex II to Regulation (EC) No 854/2004.

Laboratories carrying out analysis and sampling protocols were not designated by MAST in conformity with the requirements listed in Chapter II, F of Annex II to Regulation (EC) No 854/2004.

5.4 Approval of establishments

Legal requirements

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

Findings

According to information provided by MAST in its reply to the Authority's pre-mission questionnaire, dispatch centres and establishments be approved according to the Icelandic legislation. The food business operators send their application to MAST. After an onsite inspection of facilities and own check systems, and compliance with the requirements in Annex II to Regulations (EC) 852/2004 and specific requirements as set up in section VII and VIII of Annex III to Regulation (EC) 853/2004 an approval is given and a licence document issued. In case of non compliance a conditional approval may be given if only minor changes are needed otherwise the application is rejected. Before the licence is issued by MAST, the food business operator also has to comply with a number of environmental and other public requirements.

The mission team noted inconsistencies by MAST in the procedures to grant conditional approval to establishments. The mission team visited a dispatch centre for blue mussels (*Mytilus edulis*) approved by MAST. The certificate issued by MAST on 1/3/2010 reported as valid until 28/02/2022. This certificate had however a watermark across the page stating it was a conditional approval. Representatives of MAST informed the mission team that by a letter from MAST the establishment had been granted a conditional approval until 1/06/2010 but a letter was not found available on the spot. MAST carried out an inspection on 9/06/2010 and extended the former conditional approval to 1/09/2010. However no letter about this conditional approval was available. The mission team visited the dispatch centre which was a section of an industrial building. This was an open space in which the area of production was demarcated by a plastic film behind which were objects totally unrelated to the production apart from the storage of packaging material and a cupboard for detergents. The layout was not in line with general hygiene requirements, permitting adequate maintenance, cleaning and/or disinfection. A wall surface was absorbent and non washable. Hand washing basins were not suitably located.

In another establishment dispatching live ocean quahog (*Arctica islandica*) a temporary licence was issued in June 2009 for three months and renewed until the withdrawal of approval valid from 21/06/2010 was issued by a letter dated 3/06/2010. The dispatch centre appeared as approved without any harvesting licence issued for live ocean quahog (*Arctica islandica*) since 2009. The approval number was issued despite the absence of a relevant HACCP manual for live bivalve molluscs.

In two establishments visited by the mission team, the approval from MAST was issued despite the control body responsible for the official controls reported in writing that one of the activities concerned was not on-going anymore. MAST issued the approval still mentioning the dismissed activity.

Conclusions

Compliance with Article 31 (c) of Regulation (EC) No 882/2004 and Article 3 of Regulation (EC) No 854/2004 was not fully ensured since MAST approved establishments which did not comply with the relevant requirements.

5.5 General hygiene requirements for food business operators

Legal requirements

Article 3 of Regulation (EC) 852/2004 establishes that food business operators, other than those carrying out primary production and associated operations, must ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.

Article 4(2) of Regulation (EC) 852/2004 establishes that food business operators must comply with the general hygiene requirements laid down in Annex II of this Regulation and Article 4(3) requires food business operators to adopt (amongst others) the following specific hygiene measures: compliance with microbiological criteria for foodstuffs, sampling and analysis.

Article 5 of Regulation (EC) 852/2004 establishes that food business operators, other than those carrying out primary production and associated operations, must put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. The same Article laid down the above mentioned HACCP principles.

Findings

5.5.1 Hygiene requirements

The mission team observed in all establishments visited various non compliances of general hygiene requirements.

The mission team observed that in all the dispatch centres and processing establishments visited packaging and wrapping materials were stored under unhygienic conditions. The wrapping materials were found stored in a manner where they were exposed to contamination.

The mission team visited a dispatch centre for blue mussels (*Mytilus edulis*) which was a section of an industrial building and found the severe shortcomings already illustrated in Chapter 5.4 of this report. In another dispatch centre for blue mussels (*Mytilus edulis*) the mission team made several observations, some of them not found in a report made by the control body on a visit two days before:

- an ice machine was located in the processing area and the ice collected in a tub which was not protected from contamination. Shellfish packed in netting was found directly touching ice so produced;
- overhead structures not constructed or finished so as to prevent the accumulation of dirt and contamination;
- storage room for packaging and wrapping material had objects not used in current production and packaging and wrapping materials were stored under unhygienic conditions in two other rooms in the building where material not used in the dispatch centre was stored;
- the layout of the dispatch centre prevented the separation of clean and unclean areas;
- unidentified products were found in the cooling room for blue mussels (*Mytilus edulis*);
- insufficient drainage from the floor of the cooling room for blue mussels (*Mytilus edulis*) resulting in the accumulation of stagnant water, and
- the doors to the processing area were not pest proof.

Potable water used in the dispatch centre is originating from a well in the area which is under surveillance of the local authority. Results of a monitoring carried out by the food business operator were available. No audit monitoring analysis were available (see relevant findings concerning this issue in Chapter 5.8 of this report (Miscellaneous)).

5.5.2 Own check systems and HACCP

All inspected HACCP manuals in establishments showed lack of understanding and definition of prerequisites, hazards, definition of critical limits, corrective measures, own checks on final products, how to proceed on recall in case of non conformity etc. Shortcomings identified by the mission team and related to microbiological, marine biotoxins and chemical parameters they are described in Chapter 5.6 of this report (Specific hygienic rules for live bivalve molluscs).

In an establishment exporting live echinoderms (sea urchins-*Echinus esculentus*) the mission team observed the following shortcomings in the HACCP system and prerequisites:

- no HACCP team had been formed;
- the hazard analysis did not mention microbiological or chemical contaminants as a hazard;
- there were no specifications of critical limits;
- efficient and accurate record keeping was absent;
- there was no accurate documentation of the modification to the HACCP system.

In a dispatch centre for ocean quahog (*Artica islandica*) which was approved till 21 June 2010, clean sea water was filtered with a sand filter and radiated with an ultraviolet radiation unit. However according to a representative of MAST the intake for sea water was at the mouth of the harbour with the possibilities of pollution by harbour activity.

Conclusions

Compliance with Article 4(2) of Regulation (EC) 852/2004 could not be fully assured since the general hygiene requirements for dispatch centres and processing establishments were not always in line with the general hygiene requirements of Annex II to the Regulation (EC) 852/2004.

Compliance with Article 5 of the Regulation (EC) 852/2004 could not be fully assured since the requirements for own control systems based on the principles of HACCP were not in line with the requirements of the article.

5.6 Specific hygiene rules for live bivalve molluscs

Legal requirements

Article 3 of Regulation (EC) 853/2004 establishes that food business operators shall comply with the relevant provisions of Annex III to this Regulation.

Section VII of Annex III to Regulation (EC) No 853/2004 applies to live bivalve molluscs. With the exception of the provisions on purification, it also applies to live echinoderms, tunicates and marine gastropods.

Chapter 1 of Annex I to Regulation (EC) No 2073/2005 lays down the food safety microbiological criteria for live bivalve molluscs, including the applicable sampling plans and the number of sample units giving values over or between the established limits.

Findings

The mission team observed that in general very few controls were carried out on live bivalve molluscs by the food business operators.

The mission team visited an establishment processing live echinoderms (sea urchins-*Echinus esculentus*). The live products were harvested in the morning, processed within the next 24-36 hours at the establishment where they were chilled, packed in a 3kg pack and shipped by air freight. The harvesting season starts in September, reaches its peak in December and slowly decreases until April. The food business operator informed the mission team that, from his point of view, no risks of biotoxins were related to this product because it was harvested during the winter season. No control on microbiology or any other parameters was carried out by the food business operator during the production or at the final stage. The company had decided to delete the instructions available in the HACCP manual for taking own control samples for analyses of *Salmonella* and *E.coli*.

The mission team visited a dispatch centre for blue mussels (*Mytilus edulis*). The company also processes fishery products and the processing equipment was 17 years old but recently bought newer equipment. The manager informed the mission team that the equipment will be installed soon in another building. Harvesting and processing is done in one day. The one-day harvest was from 700 kg to 4000 kg. In the HACCP manual it was reported that samples from the production area should be taken once a year and tested for Salmonella, *E. coli* and heavy metals; samples from the dispatch centre of final products should as well have been taken once a year and tested for marine biotoxins. However, this sampling plan was not followed by the food business operator. Limits of the hazards listed in the HACCP manual (*E. coli*, Salmonella, heavy metals and marine biotoxins) were not reported in the manual. Furthermore, no sampling and analysis of the final product was ever performed by MAST.

The mission team visited an establishment processing live bivalve molluscs (ocean quahog-*Arctica islandica*) distributing to Europe several batches (around hundred according to the food business operator with a weight variable from 1 to 50 kg) for tasting the products. Samples have been sent to many places. However, no registration documents were available concerning the live bivalve molluscs harvested and kept alive in sea water (around 1 tons of live bivalve molluscs). No invoice or commercial documents were found. The representatives of MAST informed the mission team at the opening meeting that despite the harvesters or gatherers deliver to their own dispatch centre, they had not allowed any derogation from filling out the registration document accompanying each batch of live ocean quahog (*Arctica islandica*). Sampling for testing the level of cadmium was done in April 2010 revealing value of 1.23 mg/kg. No HACCP manual had been finalised for this production. The hazards identified were generic pollutants and biotoxins without any detailed parameters and their limits.

No marine biotoxin or microbiological analyses had been performed on the live clams that were stored in the company which were harvested in areas not classified nor monitored by MAST. No analysis were carried out on the batches of live ocean quahog (*Arctica islandica*) distributed as samples in 2009 and 2010. The manager of the company confirmed that he did not have any documents of this or other distributions. At the time of harvesting there was no harvesting licence issued, all harvesting areas closed and no analyses results related to the areas concerned were available.

Conclusions

Compliance with Article 3 of Regulation (EC) 853/2004 could not be ensured since food business operators did not comply with the relevant provisions of Annex III to this Regulation. In general very few own control samples and analyses were found carried out by the food business operators in order to ensure that live bivalve molluscs placed on the market for human consumption met the standards laid down in Chapter V of Section VII of Annex III to Regulation (EC) 853/2004, in particular relating to microbiological criteria and marine biotoxins.

The microbiological criteria analysed for in live bivalve molluscs were not in conformity with the requirements laid down in Chapter 1 of Annex I to Regulation (EC) No 2073/2005.

5.7 Laboratories

Legal requirements

Article 4(2)(c) of Regulation (EC) No 882/2004 requires competent authorities to have, or to have access to, adequate laboratory capacity. Article 11 of Regulation (EC) No 882/2004 establishes requirements for sampling and analysis. Article 12 of Regulation (EC) No 882/2004

requires the competent authority to designate laboratories that may carry out analysis of samples taken during official controls. It also lays down criteria for laboratories so designated.

Regulation (EC) No 1881/2006 lays down the maximum level for certain contaminants in foodstuffs.

Regulation (EC) No 333/2007 lays down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, and benzo(a)pyrene in foodstuffs.

Findings

In relation to official analyses concerning marine biotoxins in live bivalve molluscs, MAST sends samples to a European laboratory abroad; however no formal agreement exists and MAST has not formally designated this laboratory. Representatives of MAST informed the mission team that one of the criteria chosen to send samples to this laboratory was its accreditation, however MAST had not required any formal statement from this laboratory concerning the scope of accreditation. The mission team had the possibility to see some reports on the results (PSP toxins) from this laboratory and they were without an accreditation stamp. Methods used in this laboratory were not available for MAST at the time of the mission.

The mission team visited a private laboratory analysing phytoplankton till May 2010 as official samples for MAST. The laboratory is not accredited. The sea water samples were collected as part of the monitoring programme of one of the two production areas authorised for harvesting blue mussels (*Mytilus edulis*). The laboratory is now being sent samples in the context of the MAST's monitoring programme which they forward to the Marine Research Institute of Iceland but is also analysing sea water samples in the context of the own-checks carried out by the food business operator harvesting blue mussels (*Mytilus edulis*) from the above mentioned area. MAST is not carrying out any official sampling themselves. The food business operator is taking samples before harvesting both sea samples and blue mussels (*Mytilus edulis*) samples. At the final meeting a representative of MAST informed the mission team that the samples taken by the food business operator before and during harvesting are considered as official samples and paid for by MAST. Harvesting authorisations have been issued by MAST on the basis of the analyses carried out by this laboratory. However representatives of MAST informed the mission team that the laboratory is not designated. During the visit the mission team noted that the analysis of phytoplankton were carried out without any written working instructions or standard operating procedure.

Another private laboratory was visited by the mission team; this laboratory dealt only with microbiological analyses related to several food commodities, including live bivalve molluscs. The laboratory has been accredited since 2004. Regarding live bivalve molluscs, the scope of the accreditation includes *E. coli* and Salmonella using the ISO 7251:2005 and NMKL No 71, 5th Ed, 1999 methods, respectively. Around 3000 samples were analyzed in 2009 for *E. coli* and around 300-400 samples in 2009 for Salmonella, both of them mainly concerning fishery products (prawns).

Concerning live bivalve molluscs, the laboratory is not involved in monitoring activities. Shellfish samples are practically non existent. The last sample was received in January 2009. The mission team noticed that the last sample received of live bivalve molluscs was not accompanied with the proper form prepared by MAST and there was no request in the form of the analyses required. No formal agreement between MAST and the laboratory was available. The laboratory has not been designated by MAST.

Despite the methods were accredited, the mission team noticed a lack of traceability between the results report of a water sample from an approved dispatch centre collected in November 2009 (sample code, sampling date and analysis dates were not in agreement with the laboratory records).

Equipment was marked just with a single number but without any label indicating, for example the expiration date of calibration. Some amendments (scratches) were observed in the working sheets. The laboratory participated annually in several ring tests organized by a Swedish firm including both *E. coli* and Salmonella. In the case of *E. coli*, the mission team noted that in the ring test of January 2010 results were out of the acceptable values. The file with corrective measures was not available so the mission team could not verify actions taken.

The mission team visited the Marine Research Institute of Iceland; this is the official laboratory responsible for checking the quality of seawater with respect to optimising the production and the catch of fishery products as well as environmental parameters. One of its tasks is monitoring the phytoplankton present in the seawater. Regarding live bivalve molluscs algae monitoring, the Marine Research Institute of Iceland is dealing with a weekly monitoring of one of the two approved production areas for blue mussels (*Mytilus edulis*) (samples from the other approved area were sent to the first private laboratory described under this chapter).

From the reply to the pre-mission questionnaire the Authority was informed that this was the only laboratory involved in phytoplankton analysis of approved production areas; however before the mission started MAST informed the Authority that another private laboratory (the first one mentioned in this chapter) was also carrying out analysis on phytoplankton in the other classified production area.

The mission team observed absence of inter-laboratory tests between the two laboratories dealing with phytoplankton analysis. The mission team also pointed out that there was no sharing of knowledge of the methods used between these two laboratories involved in the above analysis.

There is not available any formal agreement between MAST and the laboratory and no formal designation from MAST exists.

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 (even though with the previous form prepared by the former competent authority before MAST). Results of analysis on phytoplankton are not issued using a formal assay report but sending an e-mail with only the figures of *Alexandrium*, *Dinophysis* and *Pseudonitzschia* counting but with lack of the following information: time/day of sampling, day of analysis, other species taken into account, analyst responsible for the result.

The fourth laboratory visited by the mission team, the Icelandic Food and Biotech Research and Development Institute (MATIS), dealt with microbiological and heavy metals analyses. This is an official laboratory belonging to the Government with a staff of 75 people.

The laboratory has been accredited since 2005. Regarding live bivalve molluscs, the scope of the accreditation includes *E. coli* and Salmonella using respectively the following methods: ISO/TS 16649-3, 1st Ed, 2005 and NMKL No 71, 5th Ed, 1999. Methods of analysis related to heavy metals are not accredited.

During 2009 around 22-23 samples of live bivalve molluscs have been analysed for *E. coli* and heavy metals.

Approximately half of the *E. coli* samples were also analyzed for Salmonella. Salmonella was never found to be positive in live bivalve molluscs samples.

There is not available any formal agreement between MAST and the laboratory. The laboratory has not been formally designated by MAST. The laboratory participated annually in several ring tests organized by a Swedish firm including both *E. coli* and Salmonella and also there was a ring test available for 2007 organized by the Community Reference Laboratory. In the case of Salmonella, the mission team noted that in one internal control on the 25 May 2009 with reference materials, results were not in compliance but no corrective action was taken by the laboratory.

Regarding the heavy metals section, even though the analyses are not accredited there was available a standard operating procedure but the limit of detection and the limit of quantification had not been established. Live bivalve mollusc samples for heavy metals analyses were collected by the food business operators and sent to this laboratory without any form accompanying them (at least no forms were found available for 2009). Consequently, analysis results of those samples did not specify the date of sampling and were not expressed in the same units and with the same number of significant figures as the maximum level. The laboratory participated twice a year in inter comparison tests organized in the context of the Quality Assurance of Information for Marine Environmental Monitoring In Europe. In the case of cadmium, the mission team noted that in one ring test (January – April 2009) results were not in compliance, but no corrective action was taken by the laboratory.

Benzo(a)pyrene was not found routinely monitored.

Conclusions

MAST did not designate laboratories to support the official control of live bivalve molluscs in accordance with Article 4(2)(c) and Article 12 of Regulation (EC) No 882/2004.

The methods of analysis used for heavy metals in the context of official controls were not in conformity with the requirements laid down in Article 11 of Regulation (EC) No 882/2004.

Benzo(a)pyrene was not found to be routinely monitored, as required in Section 6, point 6.1.6. of the Annex to Regulation (EC) No 1881/2006.

Concerning heavy metals, the absence of limit of detection and of limit of quantification was not in conformity with the requirements laid down at point C.3.3.1 of the Annex to Commission Regulation (EC) No 333/2007, the absence of a form accompanying samples was not in conformity with the requirements laid down at point B.1.8 of the Annex to the above mentioned Regulation and the results of analysis were not in compliance with point D.1 of the Annex to the same Regulation.

5.8 Miscellaneous

The mission team visited some establishments processing bivalve molluscs (ocean quahog-*Artica islandica*), marine gastropods (whelk-*Buccinum undatum*) and tunicates (sea cucumbers-*Holothuroidea*). All these products are covered by the requirements laid down for fishery products as explained in the following chapter.

Legal requirements

Article 7 of Directive 98/83/EC on the quality of water intended for human consumption (including water used in food producing undertakings as clarified in Article 2 of Directive 98/83/EC) states 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 appropriate monitoring programmes shall be established by the competent authority. Those monitoring programmes must meet the minimum requirements set out in Annex II (check monitoring and audit monitoring).

Article 4(2) of Regulation (EC) 852/2004 establishes that food business operators must comply with the general hygiene requirements laid down in Annex II of this Regulation.

Article 5 of Regulation (EC) 852/2004 establishes that food business operators, other than those carrying out primary production and associated operations, must put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. The same Article laid down the above mentioned HACCP principles.

Part A of Chapter IV of Section VIII (Fishery products) of Annex III to Regulation (EC) No 853/2004 lays down the requirements for cooking crustaceans and molluscs.

Part E.2 of Chapter V (Toxins harmful to human health) of Section VIII (Fishery products) of Annex III to Regulation (EC) No 853/2004 lays down health standards for fishery products.

Chapter II of Annex III to Regulation (EC) No 854/2004 lays down the official controls of fishery products including microbiological checks (part E) and checks in relation to poisonous fishery products (part G.3). In relation to part E the controls have to be performed in accordance with the relevant rules and criteria laid down in Community legislation. Parameters for microbiological checks are laid down in Chapter 1 of Annex I to Regulation (EC) No 2073/2005.

Findings

The mission team visited an establishment processing ocean quahog- (*Arctica islandica*) and producing both meat and broth. The production was stopped in 2008. However the mission team found in the cold store of the establishment an amount of roughly 40 tons of broth obtained by boiling the clams and freezing afterwards. The broth consisted of about 42% dry material and the rest was water. However, the absence of audit monitoring (chemical parameters) on potable water used in this establishment (and in the other establishment processing blue mussels (*Mytilus edulis*) mentioned at Chapter 5.5.1 of this report) was noted by the mission team. According to the director of the local public health authority no audit monitoring was performed in this establishment. The reason was that, according to the Icelandic legislation Act no 531/2001 on potable water, the frequency of audit monitoring is taken by the local board of public health authority after consultation with MAST. MAST representatives told on the spot the mission team that they rely on the controls carried out by the local public health authority. The only parameters analysed were those for check monitoring (*E. coli*, coliform bacteria etc.).

During the inspection of the premises the following was observed by the mission team: several barrels containing broth with a date of production older than two years, several unlabelled tanks containing what the manager claimed to be broth. In the cold store the mission team found unidentified and exposed fishery products. Some of the exposed products were touching the wooden pallet it was stored on. In the processing area high pressure cleaning was going on near to where frozen fillets were being wrapped and packed with the evidence of cross contamination.

In the storage room for packaging materials the mission team observed exposed wrapping material and packaging material stored under unhygienic conditions.

No results of analysis for official controls or own-checks were available for the raw materials (live ocean quahog- (*Arctica islandica*)). In particular the absence of controls on biotoxins.

The last sanitary survey carried out by the competent authority in the area where ocean quahog was harvested was in 2001.

The HACCP plan for processed products (cooked clams and broth) did not include any plans for sampling. The intended shelf life of the frozen products was not decided or defined. The hazards identified were generic pollutants and biotoxins without any detailed parameters and their limits.

The manager responsible for the company and also for the preparation and updating of the HACCP manual did not show understanding of the difference between a hazard and a critical control point to the mission team.

The mission team visited another establishment processing tunicates (sea cucumbers-*Holothuroidea*) The sea cucumbers were both frozen and dried. The processing did not take place during June and July because at this period the sea cucumber is spawning. The company had the licence to fish sea cucumbers (*Holothuroidea*) from the Directorate of Fisheries. Iceland is divided into three zones for catching sea cucumber (*Holothuroidea*).

Products no longer produced were still in the HACCP system and changes were not incorporated into the documentation and record keeping system in order to ensure that accurate up to date information was available. All the production is exported to third countries.

The representative of the establishment informed the mission team that the establishment is constantly developing new methods and processes and they can not keep up with the updating of the HACCP system. This was confirmed by the mission team having a look at the map of the layout of the establishment in which the new process activities were not detailed.

The rapid cooling using potable water following cooking was not mentioned in the HACCP system. The manager of the establishment explained to the mission team that, in conformity with the USA Food and Drugs Administration guidance available to him (Fish and fishery products, hazards and control guidance) there is no risk concerning marine biotoxins for processed tunicates. Contaminants are the only hazards mentioned in the guidance for sea cucumber (*Holothuroidea*). However no results of controls on final products from MAST or the food business operator were found available concerning contaminants. The last results of analysis was dated June 2003 and the only parameter tested was total plate count of dried product.

The mission team visited an establishment processing marine gastropods (whelk-*Buccinum undatum*). The harvesting season for the whelk is from June to December. The company processed 300-600 tonnes of whelk for two kinds of final products: raw and cooked, individually quick frozen in shell. Customers were mainly based in the EEA for raw individually quick frozen in shell products. Cooked individually quick frozen in shell products were exclusively exported to third countries.

In 2003 some analyses for microbiological parameters, marine biotoxins and contaminants were carried out by the competent authorities. The opinion of the competent authority at that time was that monitoring of marine biotoxins was not necessary because gastropods are not filter feeders

and the representatives of MAST stated that this opinion should be still available in their database.

MAST did not take any sample of the final products in the last years.

There was no mention in the HACCP plan about product recall. Traceability to the gathering zone was not ensured but the food business operator explained to the mission team that they are working on it. The HACCP manual was found without dates and no update or verification has been done. Rapid cooling after boiling with potable water was not mentioned in the HACCP manual.

Conclusions

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

Compliance with Article 4(2) of Regulation (EC) 852/2004 could not be fully assured since the general hygiene requirements for processing establishments were not always in line with the general hygiene requirements of Annex II to the Regulation (EC) 852/2004.

Compliance with Article 5 of the Regulation (EC) 852/2004 could not be fully assured since the requirements for own control systems based on the principles of HACCP were not in line with the requirements of the article.

All the food business operators cooking molluscs did not take into account in their HACCP plan the requirements laid down in Part A of Chapter IV of Section VIII (Fishery products) of Annex III to Regulation (EC) No 853/2004.

Almost all the food business operators did not comply with the health standards for fishery products 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.

The absence of official controls of fishery products is not in conformity with requirements laid down in Chapter II of Annex III to Regulation (EC) No 854/2004, in particular the absence of official controls in relation to poisonous fishery products and on the microbiological checks. The microbiological parameters were not in conformity with the requirements laid down in Chapter 1 of Annex I to Regulation (EC) No 2073/2005.

6 Overall conclusion

The production and the placing on the market of live bivalve molluscs harvested in Iceland was not in conformity with several of the requirements listed in Regulations (EC) 852/2004, 853/2004, 854/2004 and 882/2004.

In the light of the serious weaknesses identified by the mission team in the official controls implemented by the Icelandic competent authority and the severe shortcomings at food business operators' level, there is a significant risk to the health of the final consumer, as a result of being exposed to biotoxins, microbiological and chemical contaminants.

7 Final meeting

A final meeting was held on 1 July 2010 at MAST head office in Reykjavik with representatives of 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 and recommendations could be included in the report.

The representatives of MAST and the Ministry did not have any objections to the observations made and the preliminary conclusions presented. MAST provided the mission team with a written note mentioning the corrective actions to be implemented in two establishments visited and a survey to be carried out in relation to the water supplied to food business operators situated in small communities with less than 500 inhabitants.

At the meeting the mission team also explained that, after consultation with the hierarchy in Brussels and considering the serious shortcomings identified, an urgent report could be issued within the next ten working days and that a follow-up mission would be considered next year 2011. The mission team also explained that Iceland must give its comments to the report as quickly as possible and at least within ten days after receiving the draft report. The content of the report and the procedures for sending the report are the same as usual except for the shortened timeframe for issuing the report. MAST agreed on the urgent procedure and asked the mission team to be informed as soon as possible on it because the summer holidays could influence their capacity to reply within the next ten following days.

8 Recommendations

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

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.
8	The competent authorities should ensure that establishments are only approved if they comply with the relevant requirements as laid down in Article 31(c) of Regulation (EC) No 882/2004 and Article 3 of Regulation (EC) No 854/2004.
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.
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.
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.
12	The competent authorities should ensure that food safety criteria as listed in Chapter 1 of Annex I to Regulation 2073/2005 concerning live bivalve molluscs are complied with during official controls and own checks.
13	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>
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.
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.
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.
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.
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.
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.
20	The competent authorities should ensure that food safety criteria as listed in Chapter 1 of Annex I to Regulation 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

ASP	Amnesic Shellfish Poison
Authority	EFTA Surveillance Authority
DSP	Diarrhetic Shellfish Poison
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>
PSP	Paralytic Shellfish Poison

Annex 2 - Relevant legislation

The following legislation has also to be taken into account in the context of this mission:

- 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 by the sectoral adaptations referred to in Annex XX to that 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.
- 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.
- 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 by the sectoral adaptations referred to in Annex II to that 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 from MAST to the draft report

The Icelandic Food and Veterinary Authority's response to the draft urgent report of the EFTA Surveillance Authority's mission to Iceland
June 22 to July 1 2010
Subject: Live Bivalve Molluscs
Case No 67735

Reference is made to the draft report from the EFTA Surveillance Authority (ESA) of 9 July 2010 describing the outcome of a mission in Iceland from 22 June to 1 July 2010 concerning live bivalve molluscs (Case No 67735, Event No 560078).

This reply to the draft report contains general comments and corrections to the factual contents of the draft report, the findings and the recommendations. It also contains a table of corrective actions and comments regarding each recommendation and includes attachments where this is relevant. If further information is needed please do not hesitate to contact the responsible officer at MAST.

In the summary of the report it is stated that as a result of severe shortcomings noted during the mission "there is a significant risk to the health of the final consumer as a result of being exposed to biotoxins, microbiological and chemical contaminant". The Icelandic Food and Veterinary Authority (MAST) is concerned over this serious conclusion or statement, which in its opinion is not supported by any data on toxins or other contaminants in live bivalve molluscs or any reported cases of foodborne diseases.

Furthermore, it should be well known to ESA that production areas in Iceland approved for the harvesting of live bivalve molluscs are considered as areas of low contamination, classified as being of class A, from which live bivalve molluscs are collected for human consumption. However, MAST is fully aware of shortcomings in official control and in-house control observed during the mission and is working on corrective actions, but these shortcomings are not of the nature that warrant statements on significant risk to human health. Such statements are beyond what can be supported by observations during the mission, results from official control and analytical results from monitoring programmes in Iceland, as referred to in our reply to point 7 of the recommendations of the draft report.

As a result of these facts and the following comments to the draft report, it is recommended that ESA should revise its draft report and send a new draft for comments by the Icelandic authorities.

Most recommendations in the draft report are of a general nature and concern the application of the EEA legislation on official control and hygiene that came into force in Iceland as of 1 March 2010. Even though the legislation is directly applicable for the official control and hygiene for fish and fish products, including bivalve molluscs, the competent authority in Iceland is still working on the application of this legislation and it will take some time before all relevant measures have been implemented. In this respect it should also be mentioned that from the adoption and publication of this Community legislation the Member States of the European Union received a transitional period of about 18 months prior to its date of application.

The implementation of the mentioned legislation has been notified to ESA and MAST has given additional information in the pre-mission questionnaire and to the mission team at the opening and final meeting (see also the attachment to our reply to recommendation 3 of the draft report). Therefore, MAST is also concerned about the fact that the mission team is not aware of that

Article 5 of Regulation (EC) No 882/2004 will not apply in Iceland until 1 March 2011. As a consequence, several of the findings and conclusions under chapter 5.2.2 and recommendations related to this chapter of the draft report are incorrect or not relevant and must be deleted. On behalf of MAST some information in the pre-mission questionnaire must also be corrected, since MAST has not delegated any tasks to private control bodies. These bodies are involved in official control based on legal provisions which will be in force until 1 March 2011. Furthermore, it is requested that the text concerning the “integration“ of control bodies into the structure of MAST must be deleted since the Authority has no such plans. However, MAST could take over the control tasks currently carried out by control bodies, but this is both a political and practical issue that has not been decided and should consequently not be relevant as a part of the draft report.

In chapter 5.2.2 and in fact also other chapters of the draft report ESA refers to information received from staff members of MAST and control bodies or their views. Some of this information was received during informal talks between members of the mission team and staff members of the mentioned bodies. To report such informations has not been the practice in prior missions, is not acceptable and will only result in reduced trust between staff members of Icelandic authorities and ESA staff in future missions. In addition, the information cited in the report is in some instances not relevant for the conclusions or finding or even incorrect when taking note of the fact that Article 5(3) of Regulation (EC) No 882/2004 regarding audits of control bodies is not in force in Iceland. The most prudent solution to this would be to delete all direct references to opinions or views of the mentioned staff members or to delete or totally revise chapter 5.2.2 of the draft report, when also taking note of the prior comments on the delegation of tasks to control bodies and information provided at the final meeting regarding the tasks of control bodies.

In addition to the comments above MAST will propose several corrections regarding the factual content of the draft report, which also relate to the conclusions and recommendations made by ESA and the urgency decided by the Authority when issuing the draft report. The urgency decided by ESA must also be questioned since MAST informed the mission team at the final meeting of immediate measures that were decided and taken by the competent authority. Ocean quahog harvested without licence in 2010 and observed at the establishment of a producer was removed from the premises to the production area and the producer was delisted. Removal of the product has been confirmed by the operator as can be seen in attachments to recommendation 7 in the enclosed table. It should also be noted that regular monitoring in the production areas ended in 2009 since the producer sold the ship and closed the production facilities in November 2008.

In the draft report it is stated that the producer had placed several batches of ocean quahog (around hundred) on the market during the last two years when the production areas were not classified and no harvesting licences were issued. In this paragraph of the report it is necessary to give additional information and make corrections. Firstly, the last biotoxin analysis was made on quahog samples from xxx⁶ dated 18 May 2009 and included all toxins (ASP, PSP, DSP and AZP). Results can be seen as attachments 4-6 under point 7 of the table of corrective measures. Consequently, the statement in the draft report that „*only Pectinotoxins were analysed.*“ is incorrect and must be deleted. This sampling and analysis was agreed by MAST because the producer was planning a product trial of live ocean quahog. All shipments should consequently have been marked as ”Samples“ since this was not an operational production of live quahog. The live quahog was stored in clean (potable) seawater within the premises of the company and was sent to possible retailers/distributors in small amounts. However, MAST is fully aware of that

⁶ Name deleted by the Authority

samples distributed to the market should fulfil legal requirements and should not constitute a risk to human health. Hence, the toxin analysis were conducted in order to ensure the quality of the product.

With respect to heavy metals it must be corrected that the last official control of heavy metals in ocean quahog from harvesting areas was made in 2007 (see an attachment to the reply to recommendation 7) and not in 2001, as stated in the draft report. Furthermore, the sample mentioned in the report from April 2010 was not from a production area, but rather from live quahog that had been stored in tanks for two years. This sample was analysed by request from MAST in order to find out whether the quahog stored for a long time in tanks still fulfilled the requirements for heavy metals. Additionally, because some changes had been made on seawater supply that had not been formally approved by MAST. When the results showed that the requirements for heavy metals were not fulfilled the producer immediately disposed of all live quahog stored in the tanks.

With respect to echinoderms, tunicates and gastropods and the statement that live chilled echinoderms are being placed on the EEA market without classification of production areas the competent authority would like to point out that the harvesting areas for these species are not classified since they are not filter feeding animals. Secondly, MAST would like to refer to current practice in this respect in other EEA States and to recent amendments made regarding requirements for non filter feeding animals harvested outside classified areas by Commission Regulation (EU) No 558/2010 amending Annex III to Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin. Finally, according to our risk assessment the main risk involved would be chemical contamination, as further stated and discussed in our comments to recommendation 7 of the draft report

Considering statements made on analysis and risk assessment on page 14 of the report (Blue mussels) the following has to be corrected. The comment starting with “*Representatives of MAST.....*“ is incorrect since decisions on what is sampled and analysed are based on risk assessment and scientific advice. This sentence should therefore be amended or removed from the report.

Considering the comments made by ESA on risk assessment on page 14 of the draft report it should be added for correction that the current risk assessment was established with scientific advice from the Irish Marine Institute (IMI) by establishing the toxic profile for mussels in Icelandic waters. This was based on a scientific project with the participation of MAST, MRI (Hafro) and the IMI. The conclusion was that DSP toxin in Icelandic mussels during Dinophysis outbreaks in 2007-2009 was Okadaic acid (OA), while dinophysitoxins and pectinotoxins were not found in the samples. Consequently, our DSP - toxic profile so far includes Okadaic acid rather than pectinotoxins and dinophysitoxins. PSP, ASP and AZP are in our toxic profile but not yessotoxins, since there are no evidence for the presence of that toxin or the corresponding algae, *Protoceriatum reticulatum* and *Ligulodinium polyedrum*, in Icelandic waters. Furthermore, in routine analysis for DSP in biological assays, yessotoxins and pectinotoxins should be detected but not quantifiable. So far these toxins have not been observed in the mussel samples from Iceland, only OA.

Enclosed is a table of corrective actions describing our actions and showing comments for each of the recommendations of the draft report, including relevant attachments. However, MAST would like to repeat that in its opinion this draft report should be revised and the urgency and risk related statements reconsidered based on the information received during the mission, at the final meeting and in this reply to the draft report.

Annex 4 - Corrective action taken and planned by MAST

No	Recommendation/Subject	Action	Time aspect	Enclosures
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.	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.	Ongoing	
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.	Notice has been taken of this recommendation and taken care of by the CA.	Done	
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.	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 CA 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.	The relevant legislation will apply from 1 March 2011	Attachment 1 - Official tasks of IBs
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.	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. Certain training courses and programmes have been held. See point 3.5 c) in the PMQ for the mission. A training programme will be designed for 2011 which will take notice of article 6 of	December 2010	

		Regulation (EC) No 882/2004. The aim is to cover the items listed in Ch. I of Annex II of Regulation 882/2004.		
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.	MAST already has a system in place for follow-up inspections in cases of serious deficiencies or when the number of minor deficiencies exceeds a defined limit. MAST however, takes notice of the recommendation and all measures will be taken to analyse what has to be improved and how it will best be done.	Latest March 2011	
6	The competent authorities should ensure that the operational contingency plan for crisis management is reviewed as required in Article 13 of Regulation (EC) 882/2004.	The CP will be reviewed in the coming months in light of requirements of Article 13 of Regulation (EC) No 882/2004.	November 2011	
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	<p>The control programme for production and placing on the market of live BM 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.⁷</p> <p>MAST is discussing the methods used to analyse toxins with the IMI and will eventually make some changes on the methods.</p> <p>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.</p> <p>The reports are available on Matis website.</p>	1.1.2011	<p>Attachment 2 - Draft - ISMP</p> <p>Attachment 3 - Heavy metals analysis 2007</p> <p>Attachments 4-6 Toxins</p> <p>http://www.matis.is/media/ma</p>

⁷ On the 30 July 2010 MAST informed the Authority in an email that *“Iceland is considering to decide that from now on only the mouse bioassay (MBA) will be used for samples in order to meet the requirements of the legislation. Two separate MBA tests will then be carried out, one for DSP toxins and one for YTX toxins, as the extractions are slightly different. If both MBA tests are negative (DSP and YTX) then this would cover analysis for both groups of toxins and AZAs also.”*

		<p>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.</p> <p>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.</p> <p>Live Ocean quahog has been released to the ocean again. This was a decision taken by the FBO. The confirmation is in attachment.</p> <p>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.</p>		<p>tis/utgafa/16-10-Voktun-2008.pdf</p> <p>http://www.matis.is/media/matis/utgafa/24-09%20AMSUM%202008-090820.pdf</p> <p>Attachment X - confirmation</p>
8	The competent authorities should ensure that establishments are only approved if they comply with the relevant requirements as laid down in Article 31(c) of Regulation (EC) No 882/2004 and Article 3 of Regulation (EC) No 854/2004.	<p>MAST has already taken steps towards improvements of the procedure for approving establishments. The conditions for approval will be the fulfilment of the general hygiene requirements laid down in 852/2004 and in Annex II of the same Regulation and the relevant specific requirements laid down in 853/2004 in Annex III section VII and Annex VIII.</p> <p>MAST will use the possibility of conditional approval in order to be able to verify that the HACCP system is implemented as planned and to verify that there is an understanding of HACCP before the issue of final approval. MAST's goal will be to issue final approval when the establishments have been operating for 3 months. However, a relatively large number of establishments operate only part of the year and on some occasions less than 3 months.</p> <p>The procedure for approval of establishments will be revised. As soon as it has been issued it will be audited and a plan for regular audits will be made.</p>	1.1.2011	
9	The competent authorities should ensure that food	A number of companies and private persons offer HACCP seminars and assistance in preparing quality manuals including	1.1.2011	Attachment 7- Letter to IB

	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.	the HACCP analysis and HACCP plan to FBOs. In cooperation with MAST the courses and the course material has been revised. MAST believes that gradually this will improve the HACCP knowledge in the industry. 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.		
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.	<p>A letter has been sent to one of the companies producing LBM where some remarks regarding general hygiene requirements were addressed. The company is requested to send in a plan with corrective measures.</p> <p>MAST will inspect the LBM plants ASAP in order to verify if corrective actions have been taken. An inspector from the IB will be on the team.</p> <p>A letter has been sent to inspections bodies asking them to draw a special attention to the storage of packaging materials and to cold stores in all fish processing plants and dispatch centres</p> <p>MAST plans to start a campaign in the autumn of 2010 to emphasize the importance of good practices in handling and storage of packaging materials. The campaign will be followed up by inspections by the IBs with a special focus on packaging materials.</p>	<p>Done</p> <p>August 2010</p> <p>Done</p> <p>End of 2010</p>	<p>Attachment 8 - Letter Producer</p> <p>Attachment 9 – Letter IB</p>
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.	<p>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. Three examples of letters are attached.</p> <p>A copy of this letter was sent to the IBs asking them to follow up that the sampling is done according to the sampling plans.</p> <p>MAST will set up a sampling plan for final products to verify</p>	<p>Done</p> <p>Done</p> <p>1.1.2011</p>	Attachment 10 – Letters producers

		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.		
12	The competent authorities should ensure that food safety criteria as listed in Chapter 1 of Annex I to Regulation 2073/2005 concerning live bivalve molluscs are complied with during official controls and own checks.	See point 11 above.		
13	<p>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.</p> <p>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.</p> <p>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.</p> <p>The competent authority should ensure that with relation to heavy metals, the requirements</p>	<p>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.</p> <p>Work has also started regarding agreements with laboratories in official control.</p> <p>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.</p> <p>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. The letter is attached.</p>	<p>Ongoing – to be completed end of year 2010</p> <p>1.1.2011</p> <p>Revision of sampling procedures 1.11.2010</p>	<p>Attachment 11 – Letters laboratories</p> <p>Attachment 12 – letter lab 333_2007</p>

	laid down in the Annex to Commission Regulation (EC) No 333/2007 are fulfilled.			
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.	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 xxx ⁸ was sent to ESA on July 8, 2010.	1.1.2011 Done	
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.	See point 9 above.		
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.	See point 10 above.		
17	The competent authorities	Cooling should be incorporated as a step in a flow chart and	15.8.2010	

⁸ Name deleted by the Authority

	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.	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.		
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.	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 biotoxins so there should be no risk of marine biotoxins in the broth. The results are available in an attachment.		Attachment 13a results PSP/DSP Attachment 13b Test report Attachment 13c Marine biotoxin
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.	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. Letter attached. 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.	1.1.2011	Attachment 14 – Letter producer
20	The competent authorities should ensure that food safety criteria as listed in Chapter 1 of Annex I to Regulation 2073/2005 concerning cooked mollusc shellfish is complied with during official controls and own checks.	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 As mentioned under recommendation 11-12 MAST will set up a sampling plan before the end of this year.		See point 19