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Final report

EFTA Surveillance Authority's mission to

Iceland

from 11 to 20 March 2019

in order to evaluate animal health controls in relation to aquaculture animals and official controls of live bivalve molluscs

Information from Iceland on the corrective actions already taken and planned are included in Annex 5 and 6 to the report.

Executive Summary

This report describes the outcome of a mission carried out by the EFTA Surveillance Authority in Iceland from 11 to 20 March 2019.

The objective of the mission was to verify that official controls relating to diseases affecting aquaculture animals and production and placing on the market of live bivalve molluscs were carried out in compliance with the European Economic Area (EEA) legislation.

The mission team found that the official control system put in place by the competent authority generally ensures that the requirements of Directive 2006/88/EC are fulfilled in the area of fish health and that surveillance programmes regarding farmed fish provide sufficient guarantees that a disease would be detected. However, this is currently not the case for other aquaculture animals. A national reference laboratory for diseases for fish has been designated but not all methods of analysis have been accredited.

The mission team found that official controls related to live bivalve molluscs are weak and monitoring and sampling to detect marine biotoxins, microbiological risks and presence of heavy metals is not performed as required by EEA legislation. In addition, inadequate and incorrect sampling for monitoring of phytoplankton reduces the credibility of all phytoplankton results. Therefore, at the time of the mission it could not be guaranteed that products placed on the market were safe for human consumption.

A recommendation regarding slaughter of diseased fish from the EFTA Surveillance Authority's mission regarding the application of EEA legislation related to aquatic animal health in 2013 has been partly addressed. However, there are currently no facilities equipped or authorised for slaughtering fish for disease control in Iceland and it is not clear from the contingency plan where and how disposal of carcasses will be undertaken in case of disease outbreak.

Iceland performs a risk assessment on a case-by-case basis regarding import from third countries and introduction from other EEA of live aquaculture animals. The mission team noted that this approach does not ensure compliance with EEA legislation. Furthermore, for trade of aquatic animals, Iceland applies control measures for diseases other than those listed in Directive 2006/88/EC without the necessary approval for application of such national measures having been obtained.

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 11 to 20 March 2019. The mission team comprised three inspectors from the EFTA Surveillance Authority (the Authority) and a national expert.

A pre-mission questionnaire was sent by the Authority to the Ministry of Industries and Innovation on 11 January 2019. A reply ('the pre-mission document') was provided on 22 February 2019.

The opening meeting was held with representatives of both the Icelandic Food and Veterinary Authority ('MAST') and Ministry of Industries and Innovation on 11 March 2019 at MAST's office in Hafnarfjörður. At the meeting, the mission team confirmed the objectives and the itinerary of the mission and the Icelandic representatives gave additional information to that provided in the pre-mission document.

Throughout the mission, a representative of MAST accompanied the mission team.

A final meeting was held at MAST's headquarters in Selfoss on 20 March 2019, during which the mission team presented its main findings and preliminary conclusions from the mission.

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

2 Scope and Objective of the mission

The main scope of the mission was to assess the application by the Icelandic competent authority of the following European Economic Area (EEA) Acts, as amended and adapted to the Agreement on the European Economic Area ('EEA Agreement') by the sectoral adaptations referred to in Annex I to that Agreement, and related EEA legislation:

a) *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, as corrected, as amended and adapted;

b) *Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals*, as corrected and amended;

c) *Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin;*

d) *Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.*

The main objective of the mission was to evaluate the official control system in place for the control of diseases affecting aquaculture animals, official controls regarding production and placing on the market of live bivalve molluscs ('LBMs') and laboratories involved in the monitoring and analyses of samples taken during official controls related to the scope of this mission.

The assessment was carried out based on, and related to, the EEA legislation referred to in Annex 2 to this report. The assessment was further based on the pre-mission document.

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

The meetings with the competent authorities and the visits to laboratories, to aquaculture production business operators[1] ('ABOs') to verify compliance with animal health requirements and to food business operators[2] ('FBOs') to verify compliance with public health requirements during the mission are listed in Table 1.

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

	Number	**Comments**
Competent authorities	3	An initial meeting and a final meeting between the mission team and MAST in Hafnarfjörður and Selfoss. An additional meeting with the MAST personnel responsible for official controls on LBMs was held to seek further clarification on the system of official controls in this area.
Laboratories	3	The National Reference Laboratory for diseases of aquaculture animals (Keldur). The National Reference Laboratory for LBMs and where analysis for marine toxins, microbiology and heavy metals are performed, the Icelandic Food and Biotech Research and Development Institute (Matís). Laboratory designated for analysis of phytoplankton in sea water, Hafrannsóknastofnun (Hafro).
LBM operators	1	One FBO producing and dispatching blue mussels (*Mytilus edulis*)
Aquaculture production businesses	5	A selection of ABOs operators
Fish slaughterhouses	1	Establishment slaughtering salmon.
Animal by-products plants	1	Establishment producing pet food and feed for fur animals.
Transporter of fish	2	One well boat and one truck transporter.

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;

[1] as defined in Article 3.1(d) of Directive 2006/88/EC
[2] as defined in Article 3.3 of Regulation (EC) No 178/2002

b) Article 1(e) of Protocol 1 to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice (Surveillance and Court Agreement);

c) *Commission* Decision *98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States*, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

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*, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

e) Article 58 of Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals.

Legislation relevant to this mission is listed in Annex 2.

4 Background - Previous missions

4.1 Previous missions

The Authority carried out a mission on the application of EEA legislation related to aquatic animal health in Iceland from 11 to 20 March 2013 ('mission in 2013'). The mission team found that the majority of the EEA legislation concerning aquaculture animal health had been implemented in national law. Nevertheless, some delays in implementation were noted. MAST, the responsible competent authority for official controls, was clearly designated and legal powers were in place to carry out official controls and to enforce the legislation. The National Reference Laboratory (NRL) for diseases for fish, molluscs and crustaceans had been designated in February 2013. The methods used for detecting fish diseases were accredited in 2011. However, it was noted that the methods used for detection of mollusc diseases had not yet been accredited. The authorisation process of aquaculture production businesses had not yet been initiated by the competent authorities. A system for notification of the presence of diseases was in place and a contingency plan for fish diseases had been established. However, there were no facilities equipped or authorised for slaughtering fish for disease control at the time of the mission.

The Authority carried out two missions related to production and placing on the market of LBMs. The first mission was carried out from 22 June to 1 July 2010 and a second follow-up mission from 23 to 27 May 2011. The first mission in 2010 concluded that the production and the placing on the market of LBMs harvested in Iceland was not in conformity with several EEA legal requirements and that, in the light of the serious weaknesses identified by the mission team in the official controls, this constituted a significant risk to the health of the final consumer. The follow-up mission in 2011 concluded that the competent authority had taken into consideration the recommendations made by the Authority after the mission in 2010 and implemented appropriate corrective actions. Official controls and food business operator procedures were in general in conformity with the requirements of the legislation and LBMs produced in Iceland generally fulfilled the legal requirements for their harvesting and placing on the market.

However, there was still a need for improvement in some areas, including official sampling of LBMs and designation of laboratories for official controls of LBMs.

Final reports from these earlier missions can be found on the Authority's website.

4.2 Information on production

The aquaculture industry in Iceland is currently dominated by production of salmon, arctic char and rainbow trout for food purposes. There is less production of marine species such as cod, halibut and turbot compared to that seen during the mission in 2013. The production of blue mussels, although still small scale, has increased. Production data for 2017 and 2018 is summarised in Annex 3.

5 Findings and conclusions

5.1 Legislative and implementing measures

Legal requirements

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

Findings

1. According to information provided by Iceland in its reply to the Authority's pre-mission document, the relevant EEA legislation regarding aquatic animal health and production and the placing on the market of LBMs is implemented in Iceland.
2. During the mission, the competent authority confirmed that Commission Implementing Decision (EU) 2015/1554 of 11 September 2015 laying down rules for the application of Directive 2006/88/EC as regards requirements for surveillance and diagnostic methods has not been implemented into Icelandic law, contrary to Article 7 of the EEA Agreement.
3. IS Regulation No. 1254/2008, implementing Directive 2006/88/EC, recommends a lower inspection frequency than that laid down in Part B of Annex III to the Directive for zones or compartments not known to be infected but not subject to surveillance programme for achieving disease-free status, i.e. health status category III.
4. Iceland adopted IS Regulation No. 300/2018 laying down requirements for disinfection of all effluent water from slaughterhouses and from well-boats slaughtering farmed fish in the vicinity of sea cage farms. All new slaughter facilities must fulfil these requirements. For existing facilities, only those located close to sea cage farms are required to treat effluent water and must comply with the requirements by 30 September 2019.
5. Iceland adopted IS Regulation No. 1170/2015 establishing criteria for authorisation of ABOs. The authorisation of ABOs farming aquatic animals other than fish is not covered by IS Regulation No. 1170/2015.

Conclusions

6. The majority of relevant EEA requirements in the field of animal health in aquaculture and in the production and the placing on the market of LBMs have been implemented. However, Commission Implementing Decision (EU) 2015/1554 has not been incorporated into the Icelandic legal order, contrary to Article 7 of the EEA Agreement. This reduces the competent authority's ability to fully implement disease control measures.

5.2 Competent authorities

5.2.1 Designation of competent authorities and organisation of official controls

Legal requirements

Article 54 of Directive 2006/88/EC

Article 4(1) of Regulation (EC) No 882/2004

Findings

7. The Icelandic Food and Veterinary Authority ('MAST') is the competent authority in charge of official controls of animal health in aquaculture and official controls in LBMs. A detailed description of the distribution of competencies and tasks between the different competent authorities and other services involved in related official controls and monitoring is provided in chapters 2.1 and 2.2 in the Country Profile for Iceland, part 1[3].

8. Within MAST, the main responsibility related to health of aquaculture animals lies with the office of animal health and welfare. The main responsibility for monitoring of LBMs lies with the office of consumer protection.

9. The Icelandic Act No 71/2008 on Aquaculture animals was amended in 2014. This designated MAST as the competent authority to issue operation licences for aquaculture establishments, transferring this competence from the Icelandic Directorate of Fisheries ('DoF') from 1 January 2015.

10. In their reply to the pre-mission document, MAST stated that the local competent authorities ('LCAs') are responsible for controls of LBMs at retail level, for example, in restaurants and shops.

11. A Fish Disease Committee ('FDC') advises MAST in case of an outbreak of fish diseases and on importing fish, other live animals and equipment (such as means of transport) for aquaculture purposes. The chairman of the FDC is the Chief Veterinary Officer and the assistant chairman is the Veterinary Officer for Fish Diseases. Other representatives are members from the NRL Keldur, the Institute of Fresh Water Fisheries, the Directorate of Fisheries and the Marine Research Institute. The FDC also deals with all applications regarding import and introduction of live fish and eggs/gametes. The final decision of MAST on imports and introductions is based on a risk assessment (performed on a case-by-case basis) carried out by the FDC.

Conclusions

[3] http://www.eftasurv.int/media/food-safety/27.01.2017-10-13-00_FINAL-Country-Profile-Iceland-version-2017_-PART-1.pdf

12. The competent authorities in charge of official controls in animal health in aquaculture and official controls in LBMs are clearly defined.

5.2.2 Personnel and training of staff

Legal requirements

Article 4(2)(c) of Regulation (EC) No 882/2004

Article 6 of Regulation (EC) No 882/2004

Findings

13. According to information provided by Iceland in its reply to the Authority's pre-mission document, there are two official veterinarians who perform official controls related to aquatic animal health ('OVs for fish health') in Iceland. One is placed at MAST central level and the second one is placed at a local office in the West-fjords, where most salmon sea-cage farming has occurred in the last years. The two OVs have the same legal competence.
14. The mission team noted that OVs for fish health regularly participate in seminars and trainings offered by the World organisation for Animal health ('OIE'), the European Commission and European Association for Fish Pathologists ('EAFP'). The OVs met by the mission team who were involved in aquaculture demonstrated a good knowledge of aquatic animal health.
15. Currently, there is only one marine and fish biologist at MAST responsible for official controls and surveillance of LBM production and marketing. Staff responsible for official controls in this area have undergone frequent changes. Limited training has been made available to staff responsible for LBMs in recent years, although the current person responsible attended the BTSF training on LBMs in 2018.
16. MAST food safety inspectors are responsible for official controls in LBM food establishments. The most recent training for staff on LBMs was organised in 2013 by TAIEX Office of the EU Commission.

Conclusions

17. Competent authority staff are in general qualified and experienced. However, it is not always ensured that there are a sufficient number of such staff or that they receive appropriate training so as to be kept up to date in their area of competence.

5.2.3 Documented control procedures and reporting on official controls

Legal requirements

Article 8(1) of Regulation (EC) No 882/2004

Article 9 of Regulation (EC) No 882/2004

Article 54 of Regulation (EC) No 882/2004

Annex II, Chapter II of Regulation (EC) No 854/2004

Article 3 and Annex II of Regulation (EC) No. 853/2004

Findings

18. All documented procedures are published in the Quality Manual on MAST's website. A check-list is used for controls on fish farms and reports are issued according to this. Reports comprising the completed checklist, covering both official controls and animal health surveillance schemes, are issued to the farm in question with a copy to the relevant district veterinarian. Copies of reports, both from routine visits by MAST as well as investigations of increased mortality carried out by MAST, were present on fish farms visited.

19. The latest inspection reports by MAST were reviewed by the mission team at all fish farms visited. In all fish farms, the same template report had been used. The inspection reports checked were comprehensive, covering all relevant issues in relation to Directive 2006/88/EC as well as the use of veterinary medicine/chemicals and vaccinations, animal welfare and environmental conditions. However, no reports were available at mollusc farms relating to checks of animal health requirements required by Directive 2008/66/EC (for example, mortalities).

20. Reports checked on-the-spot by the mission team provided evidence that the OV for fish health had carried out thorough inspections in the fish farms visited. The inspection reports contained recommendations or suggestions for improvements. Examples were seen where recommendations had been followed up by fish farm management in cooperation with the OV for fish health.

21. MAST has issued a number of relevant guidance documents, including guidelines on risk based monitoring of LBM production areas, instructions for taking samples required for issuing harvest authorisations and templates of the accompanying documents for these samples. These documents were produced or revised in April 2018 and in February 2019. Certain inconsistencies were noted, such as incorrect levels of polycyclic aromatic hydrocarbons (PAHs) (see also paragraph 102). During the mission, MAST acknowledged inconsistencies in these guidelines and the consequent need to revise them.

22. Reports performed by MAST food safety inspectors at LBM dispatch and processing establishments were available and covered the requirements of Article 3 and Annex II of Regulation (EC) No. 853/2004. However, no reports were available for primary production to address the requirements of Regulation (EC) No 854/2004, Annex II, Chapter II.

23. Examples of follow-up of recommendations by MAST food safety inspectors at subsequent visits to LBM dispatch and processing establishments were seen by the mission team. Actions to address non-compliances were generally taken by FBOs.

Conclusions

24. Documented control procedures are in place for official controls related to animal health on aquaculture farms. These are well implemented on fish farms. However, official controls on molluscs farms do not include checks on animal health requirements which reduces the likelihood of early detection of the listed diseases

in Directive 2006/88/EC for molluscs.

5.2.4 Authorisation of ABOs and approval of FBOs

Legal requirements

Article 31 of Regulation (EC) No 882/2004

Article 3 of Regulation (EC) No 854/2004

Article 4 of Directive 2006/88/EC

Article 6 and Annex II of Directive 2006/88/EC

Commission Decision 2008/392/EC

Article 43 of Directive 2006/88/EC

Annex II of Regulation 852/2004

Sections VII ad VIII of Annex III to Regulation 853/2004

Findings

25. According to information provided by Iceland in its reply to the Authority's pre-mission document, ABOs must apply for both an operation licence from MAST and a pollution license from the Environment Agency of Iceland ('UST'). Before MAST issues an operation licence, the applicant has to submit information to MAST in accordance with the criteria outlined in Article 12 of IS regulation No 1170/2015 on aquaculture, including information relevant for aquatic animal health.

26. The mission team noted that all fish farms are authorsised in accordance with Article 4(1) of Directive 2006/88/EC. OVs for fish health are routinely consulted prior to issuing operational licences for fish farms.

27. ABOs rearing, keeping or cultivating aquaculture animals other than fish and quarantine facilities are not authorised, contrary to Article 4(1) of Directive 2006/88/EC. One licence for quarantine facilities seen by the mission team referred only to animal welfare and experimental animal requirements, not aquatic animal health legislation. No processing establishments have yet been authorised to slaughter fish for disease control purposes, contrary to Article 4(2) of Directive 2006/88. (see also paragraph 50).

28. MAST has established, and keeps up to date, a publicly available list in word format of all fish farms in Iceland, in accordance with Article 6 of Directive 2006/88/EC. In addition, registered transporters of live fish are included in this list but quarantine facilities are not. In addition to the abovementioned list, MAST also maintains an internet-based information page containing information on aquaculture business operators, including mollusc farms. However, the combination of both lists does not provide all information required in Article 6 and Annex II of Directive 2006/88/EC and Annex I and II of Commission Decision 2008/392/EC, for example, details on the farms' water supply.

29. The mission team further noted that the information provided in the internet information pages was not always accurate. For example, the list indicated an ongoing eradication program for bacterial kidney disease (BKD), although Iceland has not submitted such an eradication program for approval to the Authority, as required in that case by Article 43 of Directive 2006/88/EC.

30. LBM FBOs (dispatch centres and establishments) are approved as required by Article 3 of Regulation (EC) No 854/2004. The FBOs send their application to MAST. After an onsite inspection of the facilities, own check systems and of compliance with the requirements in Annex II to Regulation (EC) 852/2004 and sections 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 corrections are needed. Otherwise, the application is rejected. Before the licence is issued by MAST, the FBO must also comply with a number of environmental and other public health requirements.

Conclusions

31. MAST has a system in place for authorisation of aquaculture business operators and approval of LBM food business operators. However, not all aquaculture business operators are authorised. MAST's information on aquaculture production business operators is currently inaccurate and incomplete.

5.3 Official controls in aquaculture

Legal requirements

Article 3 of Regulation (EC) No 882/2004

Article 7 and Article 10 of Directive 2006/88/EC

Findings

32. The mission team noted that MAST is responsible for both official controls of ABOs in accordance with Article 7 of Directive 2006/88/EC and inspections under the risk-based animal health surveillance scheme foreseen by Article 10 of the same Directive.

33. According to information provided by Iceland in its reply to the Authority's pre-mission document, Icelandic law bans all import of used aquaculture equipment. Exemptions may be granted by MAST if the equipment is adequately cleaned and disinfected. Sea-cage farms in Iceland use their own well-boats, in addition to vessels introduced from Norway which have been issued an import licence by MAST.

34. The mission team noted that transporters of live aquaculture animals are in general not subject to official controls. Having entered Iceland, responsibility for the transporter rests with the company leasing/operating the vehicle. The well-boat visited was approved for introduction into Iceland and records of official supervision of cleansing and disinfection on entry were available and satisfactory. Since then the well boat had not been subject to official controls and neither had a second (land) transport vehicle seen by the mission team.

Conclusions

35. Iceland has in place a risk based system for official controls and risk-based animal health surveillance schemes, which are both delivered by the competent authority.

However, these controls are incomplete as not all aquaculture production businesses are monitored, which may increase the risk of spread of disease between farms.

5.3.1 Animal health surveillance schemes and measures for control of diseases of aquaculture animals

Legal requirements

Article 4(2) of Directive 2006/88/EC

Article 7 of Directive 2006/88/EC

Article 10 of Directive 2006/88/EC

Chapter V of Directive 2006/88/EC

Article 47 of Directive 2006/88/EC

Article 49 of Directive 2006/88/EC

Article 50 of Directive 2006/88/EC

Article 52 of Directive 2006/88/EC

Part B of Annex III of Directive 2006/88/EC

Article 10(i) of Regulation (EC) No 1069/2009

Article 24(2) of Regulation (EC) No 1069/2009

Article 25 (e) of Regulation (EC) No 1069/2009

Commission Decision 2008/896/EC

Findings

36. According to information provided by Iceland in its reply to the Authority's pre-mission document, no clinical viral fish disease has been detected in Iceland to date, although some fish viruses have been isolated through national monitoring program of both wild and farmed fish. MAST considers Iceland as one zone regarding the diseases listed in Part II of Annex IV to Directive 2006/88/EC, except for Infectious salmon anaemia (ISA) and Viral haemorrhagic septicaemia (VHS). This conclusion is based on active surveillance and regular testing in fish farms throughout the country since 1985.

37. The mission team noted that the following health statuses are recognised in Iceland in accordance with Directive 2006/88/EC:

    a. Infectious haematopoietic necrosis (IHN): The whole country is Category I, declared disease-free in accordance with Article 49(1)(c) of Directive 2006/88, as recognised by the Authority's Decision No 227/04/COL, later amended by Decision No 036/16/COL. MAST maintains targeted surveillance.

    b. Viral haemorrhagic septicaemia (VHS): Three compartments are Category I, declared disease-free in accordance with Article 50(1)(c) of Directive 2006/88, as recognised by the Authority's Decision No 034/16/COL. The remaining part of the country is Category III, *i.e.*, not known to be infected but not subject to surveillance programme for achieving disease-free status. MAST maintains targeted surveillance.

c. Infectious Salmon Anaemia (ISA): Four compartments are Category I, declared disease-free in accordance with Article 50(1)(c) of Directive 2006/88, as recognised by the Authority's Decision No 173/13/COL. One of the compartments was not in operation at the time of the mission. The remaining part of the country is category III. MAST maintains targeted surveillance.

d. Koi herpes virus **(**KHV): The whole country is Category III, not known to be infected but not subject to surveillance programme for achieving disease-free status. No surveillance is undertaken

e. Marteilia refringens: The whole country is Category III, not known to be infected but not subject to surveillance programme for achieving disease-free status. Intermittent sampling is undertaken by MAST.

f. White spot disease: The whole country is Category III, not known to be infected but not subject to surveillance programme for achieving disease-free status. None of the species susceptible to the disease in question are present in Icelandic aquaculture. No surveillance is undertaken by MAST.

5.3.1.1 Risk-based health surveillance

38. According to information provided by Iceland in its reply to the Authority's pre-mission document, a risk assessment has been carried out in accordance with Annex III, Part B of the Council Directive 2006/88/EC and the Commission Decision 2008/896/EC guidelines. The major factors taken into account are the health status of each farm, aquaculture animal species, water source and the type of farming (land-based or sea-cage). The list of farms and the conclusion of the risk assessment is regularly updated by the veterinary officer for fish diseases.

39. The mission team noted that, although mollusc farms are included in the risk assessment, only fish farms are inspected in accordance with the indicated frequencies. A representative of MAST confirmed that routine visits to mollusc farms were not carried out, contrary to Article 10 of Directive 2006/88.

5.3.1.2 Passive surveillance

40. According to information provided by Iceland in its reply to the Authority's pre-mission document, the person in charge of the fish farm shall immediately notify the Veterinary Officer for Fish Diseases or the local District Veterinary Officer of any sign of disease on the farm.

41. The mission team noted that all fish farms visited had pre-determined mortality rates. Mortality rates above the pre-determined limits were generally notified to MAST and/or a private veterinary service. However, the mollusc farm visited had not established a routine for notifying MAST of increased mortality.

5.3.1.3 Active surveillance

42. Official controls and health inspections were carried out on fish farms in line with planned frequency laid down in the risk assessment (see also paragraph 38). However, no official controls related to compliance with Directive 2006/88/EC were carried out on ABOs farming or cultivating other aquatic animals than fish, contrary to Article 7 of Directive 2006/88/EC. Furthermore, inspections of such ABOs under the risk-based animal health surveillance scheme are not carried out as required by Article 10 of Directive 2006/88/EC.

43. The mission team noted that MAST were notified of inexplicable increases in mortality at fish farms, in line with Article 26(1)(b) of Directive 2006/88/EC.

Investigation of increased mortalities on fish farms were undertaken by MAST and/or private veterinary services and included on-spot inspection, post-mortem examinations and samples for diagnostic purposes, pursuant to Article 28 of the Directive. No treatments can occur before a formal diagnosis has been made and prescription of medicines by the private fish health veterinarians must be approved by MAST.

5.3.1.4 Targeted surveillance

44. The mission team noted that targeted surveillance for IHN, VHS and ISA is carried out in accordance with Article 52 of Directive 2006/88/EC. The diagnostic method used for VHS and IHN was cell cultures followed by RT-qPCR, as required by Point II.2 of Part 1, and RT-qPCR for ISA, as required by Point II.2 of Part 3, of Annex I to Commission Implementing Decision (EU) 2015/1554. In addition, Iceland runs a number of national surveillance and eradication programs for other diseases not listed in part II of Annex IV 2006/88. Iceland has not submitted any of these surveillance or eradication programmes for approval, contrary to Article 43 of Directive 2006/88/EC.

45. Extensive screening of brood stock was carried out for a number of diseases. The brood stock farm visited had established routines to ensure destruction of gametes and fertilised eggs in case of positive findings. The mission team were informed that, from time to time, PCR would indicate ISA positive test results with high cycle threshold value (CT value). The mission team saw examples of such positive results with appropriate follow up. To date, presence of genotype HPR- deleted ISA virus has not been confirmed in Iceland.

46. MAST has, since the Authority's previous mission in 2013, sampled wild populations of blue mussels (*Mytilus edulis*) in 2015 (30 samples), 2016 (30 samples) and 2017 (60 samples). All samples were negative for *Marteilia refringens*.

5.3.1.5 Measures for control of diseases of aquaculture animals

47. As the NRL, Keldur is responsible for diagnosis of diseases in aquatic animals and advises MAST concerning animal diseases. The institute has an agreement with the European Reference Laboratory (EURL) for Fish Diseases in Denmark covering services urgently needed to confirm or rule out suspicion of an outbreak of an exotic animal disease.

48. Following suspicion, or confirmed diagnosis, of a contagious disease, the OV for fish health immediately applies movement restrictions and informs the NRL, the FDC and the local MAST District Veterinarian.

49. In case of outbreak of a notifiable disease, MAST will impose movement restrictions, and, in most cases, request stamping out. Each ABO is responsible for its own contingency plan for dealing with mass mortalities, including disposal of dead fish and how to carry out culling. At the time of the mission, not all ABOs had established such a contingency plan. This is contrary to Articles 34 and 38(1)(a) of Directive 2006/88/EC.

50. There are currently no processing establishments in Iceland equipped or authorised to slaughter aquaculture animals for disease control purposes in accordance with Articles 33 and 38(1)(a) of Directive 2006/88/EC, contrary to Article 4(2) of the same Directive. Certain establishments, based on geographical location, are under legal obligation to install a system to disinfect all effluent water by 30 September 2019 (see also paragraph 4) at the latest, in accordance with Article 33(3) of

Directive 2006/88/EC. Notwithstanding this, not all fish farms will have access to slaughtering establishments that treat effluents pursuant to Articles 33(3) and 38(1)(a) of Directive 2006/88/EC. This is contrary to Articles 33(2) and 38(1)(a) of Directive 2006/88/EC, which requires harvesting to be carried out under conditions which prevent the spread of the pathogen responsible for causing the disease in the case where an exotic or non-exotic disease has been confirmed.

51. An establishment receiving aquaculture ABPs is approved as a Category 3 animal by-product establishment producing pet food and noted that disinfection of containers in which dead fish and other materials were delivered to the establishment was not satisfactory, *i.e.*, cold water was used during the cleaning and disinfection process instead of hot water (as required by the manufacturer of the disinfectant). This is contrary to Article 25(e) of Regulation (EC) No 1069/2009, which requires that operators have in place appropriate arrangements for the cleaning and disinfection of containers in place to avoid risk of contamination. The containers in question are delivered back to fish farms. On one fish farm visited, poorly cleaned containers for collection of Category 3 materials were also observed.

5.3.1.6 Contingency planning for emerging and exotic diseases

52. According to information provided by Iceland in its reply to the Authority's pre-mission document, provisions governing animal diseases and preventive measures against them are laid down in The Icelandic Act no. 25/1993 *on animal diseases and disease prevention* and IS Regulation No. 300/2018 *concerning animal welfare, measures to prevent and control diseases in fish and health inspection of fish farms*. In the event of an outbreak of a serious contagious aquatic animal disease, MAST's headquarters serve as the main disease control centre.

53. The mission team noted that MAST has prepared a contingency plan for emerging and exotic diseases, as required by Article 47 of Directive 2006/88/EC for disease of aquatic animals, which is currently being updated. However, there is no operational manual available detailing how the different measures described in the plan are to be carried out. Iceland cannot therefore ensure that removal and disposal of aquaculture animals in case of exotic or emerging diseases is undertaken in accordance with Article 34(1) of Directive 2006/88/EC, which requires that dead fish and crustaceans, as well as live fish and crustaceans showing clinical signs of disease, are removed and disposed of in accordance with the requirements of EEA animal by-product legislation and the contingency plan provided for in Article 47 of Directive 2006/88/EC.

Conclusions

54. Iceland has implemented a risk based surveillance system where a combination of passive, active and targeted surveillance should ensure the early detection of the listed fish diseases in Directive 2006/88/EC.

55. An animal health risk assessment has been performed. Whilst mollusc farms are included in the risk assessment, only fish farms are inspected in line with the indicated frequencies, such that a mollusc disease outbreak may not be timely detected.

56. The absence of authorised slaughter facilities for disease control purposes increases the likelihood of spread of disease in an outbreak situation as containment of disease will be weakened. Furthermore, carcasses from some farms are not always disposed of in line with EEA animal by-products

requirements, causing further risk of spreading pathogens.

57. Poor cleaning and disinfection procedures of containers used for collecting dead fish at animal by-product establishments may increase the risk of spread of disease between farms.

5.3.2 Record keeping

Legal requirements

Article 8 of Directive 2006/88/EC

Findings

58. The mission team noted that, on fish farms visited, extensive records in line with Article 8(1) of Directive 2006/88/EC were kept mainly by using available aquaculture software. Records included, *inter alia*, the number of fish, average weight, density and feed consumption for each unit. Daily mortalities were also recorded and categorised according to cause of death. Furthermore, records of movements of eggs and live fish to and from farms were kept and movements of live fish between farms were accompanied by a Health and movement document issued by MAST.

59. Transporters visited kept records of species transported, mortalities during transport and place of loading and destination, as required by Article 8(3) of Directive 2006/88/EC. Furthermore, transporters kept records of cleaning and disinfection and had copies of the Health and movement documents issued by MAST for each consignment of live fish.

Conclusions

60. Aquaculture business production operators and transporters of live aquaculture animals in Iceland keep adequate records, which will facilitate epidemiological investigations in the event of a disease outbreak.

5.3.3 Placing on the market, introduction and import of aquaculture animals and products thereof

Legal requirements

Article 12 of Directive 2006/88/EC

Article 43 of Directive 2006/88/EC

Chapter III of Directive 2006/88/EC

Chapter III of Regulation (EC) No 1251/2008

Chapter IV of Directive 2006/88/EC

Chapter IV of Regulation (EC) No 1251/2008

Annexes II and III of Regulation (EC) No 1251/2008

Article 3(3) of Directive 96/93/EC

Findings

61. According to information provided by MAST in its reply the pre-mission document, any imports of live aquaculture animals from third countries are prohibited. MAST can however, assisted by the FDC, grant exemptions. FDC carries out a risk assessment and, in the absence of any risk of introducing diseases to Iceland, MAST issues an import licence for the consignment in question. Imported live aquaculture animals from third countries are placed in quarantine for at least 6 months before release.

62. The mission team noted that Iceland applies this administrative procedure for both import from third countries and introduction of live aquatic animals from other EEA states. The FDC's risk assessment covers diseases listed in Part II of Annex IV to Directive 2006/88, as well as other diseases of national concern included on a national list. There is no approved disease-fee status, eradication programme or surveillance programme pursuant to Article 43 of Directive 2006/88/EC for any of the diseases on the national list.

63. There is limited import of aquaculture animals from third countries. However, the mission team noted that in 2018 an import licence was issued for a consignment of live abalone for farming purposes from Japan. Japan is not listed in Annex III to Regulation (EC) No 1251/2008 as a country from where LBMs can be imported into the EEA area. In addition, this consignment did not enter Iceland via a Border Inspection Post and was not recorded in TRACES.

64. The mission team noted that MAST has a system in place for issuing animal health certificates for aquaculture animals placed on the market in another EEA state, zone or compartment declared disease free or subject to surveillance or eradication programmes. If the ABO fulfils all relevant health requirements, a health certificate in line with Annex II, Part A of the Commission Regulation No 1251/2008/EC is issued in TRACES.

65. The mission team saw a veterinary certificate for a consignment from Iceland to the Faroe Islands signed by the OV on 28 December 2018 with the date of movement entered as 2 January 2019, meaning that the relevant animals were not inspected within 72 hours of movement, as certified. In addition, the relevant OV confirmed that veterinary certificates are signed attesting that the animals have been checked within 72 hours in cases where a clinical inspection may not have been performed. This is not in full compliance with requirements of Article 3(3) of Directive 96/93/EC.

Conclusions

66. Iceland takes certain measures to prevent introduction of diseases not listed in Part II of Annex IV to Directive 2006/88/EC. Notwithstanding, no such measures have been notified to the Authority for approval, contrary to Article 43 of the Directive.

67. Iceland does not fully comply with import requirements for aquaculture animals. Imports have been permitted from countries which are considered a risk for the introduction of aquatic disease and such imports have not been subjected to required veterinary checks on arrival.

68. Veterinary certification is regularly provided which is misleading and not fully in compliance with legislative requirements. This reduces animal health assurances

to trading countries.

5.4 Official controls on LBMs

Legal requirements

Annex II, Chapter II of Regulation (EC) No 854/2004

Findings

69. According to information provided by MAST in its reply to the pre-mission document, MAST's food safety inspectors monitor LBM FBOs based on a risk assessment. MAST's risk assessment of the LBM FBO visited classified it as medium risk. LBM FBOs are in principle placed in a high risk group in light of the product they produce but may nevertheless (as was the case here) be classified in a lower risk category if production volumes are low. In accordance with MAST procedures, this establishment therefore required ten hours of checks by the OV per year. The mission team noted that four checks were done in 2016, one in 2017 and two in 2018. Reports from the 2016 checks indicated many non-compliances, which were gradually improved on in 2017 and 2018. Current non-compliances concern mainly the FBO's own checks and its Quality manual.

70. In its reply to the pre-mission document, MAST stated that their food safety inspectors are responsible for official control of dispatch centres and that they should check if the producer has all the relevant documents in place, including harvesting authorisation, registration documents and labelling for mussels. They also check if all relevant hygiene requirements are fulfilled. The mission team noted that MAST food safety inspectors are not involved in supervision of any sampling, whether official or by FBOs. Neither do they check whether FBOs respect the dates specified in harvesting authorisation to ensure that they are covered by that authorisation when placing LBMs on the market. This is contrary to Regulation (EC) No 854/2004, Annex II, Chapter II, D. 1, which requires establishment of an official control system to verify FBO compliance with requirements for levels of marine biotoxins and chemical/microbiological contaminants at all stages of production, processing and distribution.

5.4.1 Classification of production areas

Legal requirements

Chapter II of Annex II to Regulation (EC) No 854/2004

Findings

71. MAST is responsible for classification of production areas. According to information provided by MAST in its reply to the pre-mission document, all LBM Icelandic production areas are classified as class A areas in accordance with Chapter II, Annex II of Regulation (EU) No 854/2004 (threshold of 230 *E. coli*/100 g and Salmonella negative in 25 g) and their monitoring is based on a risk assessment, The products can be placed directly on the domestic market through dispatch centres without being transferred to the relaying area. No relaying area for LBMs exist in Iceland.

72. According to Icelandic Act no. 90/2011, a producer should send an application to MAST in relation to a production area, including indication of size and boundaries (map of production area). MAST has issued a guidance document "Sanitary survey of production and catching areas of LBMs, which is based on Regulation (EC) No 854/2004, Annex II, Chapter II, A. 6. The classification of production areas is based on a sanitary survey, with a sampling plan based on a coastal survey, the species to be produced and site location. A sanitary survey includes assessment of compliance with the microbiological criteria, heavy metals and chemical contamination in shellfish and a 12 month survey for *E.coli* in shellfish flesh and faecal coliforms in seawater.

5.4.2 Monitoring of production areas and decisions after monitoring

Legal requirements

Chapter II to Annex II to Regulation (EC) No 854/2004Findings

73. MAST has issued guidelines for risk based monitoring of production areas, which is based on IS Regulation No. 105/2010 implementing Annex II, Chapter II, point B. of Regulation (EC) No. 854/2005. These guidelines describe the procedure for authorisation of harvesting in a production area. The authorisation of harvesting applies from the day of sampling and is valid for a week from the day when results are received.

74. According to information provided by MAST in its reply the pre-mission document, the harvest authorisation for opening of a production area is always based on sampling and analyses of algae toxin in shellfish and poisonous algae in the sea and, as needed, analyses of micro-organisms (*E. coli*) and heavy metals (Cd, Hg, Pb). MAST stated that producers take samples according to the guidelines and send the mussel samples to Matís laboratory and the sea-samples to the Hafró laboratory. Both laboratories send the results to MAST and, if the results do not exceed the relevant threshold criteria, MAST issues an authorisation for harvest with the appropriate expiration date.

Monitoring of biotoxins

75. The CA has put in place a risk based system of official controls for monitoring biotoxins as follows:

Type of toxin	***Freq. of analyses - Winter*** *(October – May)*	***Freq. of analyses - Summer*** *(June – September)*
DSP	*1 x month*	*1 x in a week ****
PSP	*If Alexandrium exist**	*1 x in a week*
*ASP***	*1 x month*	*1 x in a week ***

** Alexandrium has not been diagnosed during the winter and therefore no need to regularly analyse PSP during the winter months. If Alexandrium is detected at a number close to the threshold, samples should be taken for PSP analysis.*
*** ASP screening with the DSP analyses (analysis of lipophilic toxins). Pseudonitzschia algae have so far not been toxic around Iceland.*
**** By LC-MS / MS CEN 16204 (alkaline conditions) assay method is also screening for YTX, PTX, AZP.*

76. The mission team noted that all samples in 2017 and 2018 were taken and paid for by FBOs in the framework of own checks. No samples were taken by MAST to verify that the levels of marine biotoxins do not exceed safety limits, as required by Regulation (EC) No. 854/2004 Annex II, Chapter II.D.2.

77. During 2018, the FBO's sampling for toxin analyses in a mussel production area was not undertaken weekly in the summer, being a high risk period for the development of toxic phytoplankton, as required by Regulation (EC) No 854/2004, Annex II, Chapter II, B, point 5 and as stated in MAST's sampling programme. Harvesting was allowed for most of the summer, even in periods when no samples were taken. The absence of sampling means that it would not be possible to comply with Point C.1. to Annex II to Regulation (EC) No 854/2004, which sets out decisions that must be taken in the event of unfavourable sampling or when there might otherwise be a risk to human health, including provisions on closing and subsequent re-opening of production areas.

78. At the LBM FBO visited in 2018, two samples were taken in June, three in July, one in August, one in September and none in November. The FBO was authorised by MAST to harvest for most of the summer, including during periods when no weekly samples were taken. The FBO's records revealed that mussels were placed on the market during the whole of 2018, even during periods not covered by a harvesting authorisation. No official controls by MAST have been performed to ensure that the product was not placed on the market during the period when no authorisation was given. This means that conditions of Regulation (EC) No. 854/2004 Annex II, Chapter II.D.1 are not fulfilled.

79. For the other LBM FBO, the results of biotoxins analysis were reviewed on a MAST web page. Although lipophilic toxins of the group of okadic acid were detected (90 µg/Kg) in mussels in January 2019 and samples taken in March 2019 showed a steady increase in levels of these toxins (160 µg/Kg, which is the upper limit for the presence of this toxin), detection was not followed by intensive sampling as required by Regulation (EC) No 854/2004, Annex II, Chapter II, B, point 4 (a). In fact, MAST issued a harvesting licence to the FBO to harvest for another week after receiving the results. This is contrary to Point C.1. to Annex II to Regulation (EC) No 854/2004.

80. Sampling and testing of PSP (Paralytic Shellfish Poisoning) toxins was not performed in accordance with the MAST sampling plan. In 2018, instead of taking samples every week during the summer period, only four samples were taken and analysed during four summer months, contrary to Regulation (EC) No. 854/2004 Annex II, Chapter II.B.5.

81. The MAST risk analysis also indicates that sampling for biotoxins in winter months is required only once per month, stating that the analysis did not show a high probability of presence of biotoxins in winter months and that the frequency of one sample a month is sufficient. On the contrary, it is clear from the results presented by Matís and Marine Institute from Ireland that there is activity in algae in Icelandic waters producing DSP toxins (see also paragraph 79). These results indicate that MAST's risk analysis did not take into account all necessary risk factors.

82. The mission team examined publicly available results of biotoxin analysis on MAST's website. It was found that the results did not correlate to those received separately by the mission team in hard copy. Representatives of MAST, who are responsible for publishing these results, were unable to provide an explanation.

Monitoring of toxic algae

83. The CA has put in place a system of official controls for monitoring of toxic algae in the sea by season and species as follows:

Species / Season	***Winter*** *October - April*	***Summer*** *June - August*	*May*	*September*
Blue Mussels (*Mytilus edulis*)	*Monthly*	*Weekly*	*Frequency is determined by the results of monitoring of toxic algae in April.*	*Frequency is determined by the results of monitoring of toxic algae during summer months.*

84. At the LBM FBO visited, water samples for phytoplankton were in 2018 taken more regularly, in accordance with MAST plan (with one exception – no samples were taken between 23 July and 6 August). The mission team noted that the ABO take samples from the inlet hose of sea water within the dispatch establishment. This is contrary to Regulation (EC) No 854/2004, Annex II, Chapter II, B, point 1c and point 7, which requires that sea samples for monitoring of plankton be taken in the mussel production area and by a representative water column. This was not checked and/or detected by MAST during their official controls of the dispatch establishment.

Monitoring of microbiological quality

85. The CA has put in place a system of official controls for monitoring of microbiological quality of LBMs as follows:

Number of E. coli as a percentage of limit criteria %	***Risk***	***Frequency*** (*can change due to irregular harvest periods)*
80%	*H*	*MAST - every other month* *FBO - weekly*
50 - 80 %	*M*	*MAST - 3 times per year* *FBO - 4 times per year*
< 50%	*L*	*MAST - 1 every year* *FBO - 2 per year*

86. All production areas in Iceland are considered by MAST as low risk areas. MAST's plan requires taking of samples for microbiological analysis once a year by MAST and twice yearly by the FBO. In 2017 and 2018, MAST did not take any samples and relied on the samples taken by the FBO. This is contrary to Regulation (EC) No 854/2004, Annex II, Chapter II, B, point 1(b).

Monitoring of heavy metals

87. MAST's sampling programme requires one sample for heavy metals to be taken every four years. However, no samples had been taken during the last four years in the production area where the visited LBM FBO was situated. The most recent sample in this production area was taken in 2011. This is contrary to Regulation (EC) No 854/2004, Annex II, Chapter II, B, point 1(d) and 8.

Verification of sampling procedures

88. MAST has not put in place a system to verify how samples (biotoxins, microbiology, water) are taken. This is contrary to Regulation (EC) No. 854/2004 Annex II, Chapter II.D.2, which requires that a control system be set up to verify FBOs' compliance with the requirements for the end product at all stages of production, processing and distribution. For example, as mentioned above, the FBO visited did not take sea samples for monitoring of plankton in a way requested by MAST, contrary to Regulation (EC) No. 854/2004 Annex II, Chapter II.B, points 1(c) and 7 (see also point 84).

Additional issues

89. The FBO visited stated that it gathered mussel seed and adult mussels from an area which is closed due to the presence of marine toxins above the legal limit, contrary to Regulation (EC) No 853/2004, Annex III, Section VII, Chapter II, A, Point 6. These mussels were then taken to an undefined part of a classified production area known only to the FBO.

90. MAST does not check if the FBO is placing mussels on the market during non-authorised periods, contrary to Regulation 854/2004 Annex II, Chapter II.D.1. Official controls performed at dispatch centres by MAST officials do not include checking on dispatch of the product during closure periods. MAST stated that it is not its responsibility to check this, but rather that of the Local Health Authorities (LCAs). According to a representative of Matís, no mussels samples were received by Matís from LCAs during 2017 or 2018. When asked if MAST inform LCAs about authorisations issued, they replied that the information is available on MAST website and that they do not consider it necessary to inform the LCAs about this. However, evidence was provided to the mission team of MAST reacting to a newspaper article about a restaurant serving mussels from an unknown origin and informing the relevant LCA that they should check this restaurant. There is no information on what actions LCA or MAST took following this information.

Conclusions

91. Monitoring and sampling to detect marine biotoxins, microbiological risks and presence of heavy metals was not performed as required by EEA legislation to ensure that the product placed on the market is safe. Inadequate and incorrect sampling for monitoring of phytoplankton reduces the credibility of all phytoplankton results and increases the public health risk.

92. The absence of an official control system to verify food business operators' compliance with the requirements for end products at all stage of production, processing and distribution of LBMs reduces the guarantees that the product placed on the market is safe for human consumption.

5.5 Laboratories

The mission team visited one laboratory involved in analysing samples of aquaculture animals in accordance with Directive 2006/88/EC and two laboratories analysing samples of LBMs in accordance with Regulation (EC) No 854/2004.

Legal Requirements

Annex III, Section VII, Chapter V, point 2 (a) of Regulation (EC) No 853/2004

Annex II, Chapter II, B, point 7. of Regulation (EC) No 854/2004

Article 4(2)(c) of Regulation (EC) No 882/2004

Article 11 of Regulation (EC) No 882/2004

Article 12 of Regulation (EC) No 882/2004

Article 33 of Regulation (EC) No 882/2004

Articles 56 and 57 of Council Directive 2006/88/EC

Point 1(i) of Part II of Annex VI of Directive 2006/88

Annex III of Regulation (EC) No 2074/2005

Findings

93. A National Reference Laboratory (NRL) for diseases of aquatic animals has been designated by the competent authorities as required by Article 56 of Directive 2006/88/EC. No other laboratory in Iceland is designated to perform laboratory examinations for the purpose of that Directive. The diagnostic service is to confirm or rule out suspicion of an outbreak of the non-exotic fish virus diseases: Infectious salmon anaemia, Infectious haematopoietic necrosis and Viral haemorrhagic septicaemia. In addition, they also perform diagnostics of Salmonid alpha virus and Infectious pancreatic necrosis. OV for fish health confirmed that few mollusc samples are sent to the NRL for animal health diagnostic purposes.

94. Additional virology is performed by the Food, Veterinary and Environment Agency of the Department of Fish and Animal Diseases in the Faroe Islands. Annex 4.a of this mission report lists the diseases and testing methods used. CA confirmed that the NRL has an agreement with the Danish Veterinary Institute (EU Reference Laboratory) to provide a rapid diagnostic service for viral diseases of fish including: IPN, EHN, IHN, VHS, KHV or ISAV. Annex 4.b of this mission report lists the number of samples analysed in Iceland for VHS, IHN, IPN and ISAV between 2014 - 2018.

95. The NRL for fish diseases has participated in the annual inter-laboratory proficiency test for listed viral fish diseases run by the EURL since 2004. The mission team reviewed results for 2016 and 2017, which were fit for purpose. Results for 2018 were not available at the time of the mission. NRL also participates in biennial proficiency testing of molluscs (histology) with acceptable results.

96. The mission team noted that the cell culture method was accredited. However, the RT-qPCR analysis used in combination with this as the diagnostic method for maintaining disease-free health status for VHS and IHN was not accredited, contrary to Regulation (EC) No 882/2004, Article 12, point 2 (a) and Article 56(5) of Directive 2006/88/EC and Points 1(i) and 2 of Part II of Annex VI of the same Directive.

Conclusions

97. The national reference laboratory for aquaculture provides a reliable diagnostic service for listed fish diseases. However, the diagnostic method used for VHS and

IHN is not accredited.

Laboratories analysing LBMs

98. Analyses of samples for marine toxins (lipophilic, PSP and ASP) taken by FBOs were carried out in the NRL which is not accredited in accordance with EN ISO/IEC 17025 for any marine biotoxins analyses method. Even if these samples were to be considered as official samples (see point 86), those analyses are contrary to Regulation (EC) No 882/2004, Article 12, point 2 (a). However, the mission team examined the Standard Operating Procedures ('SOPs') for the method used for analysing lipophilic toxins, being LC-MS/MS CEN 16204. The SOP revealed that the reference method established by Regulation (EC) No 2074/2005 was being followed. The results of the Proficiency Tests carried out for this method during the last three years were generally satisfactory. However, several reports of liphophilic toxins analyses provided to the mission team only contain toxins of the okadaic acid group and not toxins of the YTX, PTX and AZA groups, contrary to Regulation (EC) No 2074/2005, Annex III, Chapter III, point A (1).

99. Regarding PSP toxins, the official method AOAC 2005.06 is used for analysis, being the reference method under Regulation (EC) No 2074/2005, Annex III, Chapter I, point 2. In the last Proficiency Tests organised by the EURL for LBMs for this method, most results obtained by Matís were unsatisfactory, including an outlier result for GTX2,3, being the characteristic toxin of the *Alexandrium* species detected in Icelandic waters. None of the reports of PSP toxins provided to the mission team had concentration units expressed in µg/kg of PSP, contrary to Regulation (EC) No 853/2004, Annex III, Section VII, Chapter V, point 2 (a).

100. The result of a biotoxin analysis (detected at its upper limit) reviewed by the mission team was, during the mission period, assigned to a different FBO. The explanation provided was that the samples for analysis were placed in the wrong order in the liquid chromatography equipment. Matís' Quality Manager explained that they were preparing an action plan aimed at preventing this from happening again.

101. During 2018, analyses of ASP toxins in samples taken by the FBO were carried out using a semi-quantitative method, which was neither the reference method nor the accepted 2006.02 ASP ELISA screening method, nor any method internationally validated for these type of toxins as defined in Regulation (EC) No 2074/2005, Annex III, Chapter II. A person in charge of both lipophilic and ASP toxins commented that in case of detection of ASP in a sample, the relevant sample would be sent to The Marine Institute in Ireland for quantification using an accredited method.

102. MAST had not taken into account that the maximum level for benzo(a)pyrene established at 10 µg/kg by Regulation (EC) No. 1881/2006 has since been amended to 5 µg/Kg for LBMs. In addition a new maximum level of 30,0 µg/Kg had been set up for the sum of four substances (PAH4) (benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene).

103. Representatives from Hafro informed the mission team that two kinds of water sample are taken from each production area; namely, a net haul sample and a sample of non-concentrated seawater. However, only the net sample is always checked for toxin producing algae and the water sample being checked only where the net sample is positive. This does not ensure a representative sample of the water-column, contrary to Regulation (EC) No 854/2004, Annex II, Chapter II, B, point 7.

104. CA have designated an NRL for microbiological testing of LBMs, which, along with two other laboratories, perform microbiological analysis of, for example, *E. coli* and *Salmonella*. CA confirmed that NRL does not coordinate the activities of these official laboratories, contrary to Article 33(2) of Regulation (EC) No 882/2004.

Conclusions

105. The national reference laboratory for LBMs is not accredited and cannot provide reliable results on liphophilic, PSP or ASP toxins due to several shortcomings in its methods and procedures. Although the proficiency tests for methods of analysis for lipophilic toxins were in general satisfactory (not being the case for PSP), the reliability of results is undermined by the fact that the method used is not accredited, not all lipophilic toxins are analysed and the SOPs do not prevent samples being mixed.

106. Results from the laboratory for phytoplankton are not reliable because the procedures put in place do not always guarantee that the results are representative of the water column. Consequently, certain phytoplankton may remain undetected if present in the production area.

6 Final meeting

A final meeting was held on 20 March 2019 at MAST's premises in Selfoss with representatives from the Ministry of Industries and Innovation and MAST. At this meeting, the mission team presented its main findings and preliminary conclusions of the mission.

The representatives of the competent authority accepted the mission findings and preliminary conclusions. At the meeting, the competent authority presented an action plan indicating measures to be taken in the field of official controls on LBMs.

Due to the public health risks relating to the Authority's findings concerning official controls on LBMs, the Authority sent the Icelandic Government a letter dated 1 April 2019 outlining a preliminary list of findings related to official controls on LBMs and providing preliminary comments on the initial action plan presented by MAST at the final meeting. In that letter, the Authority requested urgent action from the Icelandic Government concerning official controls of production and placing on the market of LBMs. On 12 April 2019, the Authority received a reply to that request indicating corrective actions taken.

7 Recommendations

In order to facilitate the follow-up of the recommendations hereunder, Iceland should notify the Authority no later than **30 August 2019**, by way of written evidence, of additional corrective actions planned or taken other than those already indicated in the reply to the draft report of the Authority. In case no additional corrective actions have been planned, the Authority should be advised. The Authority should be kept continuously informed of changes made to the already notified corrective actions and measures, including changes of deadlines for completion, and completion of the measures included in the timetable.

No	Recommendation
1	The competent authorities should ensure that all the relevant legislation concerning aquatic animal health is made part of its legal order, pursuant to Article 7 of the EEA Agreement. Conclusion No. 6 Associated findings: 2
2	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. Conclusion No. 17 Associated findings: 15, 16
3	The competent authorities should ensure that all aquaculture production businesses are duly authorised by the competent authority, in accordance with Article 4(1) of Directive 2006/88/EC, and that information included in the publicly available register required by Article 6 of Directive 2006/88/EC is in accordance with Annex II of that Directive as well as Annex I and II of Commission Decision 2008/392/EC. Conclusion No. 31 Associated findings: 5, 27, 28, 29
4	The competent authorities should ensure that all aquaculture production businesses are subjected to regular official controls, as required by Article 7 of Directive 2006/88/EC. Conclusion No. 24, 35 Associated findings: 19, 34
5	The competent authorities should ensure that mollusc farms are inspected in line with the indicated frequencies, as required by Article 10 of Directive 2006/88/EC. Conclusion No. 55 Associated findings: 39, 42
6	The competent authorities should ensure that harvesting and disposal of carcasses in case of disease outbreaks are carried out in accordance with Article 33 and 34 of Directive 2006/88/EC respectively. Furthermore, processing establishments slaughtering aquaculture animals for disease control purposes in accordance with Article 33 must be equipped and authorised under Article 4(2) of Directive 2006/88/EC. Conclusion No. 56 Associated findings: 4, 27, 49, 50, 51, 53
7	The competent authorities should ensure that the operators have appropriate arrangements for the cleaning and disinfection of containers in place to avoid risk of contamination, as required by Article 25 (e) of Regulation (EC) No 1069/2009. Conclusion No. 57 Associated findings: 51
8	The competent authorities should ensure that only measures notified to the

	Authority for approval as required by Article 43 of the Directive 2006/88/EC are applied to prevent introduction of diseases not listed in Part II of Annex IV to Directive 2006/88/EC. Conclusion No. 66 Associated findings: 29, 44, 62
9	The competent authorities should ensure that aquaculture animals are only imported if they fulfil the conditions laid down in Chapter IV of Regulation (EC) No 1251/2008, including the requirement that they come from third countries, territories, zones or compartments listed in Annex III Regulation (EC) No 1251/2008. Conclusion No. 67 Associated findings: 63
10	The competent authorities must ensure that certifying officers are informed of the rules to be followed for drawing up and issuing certificates to prevent false or misleading certification in line with Article 3(3) of Directive 96/93/EC. Conclusion No. 68 Associated findings: 65
11	The competent authorities should ensure that monitoring and sampling to detect marine toxins, microbiological risks and presence of heavy metals relating to LBMs is performed as required by Chapter II, B.1 of Annex II to Regulation (EC) No 854/2004. Conclusion No. 91 Associated findings: 76, 77, 78, 79, 80, 81, 82, 84, 86, 87, 88
12	The competent authorities should ensure that a control system is put in place comprising laboratory tests to verify food business operators' compliance with requirements for end products at all stage of production, processing and distribution molluscs as required by Regulation (EC) No 854/2004, Annex II, Chapter II, D.2. It should also ensure that checks are performed to verify if the FBO is placing mussels on the market when authorisation is not granted, as required by Regulation 854/2004 Annex II, Chapter II.D.1. Conclusion No. 92 Associated findings: 88, 90
13	The competent authorities should ensure that the National Reference Laboratory for aquatic animal diseases uses methods for surveillance and diagnosis of VHS and IHN, as required by Regulation (EC) No 882/2004, Article 12, point 2 (a) and Article 56(5) of Directive 2006/88/EC and Points 1(i) and 2 of Part II of Annex VI of the same Directive. Conclusion No. 97 Associated findings: 96
14	The competent authorities should ensure that the national reference laboratory for LBMs is accredited and adopts methods and procedures which would enable reliable results on liphophilic, PSP and ASP toxins, as required by Regulation (EC) No 882/2004, Article 12, point 2 (a).

	Conclusion No. 105 Associated findings: 98, 99, 100, 101, 102
15	The competent authorities should ensure that procedures put in place in the laboratory for phytoplankton ensure that results are representative for the water column, as required by (EC) No 854/2004, Annex II, Chapter II, B, point 7. Conclusion No. 106 Associated findings: 103

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

ASP	Amnesic Shellfish Poison
AZA	Azaspiracid
The Authority	EFTA Surveillance Authority
ABO	Aquaculture Production Business Operator
DoF	Directorate of Fisheries
DSP	Diarrhetic Shellfish Poison
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EHN	Epizootic haematopoietic necrosis
EU	European Union
EURL	EU Reference Laboratory
FBO	Food Business Operator
FDC	Fish Disease Committee
IHN	Infectious haematopoietic necrosis
IPN	Infectious pancreatic necrosis
ISA	Infectious salmon anaemia
KHV	Koi herpes virus disease
LBM	Live Bivalve Mollusc
LCA	Local competent authority
MANCP	Single integrated multi annual national control plan
MAST	Icelandic Food and Veterinary Authority
NRL	National Reference laboratory
OV	Official veterinarian
OIE	Office International Epizootic (World Animal Health Organisation)
PCR	Polymerase chain reaction
PD	Pancreas disease
PSP	Paralytic Shellfish Poison
RASFF	Rapid Alert System for Food and Feed
rt-qPCR	Real time - quantitative polymerase chain reaction
SOP	Standard operating procedure
VHS	Viral haemorrhagic septicaemia
YTX	Yessotoxin
PTX	Pectenotoxin

Annex 2 - Relevant legislation

The following EEA legislation was taken into account in the context of the mission:

a) The Act referred to at Point 8a of Part 3.1 of Chapter 1 of Annex I to the EEA Agreement, *Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

b) The Act referred to at Point 42 of Part 3.2 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2008/896/EC of 20 November 2008 on guidelines for the purpose of the risk-based animal health surveillance schemes provided for in Council Directive 2006/88/EC*, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement*;*

c) The Act referred to at Point 86 of Part 4.2 of Chapter 1 of Annex I to the EEA Agreement, *Regulation (EC) No 1251/2008 implementing Council Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement*;*

d) The Act referred to at Point 87 of Part 4.2 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2008/392/EC of 30 April 2008 implementing Council Directive 2006/88/EC as regards an Internet-based information page to make information on aquaculture production businesses and authorised processing establishments available by electronic means*, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement*;*

e) The Act referred to at Point 11 in Part 1.1 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

f) The Act referred to at Point 12 of Part 1.1 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I thereto;

g) The Act referred to at Point 74 of Part 1.2 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States*, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

h) The Act referred to at Point 16 in Part 6.1 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

i) The Act referred to at Point 17 of Part 6.1 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

j) The Act referred to at Point 8b of Part 3.1 of Chapter I of Annex I to the EEA Agreement, *Commission Implementing Decision (EU) 2015/1554 of 11 September 2015 laying down rules for the application of Directive 2006/88/EC as regards requirements for surveillance and diagnostic methods (notified under document C(2015) 6188)*, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

k) The Act referred to at Point 9b of Part 7.1 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

l) The Act referred to at Point 9 of Part 1.1 of Chapter I of Annex I to the EEA Agreement, *Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products*, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

m) The Act referred to at Point 134 of Part 1.2 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 and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

n) The Act referred to at Point 54zzzz of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

Annex 3 - Information on production provided by Iceland in their reply to the pre-mission document

Table 1: Production of live aquaculture animals and products thereof in Iceland

Species Common name (*scientific name*)	For human consumption (metric tonnes)		Farming purposes (no. of smolt/juveniles)	
	2017	2018	2017	2018
Atlantic salmon (*Salmo salar*)	11.265	13.448	5.586.000	7.591.000
Arctic char (*Salvelinus alpinus*)	4.454	4914	4.650.000	4.960.000
Rainbow trout (*Oncorhyncus mykiss*)	4.628	295	0	0
Senegal sole (*Solea senegalensis*)	400	391	0	0
Cod (*Gadus morhua*)	29	29	0	0
Blue mussel (*Mytilus edulis*)	82.7	108.3	0	0
Ocean quahog (*Arctica islandica*)	37.2	19.6	0	0
Oyster (*Crassotera gigas*)	0	0.2	0	0

Table 2: Live aquaculture animals placed on the market in other EEA member states

Species Common name (*scientific name*)	Human consumption (metric tonnes)		Farming purposes (no. smolt/juveniles or larvae / no. litres eyed eggs)		Other Aquaculture purposes (no. smolt or juveniles / no. litres eyed eggs)	
	2017	2018	2017	2018	2017	2018
Atlantic salmon (*S. salar*)	7.900	8.000	1.020.000 / 12.318	0 / 14.062	6.685 / 0	13.425 / 0
Arctic char (*S. alpinus*)	1.400	1.800	0	0	0	0
Rainbow trout (*O. mykiss*)	1.050	0	0	0	0	0
Senegal sole (*S. senegalensis*)	348	302	0	0	0	0
Wolffish (*A. lupus*)	0	0	0	0	1.200 / 0	0
Turbot (*P. maxima*)	0	0	80.000 / 0	900.000 / 0	0	0
Lumpfish (*C. lumpus*)	0	0	0	0	2.109.000 / 44	2.581.000 / 22

Table 3: Live aquaculture animals introduced from other EEA member states

Species Common name (*scientific name*)	Human consumption (metric tonnes)		Farming purposes (no. smolt/juveniles or larvae / no. litres eyed eggs)	
	2017	2018	2017	2018
Atlantic salmon (*S. salar*)	230	219	0	0
Arctic char (*Salvelinus alpinus*)	0	0	0	0
Rainbow trout (*Oncorhyncus mykiss*)	0	0	0 / 37	0 / 30
Senegal sole (*Solea senegalensis*)	0	0	2.925.000 / 0	2.870.000 / 0
Oysters (*Crassostrea gigas*)			500.000 / 0	500.000 / 0
Abalone (*Haliotis discus hannai*)			285 / 0	400 / 0

Table 4: Live aquaculture animals exported to third countries

Species Common name (*scientific name*)	Human consumption (metric tonnes)		Farming purposes (no. smolt/juveniles or larvae / no. litres eyed eggs)	
	2017	2018	2017	2018
Atlantic salmon (*Salmo salar*)	1.100	1.000	0 / 2.277*	0 / 3.022*
Arctic char (*Salvelinus alpinus*)	1.600	1.900	0	0
Rainbow trout (*Oncorhyncus mykiss*)	700	0	0	0
Senegal sole (*Solea senegalensis*)	52	90	0	0
Lumpfish (*Cycloopterus lumpus*)	0	0	0	385.000 / 0

*Export of Atlantic salmon eyed eggs to Chile, USA, Canada, China and Dubai and Taiwan.

Table 5: Live aquaculture animals imported from third countries

Species Common name (*scientific name*)	Human consumption (metric tonnes)		Farming purposes (no. smolt/juveniles or larvae / no. litres eyed eggs)	
	2017	2018	2017	2018
Abalone (*Haliotis discus hannai*)	Negligible quantity		450*	0

*Imported from Japan

Annex 4 - Laboratories for animal health

a) List of the diseases and testing methods

Laboratory	Disease(s)	Method(s)
Institute for Experimental Pathology at Keldur (NRL), University of Iceland, Keldnavegur 3, 112 Reykjavík (public)	**ISAV, IPNV, VHSV, IHNV, PD/SAV, PMCV (CMS), PRV, Rana virus, SGPV, Yersinia ruckeri and BKD**	**Real-time PCR and Real-time RT-PCR**
	VHSV, IHNV, OMV and IPNV	**Cell-lines, ELISA**
	BKD	**ELISA, Double-sandwich, FAT, qPCR and culture**
National Reference Laboratory for Fish and Animal Diseases, Food and Veterinary Agency, V.U. Hammershaimbsgøta 11, FO-100 Thorshavn, Faroe Islands (public)	**ISAV, IPNV, VHSV, IHNV, PD/SAV, PMCV (CMS), PRV, SGPV, SRS, Yersinia ruckeri and BKD**	**Real-time RT-PCR**

b) Number of samples analysed

Number of samples analyzed for VHS, IHN and IPN (2014 – 2018)
(BF-2, EPC and CHSE-214 cell-lines)

Year	Number of individuals sampled	Number of farms sampled	Number of negative samples	Number of positive samples
2014	432	12	432	0
2015	753	13	741	12*
2016	1.155	12	1.155	0
2017	1.127	12	1.127	0
2018	966	12	966	0

* VHS virus positive **lumpfish of wild origin** in 1 farm.

Number of samples analyzed for VHS; 2017 - 2018
(Real-time RT-PCR)

Year	Number of individuals sampled	Number of farms sampled	Number of negative samples	Number of positive samples
2017	206	4	206	0
2018	1.094	4	1.094	0

Number of samples analyzed for IHN; 2017 - 2018
(Real-time RT-PCR)

Year	Number of individuals sampled	Number of farms sampled	Number of negative samples	Number of positive samples
2017	22	2	22	0
2018	636	2	636	0

Number of samples analyzed for ISA (HPR-deleted genotype); 2014 – 2018

Year	Number of individuals sampled	Number of farms sampled	Number of negative samples	Number of positive samples
2014	10.355	4	10.355	0
2015	14.151	8	14.151	0
2016	13.427	8	13.427	0
2017	13.296	6	13.296	0
2018	10.817	8	10.817	0

Annex 5 - Iceland's action plan for corrective actions

ESA mission on aquaculture animals & live bivalve molluscs health 2019				
	Recommendation:	**Action:**	**Time aspect**	**Enclosures**
1	The competent authorities should ensure that all the relevant legislation concerning aquatic animal health is made part of its legal order, pursuant to Article 7 of the EEA Agreement. Conclusion No. 6 Associated findings: 2	The Ministry´s stance regarding EU decisions is as follows: EU decisions are genarally not implemented into the national legislation unless upon a specific request from MAST. Naturally it is necessary to implement rules if authorities intend to make decisions that are directed at individuals or legal entities based on those rules. Such rules are generally found in directives and regulations. However, if a decision concerns the organization of supervision or relations with the EU (ESA), then it is generally considered that MAST can act in accordance with that decision and organize its work accordingly, without the need for implementation into the national legislation.	N/A	
2	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. Conclusion No. 17 Associated findings: 15, 16	Inspectors have been designated for official control of dispatch centres and production areas. In house training of the inspectors is on the agenda 05.06.2019. Training in sampling of seawater will be included in the training.	June 2019	
3	The competent authorities should ensure that all aquaculture production businesses are duly authorised by the competent authority, in accordance with Article 4(1) of Directive 2006/88/EC, and that information included in the publicly available register required by Article 6 of Directive 2006/88/EC is in accordance with Annex II of that Directive as well as Annex I and II of Commission Decision 2008/392/EC. Conclusion No. 31 Associated findings: 5, 27, 28, 29	All new and renewed operation licenses issued by the Icelandic Food and Veterinary Authority for aquaculture businesses will hereafter be issued in accordance of Directive 2006/88/EC	As of now	
4	The competent authorities should ensure that all aquaculture production businesses are subjected to regular official controls, as required by Article 7 of Directive 2006/88/EC. Conclusion No. 24, 35	The Icelandic authority is aware of lack in the official health controls by means of visiting the mollusc farms and transporters followed up with an inspection report. The health surveillance of mollusc farms have been		

	Associated findings: 19, 34	based on passive control with focus on taking the necessary samples for testing of the listed diseases in the Directive 2006/88/EC. Due to lack of veterinarians in the field of aquaculture animals the CA has prioritized the surveillance activity with focus on fish diseases. MAST is working on this matter in cooperation with the Ministry and will improve the inspection activity of the mollusc farms and transporters in the future. LBM: Under OC of dispatch center it will be checked if the FBO has procedures in place regarding reporting signs of disease in mollusc.	June – July 2019	
5	The competent authorities should ensure that mollusc farms are inspected in line with the indicated frequencies, as required by Article 10 of Directive 2006/88/EC. Conclusion No. 55 Associated findings: 39, 42	See no. 4.		
6	The competent authorities should ensure that harvesting and disposal of carcasses in case of disease outbreaks are carried out in accordance with Article 33 and 34 of Directive 2006/88/EC respectively. Furthermore, processing establishments slaughtering aquaculture animals for disease control purposes in accordance with Article 33 must be equipped and authorised under Article 4(2) of Directive 2006/88/EC. Conclusion No. 56 Associated findings: 4, 27, 49, 50, 51, 53	General improvements have been done in the field of animal by-products and in the spring 2019 a special veterinarian was hired by MAST working entirely on animal by-products. All necessary actions will be taken to improve the handling of disposals. New regulation no. 300/2018 requires disinfection of all effluent water from slaughterhouses and well-boats slaughtering farmed fish in the areas of fish farming from 30 Sept. 2019. Currently there are only two slaughterhouses and harvesting plants in the areas of sea-cage farming, one in the Westfjords and one in the Eastfjords. Both are now constructing a new ozone-based disinfection system. This will be followed up by MAST and approved before the time limit run out.		
7	The competent authorities should ensure that the operators have appropriate arrangements for the cleaning and disinfection of containers in place to avoid risk of contamination, as required by Article 25 (e) of Regulation (EC) No 1069/2009. Conclusion No. 57 Associated findings: 51	Action was taken at the spot of the particular finding and will be followed up by MAST.		

8	The competent authorities should ensure that only measures notified to the Authority for approval as required by Article 43 of the Directive 2006/88/EC are applied to prevent introduction of diseases not listed in Part II of Annex IV to Directive 2006/88/EC. Conclusion No. 66 Associated findings: 29, 44, 62	MAST will take notice of that.		
9	The competent authorities should ensure that aquaculture animals are only imported if they fulfil the conditions laid down in Chapter IV of Regulation (EC) No 1251/2008, including the requirement that they come from third countries, territories, zones or compartments listed in Annex III Regulation (EC) No 1251/2008. Conclusion No. 67 Associated findings: 63	Only one small import of abalones was made from Hokkaido in Japan which showed not to fulfil the mentioned conditions. The animals were put into a quarantine facility under a strict health control. MAST will take notice of this and prevent all such imports in the future.		
10	The competent authorities must ensure that certifying officers are informed of the rules to be followed for drawing up and issuing certificates to prevent false or misleading certification in line with Article 3(3) of Directive 96/93/EC. Conclusion No. 68	It must be stressed that the Icelandic authorities are fully aware and well informed of the rules according to issuing health certificates. The veterinary officers for fish diseases issue several hundred certificates each year to all over the world and have a		
	Associated findings: 65	faultless record through over 25 years. The referred finding and conclusion is one particular veterinary certificate on live lumpfish (cleaner-fish) exported to the Faroe Islands on the first active day in 2019 (Wednesday 2 January). Because of the Holidays by the New Year the receiver of the lumpfish asked the exporter and the MAST to issue the health certificate on the last working day of the year 2018 (Friday 28 Dec.). Taken the special timing and conditions into account the veterinary officer for fish diseases could meet this request and issued the certificate on the last working day. The receiver of the fish must apply to the Faroes authorities for every single import and that was the only way to do it for getting an import license in time. It must also be underlined that all parentfish of the lumpfish juveniles exported are routinely sampled and screened thoroughly for all known pathogens, as well as the offsprings. 2-3 containers are being shipped over to the Faroes every Wednesday all year around and in		

		the light of this, the Faroes authority accept and approve clinical inspections of the juveniles in a little bit more than 3 days in advance in some cases. MAST is taken the task of issuing health certificates very seriously and no exception is made without fully cooperation with the receiving farms and related authorities.		
11	The competent authorities should ensure that monitoring and sampling to detect marine toxins, microbiological risks and presence of heavy metals relating to LBMs is performed as required by Chapter II, B.1 of Annex II to Regulation (EC) No 854/2004. Conclusion No. 91 Associated findings: 76, 77, 78, 79, 80, 81, 82, 84, 86, 87, 88	Samples will be analysed according to offical sampling plan for LBM. The frequency of sampling will be according to MAST´s revised risk assessment. The revised document will be published on MAST´s website latest 31.07.2019 Reference is made to Mast‘s plan for corrective actions in annex I. ii, vi, viii and ix.	As of now	
12	The competent authorities should ensure that a control system is put in place comprising laboratory tests to verify food business operators' compliance with requirements for end products at all stage of production, processing and distribution molluscs as required by Regulation (EC) No 854/2004, Annex II, Chapter II, D.2. It should also ensure that checks are performed to verify if the FBO is placing mussels on the market when authorisation is not granted, as required by Regulation 854/2004 Annex II, Chapter II.D.1. Conclusion No. 92 Associated findings: 88, 90	According to MAST‘s sampling plan one sample from each producer will be taken on the marked for analysis of marine biotoxins, E.coli and salmonella. Meeting with the LCAs will be in the beginning of June. Control on the market will be discussed and a procedure regarding communication between Mast and the LCAs will be dicussed.	July – august 2019 June 2019	
13	The competent authorities should ensure that the National Reference Laboratory for aquatic animal diseases uses methods for surveillance and diagnosis of VHS and IHN, as required by Regulation (EC) No 882/2004, Article 12, point 2 (a) and Article 56(5) of Directive 2006/88/EC and Points 1(i) and 2 of Part II of Annex VI of the same Directive. Conclusion No. 97 Associated findings: 96	The cell culture method is accredited; that includes isolation of VHS and IHN. In case of suspicion of a notifiable disease, such as VHS or IHN, the Institute for Experimental Pathology at Keldur (the NRL) has an agreement with the European Union Reference Laboratory for fish diseases (EURL: DTU – National Veterinary Institute, Denmark) for assistance. Therefore, samples would in all such uncommon cases be sent for diagnosis and confirmation to the EURL.		
14	The competent authorities should ensure that the national reference laboratory for LBMs is accredited and adopts methods and procedures which would enable reliable results on liphophilic, PSP and ASP toxins, as required by Regulation (EC) No 882/2004, Article 12, point 2 (a). Conclusion No. 105 Associated findings: 98, 99, 100, 101, 102	Reference is made to Mast´s plan for corrective actions in annex I, xii. The laboratory will apply for accreditation if it is foreseen that the production of LBM will continue in Iceland and the number of sample runs will be enough to get accreditation. Mast have demanded a plan for PT tests, reports from PT tests, Matís´s evaluation of performance in PT test and deviation reports for all analysis where errors are discovered. Mast will also perform regular audit of Matís‘s procedures regarding analysis of Marine biotoxins.	31.12.2019	
15	The competent authorities should ensure that procedures put in place in the laboratory for phytoplankton ensure that results are representative for the water column, as required by (EC) No 854/2004, Annex II, Chapter II, B, point 7. Conclusion No. 106 Associated findings: 103	At a meeting 30.04 2019 with the producers the sampling procedure for seawater was presented and discussed. On the spot training of sampling will be offered 05.06.2019. The aim is to ensure and verify that the samples are representative for the water column. Both net samples and water samples have been analysed since April 2019. Sampling methods of sea water will be checked by Mast´s inspectors during official control in June-July		

Annex 6 - Action plan proposed by Iceland concerning urgent measures in relation to official controls of production and placing on the market of LBMs

(The annexes referred to in the table below have been provided to the Authority, by the competent authority, and offer clarification and/or additional information to the actions proposed.)

Comment	Action	Date – status 31.05.2019
i. MAST food safety inspectors met by the mission team were not involved in official controls of live bivalve molluscs, except as regards approval and controls of food establishments (*i.e.*, no involvement in sampling and monitoring). The conditions of Regulation (EC) No 854/2004 Annex II, Chapter II.D., point 2 are therefore not fulfilled.	A four-person team from Mast will receive sample training for LBM, managed by specialist from Hafró and Mast. A team of two inspectors will perform inspections in production areas, one responsible for the food safety/hygiene part and one responsible for official controls of LBM. A specific guidance will be made to assist inspectors in inspection of production areas and establishments. A document that contains guidance and checklists for inspectors involved in official controls of LBM. The guidance is based on relevant legislation concerning LBM and aims to fulfill all requirements which have not been completely fulfilled, as ESA has pointed out (most importantly; sampling procedures, frequency and analysis).	5th of June 2019. Next planned inspection June 2019 See annex XI.
ii. The mission team noted that all samples in 2017 and 2018 were taken and paid for by the FBOs as sampling in the framework of own checks and most of them were not taken in the production area, but on the end product at a dispatch centre. No samples were taken by MAST to verify that the levels of marine biotoxins do not exceed safety limits, as required by Regulation (EC) No. 854/2004 Annex II, Chapter II.D., point 2.	MAST has prepared an official sampling plan of LBM's in production areas. Funding of sample analysis have been discussed with the ministry. And additional funds have been requested.	The first samples will be taken June 2019 Official sampling plan was included with the action plan. See Annex X. The meeting took place on April 30, 2019 at the Ministry. No response from the ministry yet.
iii. Sampling by FBOs for toxins in a mussel production area was not undertaken weekly in the high-risk period (summer) as required by MAST. This is contrary to Regulation (EC) No 854/2004, Annex II, Chapter II. B., point 5. Harvesting of mussels was allowed throughout most of the summer, which included periods when no samples were taken.	Sampling will be performed strictly according to the risk assessment, including official samples. See annex IV	The procedure was formally announced at a meeting with the producers, held on 30 April 2019. Agenda, participation list and presentations are in Annex A.
iv. FBO records revealed that mussels were placed on the market throughout the whole of 2018, including during periods where there was no valid authorisation from MAST permitting this. No official controls by MAST were performed to ensure that mussels were not placed on the market during such periods. This is contrary to Regulation (EC) No. 854/2004 Annex II, Chapter II.D., point 1.	FBO's harvest LBM's during valid authorization periods and keep them alive for some time. LBM's must not be stored in running sea water from areas with no valid harvesting license. This was formally announced at a meeting with the producers held on 30 April 2019. The FBO can therefore market product when no authorization is valid, if the harvest can be linked to registration documents from periods when authorization was valid. See annex III and IV	Formally introduced as of 30. April 2019. Will also be included in the revised risk assessment.
v. At one live bivalve mollusc farm, lipophilic toxins of the okadaic acid group (which cause Diarrhoeic Shellfish Poisoning) were detected (90 µg/Kg) in	This deviation will be taken into account and the procedures for issuing harvesting licenses will be improved.	The rdocument on risk assessment will be revised and published on Mast's website latest 31. July 2019.

mussels in January 2019. However, this detection was not followed by intensive sampling as required under Regulation (EC) No 854/2004, Annex II, Chapter II.B., point 4 (a). Despite the fact that samples taken in March showed an increase of such toxins (160 µg OA equiv./Kg, which is the upper limit for the presence of this group of toxins), MAST did not request any additional sampling and issued a licence for harvesting for two weeks.	The risk assessment has been revised, and the following procedures added. If the amount of biotoxins will exceed 50% of allowed maximum limit during winter, the harvesting license will only be issued for two weeks. If the FBO wishes to extend the harvesting license, he must present new samples with acceptable results. See Annex III.	The procedures was formally informed on the meeting 30 of April 2019 and followed from that date.
vi. Sampling and testing of PSP (Paralytic Shellfish Poisoning) toxins was not performed in accordance with MAST's sampling plan. Instead of taking samples every week during the summer period, only four samples were taken and analysed over four summer months. Taking into account that PSP outbreaks may happen in Iceland during summer months, the requirements of Regulation (EC) No 854/2004 Annex II, Chapter II.B. point 5 are not fulfilled. vii. In a live bivalve mollusc farm visited, water samples for phytoplankton were taken by the FBOs in accordance with MAST's plan during 2018. However, such samples were not taken in the mussel production area	Sampling will be performed strictly according to the risk assessment, including official samples. However, in some cases, circumstances can arise such as bad weather, difficulties in transport. If LBM productions area has been closed, i.e. due to increase in the amount of toxic phytoplankton, the period between sampling can be longer. It depends on the producer´s decision to harvest and apply for authorization for harvesting. According to the risk assessment analysis of PSP begins in the spring / summer when the number of Alexandrium cells exceeds 40/liter. Sea samples should be analysed once a week from 1.05.2019	The revision of the risk assessment was formally introduced at the meeting 30. April 2019. See an attached summary of the samples that have been analyzed in 2019 in Annex B. Sampling sheet for analysis of marine biotoxins has been updated. See Annex C.
nor in a representative water column, as required by Regulation (EC) No 854/2004, Annex II, Chapter II.B., point 7.	Meeting with Hafro and FBO's to present sampling methods for sea water analysis.	Formally in the meeting on the 30. April 2019 (Annex A)
viii. MAST's plan requires taking of samples for microbiological analysis once a year by MAST and twice yearly by FBOs. In practice, MAST does not take any samples and relies solely on samples taken by FBOs. This is contrary to Regulation (EC) No 854/2004, Annex II, Chapter II.A., point 6 (d).	Sampling will be performed strictly according to the risk assessment, including official samples. FBO's have presented updated sampling plans for microbiological analysis and heavy metal analysis. They already have started, and Mast two inspectors will ask for the results in every inspection.	As of now. Official sampling plan was included with the action plan. See Annex X
ix. Despite the requirement in MAST's plan to take one sample for heavy metals every four years, no such samples had been taken since 2011 in the production area where a live bivalve mollusc producer visited was situated.	Sampling will be performed strictly according to the risk assessment, including official samples. MAST has prepared an official sampling plan of LBM's in production areas. Mast took a sample in February from the marked. The origin of the sample was Króksfjörður (Nesskel). The sample was analysed for heavy metals, PAH, and dioxins, E. coli and salmonella. See results in Annex IX and Annex V	As of now. Official sampling plan was included with the action plan. See Annex X
x. There is no system in place to verify how samples (biotoxins, microbiology, water) are taken by FBOs, contrary to Regulation (EC) No. 854/2004 Annex II, Chapter II.D., point 2. Absence of verification by MAST of how,	Sampling procedures of FBO's will be reviewed during official controls. Meeting with Hafro and FBO's to present sampling methods for sea water analysis. The discussions included necessary training of FBO´s to assure correct sampling methods.	June 2019 The meeting was on the 30 of April (Annex A) and the training is on the agenda 5th of June 2019.
when and where samples are taken presents a public health risk.		
xi. MAST does not check if FBOs place mussels on the market in production areas where authorization is not granted. This is contrary to Regulation 854/2004 Annex II, Chapter II.D., point 1. MAST states that it is not their responsibility, but that of Local Health Authorities, to check this. A representative of MATIS (the national reference laboratory for live bivalve mollusks) confirmed that no mussel samples had been received by them from local competent authorities in 2017 or 2018.	Control of LBM on the market will be discussed in the food control group (which includes Local Health Authorities). Local Health Authorities will be informed about valid harvesting licenses of FBO's by e-mail. See annex II	June 2019.
xii. The laboratory designed by the competent authority to carry out the analyses of samples for official controls of marine biotoxins is not accredited in accordance with the norm EN ISO/IEC 17025 for such analyses. This is contrary to Regulation (EC) No 882/2004, Article 12, point 2 (a).	A meeting took place with the reference laboratory (Matís) to discuss analysis of samples and the need for accreditation. The conditions for accreditation were discussed at the meeting. A minimum of 20 analysis is needed (equipment used 20 times). If the number of samples will increase this year and it is foreseen that the production of LBM will continue, Matis will apply for accreditation next year. Until then Mast will visit Matis and get information of their quality assurance of the analysis and PT tests.	10. April. 2019 Reference is made to recommendation no. 14in the document ; Answers to Recommendations of ESA Draft-Report - Table of corrective actions