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Final report

EFTA Surveillance Authority's follow-up audit to

Iceland from 30 August to 2 September 2022

in order to evaluate animal health controls in relation to aquaculture animals

and official controls of live bivalve molluscs

Comments from Iceland to the draft report are included in Annex 3 and information on the corrective actions already taken and planned are included in Annex 4 to the report.

Executive Summary

This report describes the outcome of a follow-up audit carried out by the EFTA Surveillance Authority ('the Authority') in Iceland from 30 August to 2 September 2022.

The objective of the follow-up audit was to assess the implementation and effectiveness of measures and actions taken by the competent authorities ('CAs') following the Authority's earlier mission to Iceland from 11 to 20 March 2019 to evaluate animal health of aquaculture animals and related official controls concerning live bivalve molluscs ('LBMs') ('the 2019 mission'). Actions and measures taken to address six outstanding recommendations from the 2019 mission (Recommendation Nos 2, 3, 11, 12, 14 and 15) were assessed during this follow-up audit.

The audit team found that progress has been made since the 2019 mission. Following this follow-up audit, three out of the six outstanding recommendations (Recommendation Nos 2, 3 and 15) will be closed on the basis of the Authority's finding that adequate actions and corrective measures have been taken by the CA to address them.

Recommendation No 11 will not be closed until the CA ensures that monitoring and sampling of marine biotoxins and phytoplankton is undertaken in accordance with EEA legislation.

Regarding Recommendation No 12, recent findings by MAST that a producer deliberately placed LBMs on the market that were harmful for consumer health and that another producer placed LBMs on the market without a valid harvesting authorisation suggest that the CAs have not yet established a system of official controls that prevents such non-compliances. The CAs should ensure that, apart from checks on food business operators ('FBOs'), a robust system of official controls is put in place to prevent products from production areas without valid harvesting authorisation being placed on the market.

Recommendation No 14 will not be closed until the CA ensures that the designated laboratory performs analyses of marine biotoxins in line with the methods and procedures required under EEA law such as to enable reliable results to be obtained.

No additional recommendations were issued as a result of this follow-up audit. Iceland should inform the Authority of additional corrective measures and actions taken in relation to Recommendation Nos 11, 12 and 14 from the report of the 2019 mission to address the issues detected during the follow-up audit.

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1 Introduction

The audit took place in Iceland from 30 August to 2 September 2022. The audit team comprised two auditors from the Authority and a national expert.

The Authority sent a pre-audit questionnaire to the Ministry of Food, Agriculture and Fisheries ('the Ministry') on 12 July 2022 and received a reply ('the pre-audit document') on 16 August 2022.

The opening meeting was held with representatives of both the Icelandic Food and Veterinary Authority ('MAST') and the Ministry on 30 August 2022 at MAST's office in Hafnarfjörður. At the meeting, the audit team confirmed the objectives and itinerary of the audit. The Icelandic representatives provided additional information to that set out in the pre-audit document.

Throughout the audit, two representatives of MAST accompanied the audit team.

A final meeting was held at MAST's office in Hafnarfjörður on 2 September 2022, during which the audit team presented its main findings and preliminary conclusions from the audit.

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

2 Objectives and scope of the audit

The main objective of the audit was to assess the implementation and effectiveness of measures and actions taken following the Authority's earlier mission to Iceland from 11 to 20 March 2019 to evaluate animal health of aquaculture animals and related official controls concerning live bivalve molluscs ('LBMs') ('the 2019 mission'). Actions and measures taken to address the six outstanding recommendations from the 2019 mission (Recommendations No 2, 3, 11, 12, 14 and 15) were assessed during this follow-up audit.

The findings and conclusions of this audit are based on the information provided in the pre-audit document and in documents provided by the CAs during the audit. Such information was complemented by interviews with CA staff, a review of relevant food business operator ('FBO') documentation, interviews with FBO staff and on-the-spot visits at FBO sites.

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

Meetings with the competent authorities and visits to FBO establishments during the audit are listed in Table 1.

Table 1: Competent authority meetings and FBO establishments visited during the audit

	Number	Comments
Icelandic Food and Veterinary Authority (MAST)	3	An initial meeting, a clarification meeting and a final meeting between the audit

		team and MAST.
Local competent authorities (LCAs)	1	Meeting with the representatives of three local competent authorities (on-line).
LBM producer and dispatch centre (same establishment)	1	Only one LBM producer and one dispatch centre was active at the time of audit.

3 Legal basis for the audit

The audit was carried out under the general provisions of the EEA Agreement and relevant EEA legislation, in particular Articles 116, 117 and 119 of Regulation (EU) No 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products ('Regulation (EU) 2017/625').

Full references to EEA legislation relevant to this audit are provided in Annex 2.

4 Background information relating to the 2019 mission

This audit permitted the Authority to follow up on measures and actions taken by the relevant Icelandic competent authorities to address recommendations from the 2019 mission. The final report from the 2019 mission can be found on the Authority's website (www.eftasurv.int).

During the 2019 mission, the audit team found that official controls relating to LBMs and, in particular, monitoring and sampling to detect marine biotoxins, microbiological risks and presence of heavy metals were not performed as required by EEA legislation. In particular, inadequate and incorrect sampling for monitoring of phytoplankton reduced the credibility of related test results. At the time of the audit, therefore, it could not be guaranteed that LBMs placed on the market were safe for human consumption. Several recommendations to address these shortcomings were issued by the Authority in the final report from the 2019 mission and a decision to perform a follow-up audit was latterly taken by the Authority.

5 Findings and conclusions

5.1 Recommendation No 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*** *(new legal reference: Art 5(4) of Regulation 2017/625)*

1. In its replies to the Authority's draft report from the 2019 mission and to the Authority's follow-up letters concerning that mission, MAST indicated that inspectors designated for official control of dispatch centres and production areas have been trained accordingly.
2. A practical course was conducted where inspectors were trained on how to take sea samples with a dip net (extractor hood) and a hose to detect and count algae. Part of the course was recorded on video in order for LBM producers and other interested parties to learn how to take sea samples representative of the water column. The videos are available on MAST website. Link:

https://www.mast.is/is/matvaelafyrirtaeki/stofnun-matvaelafyrirtaekis-og-leyfi/skeldyraeldi-og-veidar.

3. The general MAST inspection manual was revised in 2019 and a new chapter on LBM inspections was added.
4. Inspections of dispatch centres and production areas have been assigned to a senior officer who is responsible for official controls of LBMs in production areas and in the dispatch centres.
5. Another senior officer is responsible for issuing harvesting licences to producers based on an analysis of marine biotoxins in LBM meat and detection of toxic phytoplankton in sea samples in the relevant area. Inspections of dispatch centres and production areas have been assigned to a senior officer with a good knowledge of MAST´s official control system and experience in performing official controls.
6. The audit team assessed the performance of MAST staff responsible for official controls of LBMs. Staff met were knowledgeable and adequately trained to perform effective controls in this area.

Conclusions

7. Actions taken by the CA to address Recommendation No 2 are satisfactory and this Recommendation can therefore be closed.

5.2 Recommendation No 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*** *(new legal reference: Articles 172, 173, 176, 177 and 185 of Regulation (EU) 2016/429)*

8. In replies to the Authority's draft report from the 2019 mission and to the Authority's follow-up letters from that mission, MAST stated that all new and renewed operation licenses issued by MAST to aquaculture establishments would be issued in accordance with Directive 2006/88/EC (since repealed by Regulation (EU) 2016/429 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Regulation (EU) 2016/429')).
9. MAST indicated that they would issue an annex to operations licences already issued which would contain references to the relevant requirements under Regulation (EU) 2016/429 (IS no.1254/2008) and emphasize the legal obligation on relevant operators to comply with these requirements.
10. The audit team saw evidence that all new and renewed operation licenses issued by MAST to aquaculture establishments contained references to Regulation (EU) 2016/429 and are made publicly available on MASTs website. However, operations licences already issued before the 2019 mission did not at the time of the audit contain the anticipated annex with legal references to Regulation (EU) 2016/429. At the final meeting, the CA indicated that such annexes would be issued shortly and subsequently confirmed in writing that this had been done.

Conclusions

11. Actions taken by the CA to address Recommendation No number 3 are satisfactory

and the recommendation can therefore be closed.

5.3 Recommendation No 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 *(new legal reference: Article 59 of Regulation 2019/627)*

12. MAST maintains a list of the location and boundaries of LBM production areas in Iceland. All such areas are classified as Class A areas (as per Articles 52 and 53 of Regulation (EU) 2019/627) in cooperation with the FBO. The list of production areas is available at MAST website: https://skyrslur.mast.is/primaryproduction

13. The audit team assessed sanitary surveys for two LBM production areas which had been undertaken in 2010 but had not been updated since. In both sanitary surveys, the results related to production sites which were never operational within the production areas instead of to production sites where LBMs were actually growing. This is contrary to Article 58 of Regulation 2019/627, which requires that the sanitary survey and the monitoring programme are representative of the area considered.

14. MAST updated its risk-based monitoring programme in a document issued on the 23.08.2022 (LBE-089.3.0). The updates consisted only of references to new legislation. No changes regarding sampling requirements were made. In particular, the audit team noted that MAST has not defined in this document the geographical distribution of the sampling points (no fixed points established by physical coordinates), contrary to Article 57 of Regulation (EU) 2019/627.

15. In addition it was noted that:

- The analytical method for Paralytic Shellfish Poison (PSP) toxins has not been updated from the AOAC official method OMA 2005.06 to the Standard EN 14526, contrary to Article 1 and Point 1 of the Annex to Regulation (EU) 2021/1709 concerning uniform practical arrangements for the performance of official controls on products of animal origin ('Regulation (EU) 2021/1709'). Updating the analytical method would require determination of additional PSP compounds (GTX 6, dcGTX2,3 and dcNEO) and of some technical requirements for the calibration curve as well as for the peaks resolution of the oxidation products of dcGTX2,3 and dcSTX.

- At the time of the audit Regulation (EU) 2022/617 amending Regulation (EC) No 1881/2006 as regards maximum levels of mercury in fish and salt was not yet part of the EEA law applicable in Iceland. However, the Audit team pointed out that, when incorporated, the maximum level of mercury in gastropods would need to be updated to 0,3 mg/kg as provided in Article 1 of, and the Annex to, that Regulation.

- Maximum levels of polycyclic aromatic hydrocarbons (Benzo(a)pyrene, benzo(a)anthracene, benzo(b)fluoranthene and chrysene) in LBMs exceed the maximum levels permitted under Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants ('Regulation (EC) No 1881/2006').

- Pectenotoxins continue to be included in the LBM monitoring programme, notwithstanding that (pursuant to Article 1 of, and the Annex to, Regulation (EU) 2021/1374 amending Regulation (EC) No 853/2004 on specific hygiene requirements for food of animal origin ('Regulation (EC) No 853/2004') a maximum

limit for Pectenotoxins (PTX) group toxins is no longer stipulated under Regulation (EC) No 853/2004.

16. MAST informed the audit team that an official sampling plan had been adopted in spring 2019 for classified LBM relaying and production areas and that sampling had subsequently been implemented according to that plan. Samples are taken by producers themselves and this is supervised by MAST inspectors during an annual inspection visit. MAST provided an overview of results from sampling in 2020, 2021 and samples taken so far in 2022.
17. Toxin-producing phytoplankton is monitored weekly in summer in conformity with EEA legislation.
18. Despite MAST recognising summer as the high risk period for marine biotoxins in its risk-based monitoring programme document (LBE-089.3.0), the sampling plan only provides for bi-weekly (every two weeks) LBM sampling for marine biotoxins analysis (lipophilic and amnesic toxins) during the summer period . This is contrary to Article 61(4) of Regulation (EU) 2019/627 which requires weekly sampling during harvesting periods unless a risk assessment of toxins or phytoplankton occurrence suggests a very low risk of toxic episodes. In addition, the sampling for PSP toxins is performed only if levels of phytoplankton (*Alexandrium*) cells exceed the thresholds established in the monitoring programme.
19. The audit team noted gaps of up to ten days between the time when sampling results indicate phytoplanktons in production and relaying areas and the time when results for marine biotoxins in LBMs become available. This is because the time between sampling of phytoplankton and obtaining the test results is 2-3 days and the time between sampling of marine biotoxins and obtaining the test results is 4-5 days for lipophilic results (5-6 days if PSP analyses are required) and marine biotoxin sampling and results may occur during the week following the phytoplankton sampling (due to the fact that marine biotoxin sampling is bi-weekly).

Conclusions

20. The audit team noted improvements in sampling and analyses of phytoplankton and marine biotoxins since the last audit. However, the fact that the system is relying on weekly analysis of phytoplankton and bi-weekly analysis of marine biotoxins can lead to a gap of up to 10 days between detection of phytoplankton in production and relaying areas and the results of samples for marine biotoxins in LBMs. During this interval, there is a risk that LBMs that are unsafe may be placed on the market. Another concern is that sampling for PSP marine biotoxins is undertaken only where levels of phytoplankton (*Alexandrium*) cells exceed the thresholds established in the monitoring programme, compromising the ability of the monitoring system to detect PSP toxic episodes. In addition, the sanitary survey and the monitoring programme are not representative of the area considered and geographical distribution of the sampling points is not defined. Recommendation No 11 cannot be closed until the CA takes actions to address these outstanding issues.

5.4 Recommendation No 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. *(new legal reference: Articles, 59a and 64 of Regulation (EU) 2019/627)*

21. Although local competent authorities ('LCAs'), rather than MAST, are the competent authority for sampling LBMs placed on the market (retail, restaurants, etc.), such sampling is nevertheless included in MAST's sampling plan. Analysis of the only sample of LBMs placed on the market taken by MAST in August 2022 showed a high level of cadmium. Further investigation showed that these LBMs were placed on the market by a producer holding a valid harvesting authorisation but who had purchased the LBMs from another producer which harvesting authorisation had been revoked in 2021 due to the high cadmium levels. LBMs harmful for consumers' health were therefore knowingly and intentionally placed on the market. MAST had only recently become aware of this situation and actions to address the situation were ongoing at the time of the audit. The audit team informed MAST that the Authority would carefully monitor the outcome of the case.

22. The three LCAs which participated in a meeting with the audit team confirmed that they had recently begun to perform checks to ensure that LBMs placed on the market originate from producers holding a valid harvesting authorisation. A representative of a fourth LCA was present at the final meeting and confirmed that during checks on LBMs placed on the market they never found LBMs in fish shops and restaurants. The dispatch list of the only LBM producer active at the time of the audit documented LBMs being sent to 18 different final consumers (shops, restaurants, etc.) in the fourth LCA's relevant area during the two weeks preceding the audit. The only sample of LBMs placed on the market taken by MAST in 2022 (mentioned in paragraph 21 above) which contained high cadmium levels was taken from a fish store located in the area under the control of this fourth LCA.

23. Twelve non-compliances (three of them serious) were detected by MAST in a dispatch centre during a check at one of the LBM producers active in 2021. The inspector gave the producer a deadline for rectifying the non-compliances and when these were not rectified the approval of the dispatch centre was withdrawn. This was regarded by the audit team as a good example of effective enforcement. The relevant producer did not apply to MAST for harvesting authorisation in 2022.

24. An inspection by MAST of the production area of the same producer mentioned in paragraph 23 above revealed that that producer had placed LBMs on the market on five occasions during periods of 2021 when he did not hold a valid harvesting authorisation. According to calculations of the MAST inspector, at least 500 kg of such LBMs were placed on the market in 2021, seriously jeopardising consumer health. No enforcement actions were taken against this producer. This is contrary to Article 138 of Regulation 2017/625 which requires that where non-compliance is established, competent authorities shall take appropriate measures to ensure that the operator concerned remedies the non-compliance and prevents further occurrences of such non-compliance. Although this producer did not apply for a harvesting authorisation in 2022, MAST has no information concerning whether production of mussels is still ongoing in this production area and if the producer in question continues to place LBMs on the market without harvesting authorisation as it was the case in 2021.

Conclusions

25. Recent findings of a producer deliberately and intentionally placing on the market LBMs harmful to consumer health and of LBMs being placed on the market by a producer who does not hold a valid harvesting authorisation confirm that the CAs have not established a system of official controls sufficient to prevent such non-

compliances. If the CAs had taken adequate actions to address Recommendation No 12 following the report of the 2019 mission, these malpractices could have been prevented. The CAs should ensure that, apart from checks on FBOs, a robust system of official controls is put in place to prevent products from production areas without valid harvesting authorisation being placed on the market.

26. Recommendation No 12 will remain open until the CAs ensure that effective measures are implemented to address it.

5.5 Recommendation No 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 lipophilic, PSP and ASP toxins, as required by Regulation (EC) No 882/2004, Article 12, point 2 (a).*** *(new legal reference: Articles 37(4)(e) and 100(2) of Regulation 2017/625).*

27. Toxin-producing plankton analyses are conducted in the Marine and Freshwater Research Institute *(Hafrannsóknarstofnun)* which is not accredited.

28. Microbiological analyses and heavy metals analyses are conducted by the accredited laboratory MATIS using the reference methods established in accordance with Regulation (EU) 2017/625.

29. Analyses of PCBs, dioxins and benzo(a)pyrene are conducted in an accredited laboratory in Germany. Analyses of other polycyclic aromatic hydrocarbons (such as benzo(a)anthracene, benzo(b)fluoranthene and chrysene) are not undertaken, contrary to Regulation (EC) No 1881/2006.

30. Marine biotoxin analyses are performed in a Swedish accredited laboratory using recognized chemical methods. The national reference laboratory for biotoxins, MATIS, is not accredited to perform such analyses. Rather, it receives the samples taken by the producers and sends them to the Swedish accredited laboratory for analysis. Regarding the Swedish laboratory, the audit team noted that:

    - The required method for determining paralytic shellfish poison content has been modified by Regulation (EU) 2021/1709 (see paragraph 15) to include determination of additional compounds (such as GTX 6, dcGTX2,3 and dcNEO). These additional compounds were not included in the analyses reports provided by the Swedish laboratory;
    - Following amendment of Regulation (EC) No 853/2004 (see paragraph 15), there is no longer a need to monitor pectenotoxins.

31. An evaluation of the last proficiency test of this Swedish laboratory (Quasimeme Z-Scores report from July 2022) revealed:

    - for the lipophilic toxins detection method: one outlier and three straggler results, one of the straggler results being the total okadaic acid content;
    - for the PSP method: three outliers and one straggler result, one of the straggler results being the total PSP toxicity.

Conclusions

32. The credibility of the results provided by the accredited laboratory analysing marine biotoxins (for both for lipophilic and PSP toxins) is compromised by certain non-compliances and the inconsistent results of the last proficiency tests. The CA should take actions to ensure that the laboratory used to analyse marine biotoxins provides

reliable results and takes corrective actions to improve its performance. Recommendation No 14 can only be closed after the necessary correction actions have been taken.

5.6 **Recommendation No 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.*** *(new legal reference: Article 61(7) of Regulation 2019/627)*

33. MAST confirmed that training of LBM operators on sampling procedures for seawater (including ensuring that samples are representative of the water column) took place in June 2019. Sampling methods are verified during annual official controls by MAST, including for their representativeness of the water column.
34. The audit team visited one FBO to check equipment used and the operation to collect a sea water sample for toxin-producing plankton. It was concluded that the plankton sampling operation guaranteed the representativeness of the water column, in accordance with of Article 61(7) of Regulation 2019/627.

6 Overall conclusion

Progress has been made since the 2019 mission. Following this follow-up audit, three out of six of the outstanding Recommendations from the report of 2019 mission (Recommendation Nos 2, 3 and 15) will be closed on the basis that adequate actions and corrective measures had been taken by the CA to address them.

Recommendation No 11 will not be closed until the CA ensures that monitoring and sampling of marine biotoxins and phytoplankton is undertaken in accordance with the requirements of EEA legislation.

Regarding Recommendation No 12, recent MAST findings of a producer deliberately and intentionally placing on the market LBMs harmful to consumer health and of LBMs being placed on the market by a producer who does not hold a valid harvesting authorisation confirm that the CAs have not established a system of official controls sufficient to prevent such non-compliances. The CAs should ensure that, apart from checks on FBOs, a robust system of official controls is put in place to prevent products from production areas without valid harvesting authorisation being placed on the market.

Recommendation No 14 will not be closed until the CA ensures that the laboratory used for analysis of marine biotoxins performs its analyses in line with the requirements of EEA law and is able to provide reliable results.

7 Final meeting

A final meeting was held on 2 September 2022 at MAST's office in Hafnarfjordur with representatives from MAST and LCA. At this meeting, the audit team presented its main findings and preliminary conclusions in relation to which the CAs did not express any disagreement. The representatives of MAST stated that they would consider how to strengthen enforcement measures where non-compliance was detected.

8 Recommendations

No additional recommendations were issued as a result of this follow-up audit. Was invited to inform the Authority, by way of written evidence, of the additional corrective measures and actions taken to address the issues detected during the follow-up audit in relation to Recommendations Nos 11, 12 and 14 of the report from the 2019 mission and to ensure compliance with the relevant requirements of EEA law.

In order to facilitate the follow-up of the recommendations, Iceland should notify the Authority no later than **22 January 2023**, 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.

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

AHL	Animal Health Law
AOAC	Association of Official Analytical Chemists
CA	Competent Authority
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EU	European Union
FBO	Food Business Operator
LBM	Live Bivalve Mollusc
LCA	Local Competent Authority
MAST	Icelandic Food and Veterinary Authority
OMA	Official Methods of Analysis
PCB	Polychlorinated biphenyls
PSP	Paralytic Shellfish Poison
PTX	Pectenotoxins

Annex 2 - Relevant legislation

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

a) The Act referred to at Point 11b of Part 1.1. of Chapter I of Annex I to the EEA Agreement, Regulation (EU) No 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC, as amended and as adapted to the EEA Agreement by the sectoral and the specific adaptations referred to in Annex I and Annex II to that Agreement;

b) The Act referred to at Point 13 of Part 1.1. of Chapter I of Annex I to the EEA Agreement, Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law'), as amended and as adapted to the EEA Agreement by the sectoral and the specific adaptations referred to in Annex I to that Agreement;

c) The Act referred to at Point 11bk of Part 1.1. of Chapter I of Annex I to the EEA Agreement, Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls, as amended and as adapted to the EEA Agreement by the sectoral and the specific adaptations referred to in Annex I to that Agreement;

d) The Act referred to at Point 11bk of Part 1.1. of Chapter I of Annex I to the EEA Agreement, Commission Implementing Regulation (EU) 2021/1709 of 23 September 2021 amending Implementing Regulation (EU) 2019/627 as regards uniform practical arrangements for the performance of official controls on products of animal origin, 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 17 of Part 6.1. of Chapter I of Annex I to the EEA Agreement, Commission Delegated Regulation (EU) 2021/1374 of 12 April 2021 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin, 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 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 corrected, amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement, as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to that Agreement; and

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

Annex 3 – Comments provided by the CA in reply to the draft report

Comments to factual contents of the draft report, ESA Doc. 1315971 Attachment 1

Comments to Recommendation 12

MAST does not agree with the statement that the CAs have not established system of official controls sufficient to prevent products from production areas without valid harvesting authorization being placed on the market. System of official control can never fully prevent unsafe food on the market, the FBO is responsible and MAST or the LCAs are not controlling every batch that is placed on the market. Official control sometimes detects non-compliances by traceability checks back in time and such checks can result in actions against the FBO. MAST detected non-compliances last year and it resulted in withdrawal of approval of an establishment. MAST detected this year non-compliances of products that were on the market and it resulted in withdrawal from the market, a recall, and a further investigation of the case.

Comment for corrections in the FU draft report: In chapter 5.5 in the draft report, names of laboratories and research institutions are included. MAST believes they should be removed from the text and replaced with indications giving them anonymity**.**

Comment for correction in finding no. 15 in the FU draft report on PAHs:

In finding no. 15, third point, polycyclic aromatic hydrocarbons (Benzo(a)pyrene, benzo(a)anthracene, benzo(b)fluoranthene and chrysene) in LBMs exceed the maximum levels permitted under Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants ('Regulation (EC) No 1881/2006').

MAST does not agree with this statement.

Two samples of mussels analyzed 2019 were below the detection limit in both samples. Sum of all identified PAHs was 1,6ug/kg in one sample and inapplicable in the other samples. Benzopyrene was measured in one sample 2020 and it was below detection limit. Analysis results are in attachment 1, 1 a, 2, 2 a, 3 and 3 a. Samples for analysis of PAHs were not taken in 2021 or 2022. This will be corrected and compliance with point 6.1.6. in Regulation EC (no) 2006/1881 will be verified.

Annex 4 – Corrective actions to address the recommendations

TOC – 11.11.2022 Updated Table of corrective actions ESA follow up 2022 to evaluate official control of LBM.

No.	Recommendation from 2019	Conclusion of follow up 2022	Authority	Corrective actions	Date of compliance
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 (new legal reference: Article 59 of Regulation 2019/627)**	The audit team noted improvements in sampling and analyses of phytoplankton and marine biotoxins since the last audit. However, the fact that the system is relying on weekly analysis of phytoplankton and bi-weekly analysis of marine biotoxins can lead to a gap of up to 10 days between detection of phytoplankton in production and relaying areas and the results of samples for marine biotoxins in LBMs. During this interval, there is a risk that LBMs that are unsafe may be placed on the market. Another concern is that sampling for PSP marine biotoxins is undertaken only where levels of phytoplankton (Alexandrium) cells exceed the thresholds established in the monitoring programme, compromising the ability of the monitoring system to detect PSP toxic episodes. In addition, the sanitary survey and the monitoring programme are not representative of the area considered and geographical distribution of the sampling points is not defined. Recommendation No 11 cannot be closed until the CA takes actions to address these outstanding issues.		LBM from production areas have not been placed on the market since August. MAST is not aware of any plans of placing LBM on the market the next months. MAST will review the risk assessment. The aim is to review the frequency of sampling and analysis phytoplankton and marine biotoxins. MAST will collect information regarding the activities in production areas for LBM. The licences for productions areas will be reviewed and cancelled if no activity is ongoing. The need for sanitary survey in active production areas will be evaluated and as follows a sampling plan for monitoring of E.coli, Salmonella, heavy metals and PAHs with defined sampling points will be established.	01.05.2023 01.03.2023 01.05.2023
12	**The competent authorities should ensure that monitoring and sampling to**	Recent findings of a producer deliberately and intentionally placing on the market LBMs harmful to consumer health and of		According to regulation nr. 300/2018 a producer of LBM should notify MAST and	15.01.23

	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 (new legal reference: Article 59 of Regulation 2019/627)	LBMs being placed on the market by a producer who does not hold a valid harvesting authorisation confirm that the CAs have not established a system of official controls sufficient to prevent such noncompliances. If the CAs had taken adequate actions to address Recommendation No 12 following the report of the 2019 mission, these malpractices could have been prevented. The CAs should ensure that, apart from checks on FBOs, a robust system of official controls is put in place to prevent products from production areas without valid harvesting authorisation being placed on the market. Recommendation No 12 will remain open until the CAs ensure that effective measures are implemented to address it.		get a health certificate before LBM is moved from one production area to another area. This requirement will be introduced to the producers. If this requirement is fulfilled MAST should be aware of any movement of LBM from one area to another. MAST took the discussion of the control on the marked up with the LCAs at a meeting 31.10.2022. An email was sent to the LCAs 04.11.2022 to make them aware of the situation regarding LBM on the market, see attachment 4. Guidance on control on the market will be improved and training will be organised.	05.11.22 30.03.23
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 lipophilic, PSP and ASP toxins, as required by Regulation (EC) No 882/2004, Article 12, point 2 (a). (new legal reference:**	The credibility of the results provided by the accredited laboratory analysing marine biotoxins (for both for lipophilic and PSP toxins) is compromised by certain non-compliances and the inconsistent results of the last proficiency tests. The CA should take actions to ensure that the laboratory used to analyse marine biotoxins provides reliable results and takes corrective actions to improve its performance. Recommendation No 14 can only be closed after the necessary correction actions have been taken		The CA has contacted the NRL in Iceland and the work has started to solve these issues. The annual meeting held by the EURL for MB was held in October, and there it was clear that several labs had less than ideal results on the PT test. The EURL will issue recommendation to improve the testing results and some training for these labs, including the one testing the Icelandic samples. There is also ongoing discussion about the methods used by labs at EURL level and the NRL will follow these discussions.	Update 28.02 2023 Compliance 15.05.2023.
	Articles 37(4)(e) and 100(2) of Regulation 2017/625).			Currently, no areas are open for harvesting and no producer has showed an interest in harvesting license during this winter. Therefore, the plan is to follow up on the status at the Swedish lab in 3 months, and then estimate the need to contract another lab for the analysis of the Icelandic samples in the next season.	