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Final report
EFTA Surveillance Authority's audit to
Iceland
from 9 to 18 May 2022
to verify compliance with the applicable EEA food safety legislation governing the
production of fishery products, including fish oil for human consumption, and the
implementation of official controls thereon

In response to information provided by Iceland, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote. Comments from Iceland to the draft report and information on the corrective actions already taken and planned are included in Annex 3.

Executive Summary

This report describes the outcome of an audit carried out by the EFTA Surveillance Authority in Iceland from 9 to 18 May 2022 concerning official controls to verify compliance with requirements of European Economic Area ('EEA') legislation relating to fishery products.

The objective of the audit was to verify compliance with the applicable EEA food safety legislation governing the production of fishery products, including fish oil, and the implementation of official controls thereon.

The audit team found that the relevant EEA legislation has been incorporated into the national legislation. The competent authority is clearly designated and has the relevant powers to enforce the EEA legislation. A risk-based system for official controls of fishery products has been established.

In general, the official controls system is consistently and adequately implemented and covers the fishery products production chain from catch to final product. However, a lack of control of landing sites and the absence of registration of such sites was observed. Related to that was a finding that the list of registered vessels managed by MAST was not in line with the list of licenced vessels managed by the Directorate of Fisheries.

Procedures for undertaking official controls of fishery products have been established in most cases, which, in general, enable competent authority staff to undertake such controls in a consistent and harmonised manner. However, the competent authority should ensure that all relevant official controls are carried out and documented.

Approval and enforcement were generally undertaken in a proper and consistent manner. However, the competent authority should ensure that the established approval procedures are adhered to and improved where necessary.

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 audit took place in Iceland from 9 to 18 May 2022 and was undertaken as part of the EFTA Surveillance Authority ('the Authority')'s work programme. The audit team comprised two auditors from the Authority.

A pre-audit questionnaire was sent by the Authority to the Ministry of Food, Agriculture and Fisheries ('the Ministry') on 21 February 2022. A reply ('the pre-audit document') was provided by the Ministry on 11 April 2022.

The opening meeting was held with representatives of the competent authority, the Icelandic Food and Veterinary Authority ('MAST'), on 9 May 2022 at MAST's head office in Selfoss. At that meeting, the audit team confirmed the objectives of, and itinerary for, the audit and requested additional information required for its satisfactory completion. The system for risk-based official controls of fishery products and the handling of non-compliances was presented to the audit team.

Throughout the audit, representatives from MAST accompanied the audit team. Representatives of MAST responsible for different regions participated during meetings and visits to the different establishments.

A final meeting was held at MAST's Hafnarfjörður office on 18 May 2022 at which the audit team presented its main findings and preliminary conclusions.

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

2 Objective and scope

The objective of the audit was to verify compliance with the applicable EEA food safety legislation governing the production of fishery products, including fish oil, and the implementation of official controls thereon.

In terms of scope, the audit focused on the organisation and performance of the relevant competent authority and the official controls system in place covering production, processing and distribution of fishery products placed on the market. Relevant requirements of EEA legislation referred to in Annex 2 were relied on as the legal basis for the audit.

The evaluation included gathering relevant information and appropriate verifications, by means of interviews/discussions, review of documents and records 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.

Meetings with the competent authorities and Food Business Operator ('FBO') site visits during the audit are listed in Table 1.

Table 1. Authorities and FBO sites visited by the audit team

| Authorities or FBO sites | Number of CA/FBO sites visited | Details |
|----------------------------------|--------------------------------|---|
| Competent authorities | | |
| Central level | 3 | Opening and closing meetings and one further meeting with MAST to discuss selected topics |
| Land based establishments | | |
| Processing plants | 9 | Producers of crude fish oil, fresh and frozen fishery products, salted fishery products and smoked ready to eat fishery products. |
| Cold stores | 1 | For frozen fishery products |
| Auction hall | 1 | Auction hall for iced fishery products |
| Landing sites | 5 | Landing sites in different locations |
| Fishing vessels | | |
| Factory vessel | 1 | Headed, gutted and filleted frozen fishery products |
| Registered vessel (not approved) | 1 | Gutted and iced fishery products |

3 Legal basis

The audit was carried out under the general provisions of the EEA legislation and, in particular, Articles 116, 117 and 119 of Regulation (EU) 2017/625.

Full legal references to EEA legal acts quoted in this report are provided in Annex 2.

4 Background

4.1 General background

The last audit by the Authority concerning hygiene of fishery products in Iceland was carried out between 19 to 23 October 2015. Following that audit, nine recommendations were issued to Iceland. These were subsequently closed, following corrective actions taken by the competent authority.

The present audit allowed the Authority to evaluate whether these corrective actions have sufficiently addressed the recommendations from the previous report. The final report from the 2015 audit can be found on the Authority's website (www.eftasurv.int).

4.2 Production and trade information

Iceland is a substantial producer of fishery products. For the last twenty years, annual export volumes have been between 600,000 and 800,000 metric tonnes. The total export volume in 2020 was 604,000 metric tons. The main demersal species fished are cod and

cod related species such as saithe and haddock. The main pelagic species fished are herring, mackerel, capelin and blue whiting.

The biggest export markets for Icelandic fishery products are the United Kingdom, the United States, China and certain Member States of the European Union ('EU'), including France, Spain, Denmark, Belgium and the Netherlands.

The number of establishments and vessels approved and/or registered according to relevant EEA requirements in 2020 is provided in Table 2.

Table 2. Approved establishments and registered vessels

| Type of FBO | Number in 2020 |
|------------------------------|-----------------------|
| Processing plants | 223 |
| Fresh fishery product plants | 11 |
| Auction halls | 28 |
| Freezer vessels | 3 |
| Factory vessels | 15 |
| Registered vessels* | 1,547 |

*Not including approved vessels (data from May 2022, www.mast.is)

4.3 Rapid alert system for food and feed ('RASFF') notifications

From the start of 2019 to the end of 2021, there were four RASFF notifications concerning fishery products from Iceland; zero in 2019, three in 2020 and one in 2021. These RASFF notifications concerned the following:

- *Listeria monocytogenes* in smoked salmon: one in 2020
- parasites in cod (*Anisakis*): two in 2020 and one in 2021

5 Findings and conclusions

5.1 Legislative and implementing measures

Legal Requirements

Article 7 of the Agreement on the European Economic Area ('EEA Agreement')

Article 8 of Regulation (EC) No 852/2004

Findings

1. According to information provided in the pre-audit document, the Ministry is responsible for implementation and application of EEA legislation relating to the production of fishery products, including fish oil.
2. The pre-audit document contained links to the national laws and administrative provisions implementing EEA legislation concerning the control and monitoring of the production, processing and placing on the market of fishery products.
3. Mátis ohf. (Food research institute in Iceland) has issued guidance on Hazard Analysis and Critical Control Points (HACCP) systems for seafood production as well as more specific guidance concerning different types of fishery products (<https://matis.is/midlun/handbaekur/>). However, the HACCP guidance has not been assessed by Iceland as required by Article 8(3) of Regulation (EC) No 852/2004.
4. National measures have been established concerning, for example, traditional drying of fish outdoors, production of fermented shark and the definition of marginal, local and limited retail activity (Regulation (IS) 856/2016). The Authority notes that Regulation (IS) 856/2016 has not been notified to the Authority under the EEA hygiene regulations.

Conclusions

5. The relevant EEA legislation concerning production and placing on the market of fishery products has been made part of the Icelandic internal legal order in line with Article 7 of the EEA Agreement.
6. The Icelandic Government does not have in place a system for evaluating national guidance available for producers of fishery products in Iceland, consequently its uncertain whether national guides comply with relevant EEA provisions.

5.2 Competent authorities

Legal Requirements

Articles 4, 5, 6, 8, 9, 11, 12, 28 to 33, 78 and 137 to 139 and Annex II to Regulation (EU) 2017/625

Findings

5.2.1 Designation of competent authority and operational criteria

7. MAST is the designated competent authority responsible for official controls concerning the safety of fishery products, including fish oil for human consumption and for feed use.
8. MAST began implementing changes to the organisation of official controls in this area on 1 October 2021. New operational divisions were established and others were changed. The process is still ongoing but is expected to be finalised by the end of 2022.

9. The competent authority has not delegated any official control tasks or other official activities concerning fishery products to delegated bodies or natural persons.

5.2.2 Powers, independence and supervision of the competent authority

10. MAST staff have the necessary powers to enter vessels, establishments and premises to carry out official controls (audits, inspections, sampling) and to impose, where necessary, enforcement measures. This is defined in the Icelandic Food Act No. 93/1995.
11. The independence of staff carrying out official controls is stipulated in the Icelandic Administrative Procedures Act No. 37/1993.
12. MAST has an internal audit unit that carries out internal audits of different MAST processes and procedures. The last internal audit concerning official controls of fishery products took place in 2019.
13. The Authority's audit team noted that the resulting internal audit report were detailed and that the internal audit process was well supported by relevant procedures and guidelines.

5.2.3 Resources

14. In 2021, there were five full-time equivalent inspectors and one supervisor at MAST carrying out official controls of fishery product production establishments, including fish oil producers, and approved and registered vessels. During the summer months, three additional inspectors are available for official controls of registered vessels.
15. The risk-based system in use for official controls of fishery products calculates the number of hours required for inspections of relevant approved establishments (land based and vessels) (see Chapter 5.4.1). Table 3. shows the number of each different type of approved FBO and the number of official controls of each type during 2020.

Table 3. Number of FBOs and official controls carried out in 2020

| Type of FBO | Number in 2020 | Number of official control/inspections in 2020 |
|---------------------------------|-----------------------|---|
| Processing plants | 223 | 482 |
| Fresh fishery production plants | 11 | 24 |
| Auction halls | 28 | 48 |
| Freezer vessels | 3 | 5 |
| Factory vessels | 15 | 12 |

16. Most of the establishments visited were in performance Category A (see Chapter 5.4.1, paragraph 60). Category A establishments producing fresh and/or frozen fishery products which are classified as large (producing between 1,000 to 10,000 metric tonnes of fishery products a year) will normally be the subject of seven hours of official controls annually, amounting to two inspections a year.

17. MAST bases the inspection frequency of registered vessels on the size of the vessels. Table 4. shows the size categories, the determined inspection frequency and number of vessels for each size category in May 2022.

Table 4. Categories of registered vessels, inspection frequency and number of vessels in 2022

| Size (gross tonnage) | Inspection frequency | Number of vessels |
|-----------------------------|-----------------------------|--------------------------|
| <15 | Once every three years | 1,244 |
| 15 – 249 | Once every two years | 157 |
| 250 – 1000 | Once a year | 83 |
| >1000 | Once a year | 63 |
| Total | | 1,547 |

18. For each year from 2017 to 2020, there were approximately fifteen inspections of registered vessels annually. The competent authority has in the last two years focused more on registered vessels. In 2021, three hundred and seventy-two (372) inspections were undertaken and, as of April 2022, nineteen vessels have been inspected (most vessel inspections are carried out during the summer months).
19. The audit team noted that the competent authority is able to carry out official controls of approved establishments according to the risk-based system. However, the competent authority has not been able to meet the target number of inspections for registered vessels. The audit team noted that certain vessels exceeding 1,000 gross tonnes had not been inspected annually during the period from 2018 to 2022, contrary to Iceland's risk-based system for official controls of fishery products and Article 9(1) of Regulation (EU) 2017/625.

5.2.4 *Training and knowledge of staff performing official controls*

20. MAST has procedures in place for training MAST staff and to ensure that they are competent to fulfil MAST's objectives. Every employee receives an initial 'newcomer' training and theoretical training with relevance to their background and role in the organisation. Staff carrying out official controls are trained by experienced inspectors before being allowed to carry out official controls on their own.
21. A system for online training Cloud Compliance and Quality ('CCQ') is currently being implemented to manage the training of all MAST employees. The system will help to map the training, skills and knowledge of staff. It contains different modules for initial training and will be accessible to all employees.
22. The audit team noted that newly recruited inspectors receive a varied training, including training in health claims, pest control, the official controls regulation (Regulation (EU) 2017/625) and organoleptic procedures. Staff are encouraged to take part in Better Training for Safer Food training courses organised by the European Commission.

23. The audit team noted that staff demonstrated good knowledge and understanding of the different fish processing establishments visited. However, in some cases, a more detailed understanding, and the experience to carry out audits, of HACCP systems was lacking (see Section 5.4.4, paragraphs 73 and 74).

5.2.5 *Transparency and confidentiality*

24. Results of official controls, surveillance programmes and other official control activities are reported on annually by MAST.
25. According to the Icelandic Administrative Procedures Act No. 37/1993, inspectors are obliged to maintain confidentiality in relation to information obtained through the performance of their duties.

5.2.6 *Documented control procedures*

26. MAST has numerous documented methodological procedures and guidelines in place to assist inspectors carrying out official controls and other official activities in relation to fishery products. These procedures include instructions on how to carry out official sampling, general guidance on how inspections should be carried out and procedures for approval of establishments. These procedures are kept updated and are available to all inspectors. MAST has published an inspection manual (Skoðunarhandbók-Leiðbeiningar. Matvæli úr dýraríkinu, LBE-008) that is the basis for inspections of establishments producing food of animal origin.

5.2.7 *Control activities, methods and techniques*

27. Official controls are usually performed without prior notification. However, in some cases, particularly where travel time to the relevant FBO is substantial, prior notice may be given to ensure that relevant FBO staff will be present. Audits and inspections are usually carried out by a single inspector.
28. The competent authority applies different official control methods such as verification, inspection, audit, monitoring, surveillance and sampling (see sections 5.3.1 and 5.4).

5.2.8 *Cooperation and coordination*

29. There are five inspectors responsible for official controls of fishery products. The main tool for coordination and harmonisation between the inspectors is the inspection manual (LBE-008) which contains a detailed description of the items that each inspector should cover in establishments within the relevant inspection period.
30. Opportunities for *ad hoc* informal meetings of inspectors with their supervisor are established to enable inspectors to discuss various subjects and obtain a common understanding of how to approach certain issues. Meeting minutes of topics discussed are kept.
31. Harmonisation between the inspectors is also achieved by joint inspections and by inspectors auditing establishments assigned to other inspectors.

32. The audit team noted, however, that many tools used by the competent authority for coordination and harmonisation of official controls are not formalised in procedures or subject to other practices to ensure their consistency.
33. There is cooperation between MAST and the Directorate of Fisheries ('the Directorate'). Inspectors from the Directorate carry out temperature checks of landed catches from smaller vessels, mainly in the summer months. These results are shared with MAST, however no official reports are written (see also paragraph 65). Although there has been an agreement between MAST and the Directorate in place since 2016 under which the Directorate could also undertake other relevant official controls, it has only undertaken temperature checks in recent years.
34. The audit team noted that there was a lack of cooperation between MAST and the Directorate when it comes to maintaining an accurate list of registered vessels. Registration on the Directorate's list is a pre-condition for being licensed to fish commercially in Icelandic waters, however, MAST's list of registered vessels has not been updated regularly or compared to the Directorate list (see also paragraph 52).

5.2.9 Enforcement measures

35. The competent authority has issued guidelines (VRF-022 – Beiting þvingunarúrræða – Matvæli og fóður) for the use of enforcement measures following official controls setting out the types of enforcement measures available to inspectors. These include withdrawal of approval, temporary closure of premises, withdrawal/recall of products and daily fines.
36. Enforcement action taken by the competent authority and observed by the audit team was generally appropriate and timely. The audit team noted that the competent authority uses escalating enforcement measures¹, e.g. it was observed that non-compliances that had not been rectified within a given deadline were reclassified to serious non-compliance with a seven day deadline for carrying out corrective action. The audit team observed that decisions were issued within specified deadlines and that follow-up actions were taken by the competent authority to ensure that non-compliances had been remedied.

Conclusions

37. The resources available for official controls of fishery products are in general sufficient to enable inspections to be undertaken according to the frequency established under the risk-based system. However, the competent authority does not meet its own target inspection frequency based on the risk-based system for registered vessels. This leads to some vessels not being inspected as required and an increased risk that unsafe fishery products are being placed on the market.
38. MAST inspectors demonstrated a good understanding of the fish establishments and fishing vessels visited. However, lack of sufficient training in HACCP audits increases the likelihood that incomplete or partially functioning HACCP systems

¹ In reply to the draft report the Icelandic CA clarified that procedures are in place in case the auditee does not rectify/implement corrective actions within the time frame given.

are permitted to operate and that unsafe products may consequently be placed on the market.

39. There are relatively few inspectors responsible for official controls of fishery products. Coordination and harmonisation between them could be improved by formalising some of practices currently used by the competent authority for this purpose.
40. The agreement between MAST and the Directorate gives MAST an access to qualified staff and inspectors that are more often present during landings and onboard different types of vessels. However, the agreement has not been fully utilised to have better official control of vessels, landings and landing sites.

5.3 Registration/approval of food business operator establishments

Legal Requirements

Article 6 of Regulation (EC) No 852/2004 of the European Parliament and of the Council

Article 4 of Regulation (EC) No 853/2004 of the European Parliament and of the Council

Article 10(2), 138(2)(j) and 148 of Regulation (EU) 2017/625

Article 69 of Regulation (EU) 2019/627

Findings

5.3.1 Approval of establishments

41. The competent authority has developed documented procedures for approval of establishments which describe the approval process from application to final approval decision.
42. Applications for approval must be submitted electronically and accompanied by blueprints showing flow of production, staff, the position of the main production equipment, a draft of the HACCP system, documentation concerning water quality (if own water source) and other relevant documentation (production volumes and so on).
43. New establishments generally receive initially a time limited conditional approval in accordance with Article 148(4) of Regulation (EU) 2017/625. The conditions for obtaining conditional approval are that infrastructure and equipment fulfil applicable regulatory requirements, safe production of food is ensured and that other relevant requirements will be met during the conditional approval period.
44. The maximum conditional approval period is generally three months, subject to extension by another three months. For freezer and factory vessels, the corresponding period is six months, subject to extension by another six months. Establishments which do not obtain final approval, or which are not granted an extended conditional approval period, may not continue producing food.

45. Notwithstanding the above-mentioned procedures, in one case it was observed by the audit team that an establishment received conditional approval with some structurally related issues still outstanding. A year later, after having received the final approval, the same structural issues had not been fixed, contrary to Article 148 (4) of Regulation (EU) 2017/625.
46. In another case observed by the audit team, a newly approved establishment producing ready-to-eat food was granted final approval without a review of the establishment's HACCP system to verify compliance with HACCP requirements having taken place, contrary to Article 148 (4) of Regulation (EU) 2017/625.
47. Major changes (new production facilities, new equipment and new products) may require a new audit. In such cases, the relevant FBO is required to register an application for the change through the application platform on the competent authority's webpage. MAST staff evaluate in each case the need for a new approval and an on-site visit. However, there are no guidelines on what is considered a major change.
48. The audit team noted that not all changes to approved establishments were duly registered with the competent authority in this way.
49. In one establishment visited by the audit team, a new room had been built around a roe processing line. The room was connected to a Category 3 animal by-product (ABP) production establishment and there were no facilities for changing into working clothes or for handwashing. The competent authority had not visited the establishment to inspect and approve the change in production facilities before the production of roes started.
50. The audit team noted that one FBO had recently moved activities from several locations to one location. No inspection or audit on behalf of MAST had taken place at the new centralised location to verify that the HACCP system and infrastructure requirements were met. The audit team noted that some parts of the HACCP system did not reflect the new infrastructure arrangements, contrary to the requirement of Article 148 (4) of Regulation (EU) 2017/625 that all relevant requirements of EEA food law be met in order for an establishment to be fully approved.

5.3.2 *Registration of vessels and other establishments*

51. MAST maintains a list of registered vessels to be inspected by the competent authority. The list is updated when inspectors carrying out official control of vessels at landing sites identify vessels not yet listed. However, the list is not synchronised with the list of licensed fishing vessels maintained and updated by the Directorate.
52. The audit team noted that there is a difference between the number of registered vessels on MAST's list for inspection and the number of vessels on the Directorate's list. MAST's list contained 1,547 registered vessels in May 2022. In contrast, the Directorate's list for 2019 to 2020 contained 1,151 vessels with a regular fishing licence and 1,015 vessels with a special fishing licence, constituting 2,166 registered vessels in total (some of the vessels with a special fishing licences may also have a regular fishing licence). A fishing licence is a prerequisite for a vessel to be able to catch fish in Icelandic waters. This contradicts the requirement of Article 10(2) of Regulation (EU) 2017/625 that the competent authority draw up and keep an up-to-date list of operators.

5.3.3 Approval of freezer and factory vessels

53. The number of approved vessels in Iceland in 2020 was eighteen, of which three were freezer vessels and fifteen were factory vessels.
54. The audit team visited one recently approved factory vessel. The inspector approving the vessel had followed the relevant procedures and final approval was granted only after the FBO had been able to demonstrate that all relevant EEA food law requirements were met, including that the HACCP system was functioning correctly, pursuant to Article 148(4) of Regulation (EU) 2017/625.

Conclusions

55. MAST has put in place documented procedures and guidelines for FBOs to follow when applying for approval of a new establishment or in the case of a major change to an approved establishment in order that MAST receives appropriate information to assess the FBO's compliance with relevant EEA law requirements.
56. The approval process was not always consistent with such documented procedures. There is therefore a risk that establishments are being granted conditional and full approval without all relevant infrastructure and/or equipment requirements having been met and/or being granted final approval without the establishment in question having a functional HACCP system.
57. Application for new approvals is well managed and applicants use the required competent authority web platform for applying. However, there are shortcomings in official controls undertaken to review changes (changes in processes, new equipment/facilities) to existing approved establishments. It has not been defined what constitutes a major change to an approved establishment requiring a further official control (audit or inspection) by the competent authority. This can lead to inconsistencies in the carrying out of such official controls, permitting establishments to remain approved whilst no longer meeting relevant EEA law requirements.
58. There is a difference in the number of registered vessels on the respective lists of MAST and the Directorate. Registration on the Directorate's list is a pre-condition for being licensed to fish commercially in Icelandic waters. It can therefore be concluded that MAST's list is not up-to-date with the result that non-listed registered vessels may not be subject to official controls by MAST.

5.4 Official controls of production and placing on the market

Legal Requirements

Articles 2(1)(h), 4 and 5 and Annexes I and II to Regulation (EC) No 852/2004

Article 3 and Section VIII of Annex III to Regulation (EC) 853/2004

Article 13(1) of Regulation (EU) 2017/625

Article 67(a) of Regulation (EU) 2019/627

Article 3 and Chapter 1. of Annex I to Regulation (EC) 2073/2005

Findings

5.4.1 *Official controls system in place*

59. The competent authority has developed an official control system based on the risk posed by, and the past compliance of, individual FBOs. The system was first introduced in Iceland in 2012 and reviewed in 2016 and takes into account three risk factors:

1. The type of production and the raw material that is processed;
2. The size of the company or the size of the production; and
3. The consumer group that the product is marketed for.

Points are allocated for each risk factor, the higher the total points the greater the perceived risk. The total risk points for the relevant establishment will determine the basic number of hours dedicated to official controls of that establishment annually. In addition to such basic number of hours, extra hours may be added depending on, for example, complexity of the production processes and/or the scope of labelling requirements. The system does not define what official control methods should be used.

60. There are three performance categories: A, B and C. These categories reflect the previous compliance history and the perceived capability of the establishment to ensure safety of food production. Category C relates to establishments perceived to carry the most risk, Category A the least. The categories have multipliers that determine the total number of hours dedicated to official controls: A = 0.5, B = 1.0 and C = 1.5. All new establishments are in category B. For example, if the basic number of official control hours *per annum* is fourteen hours, an establishment in category A would be subject to seven hours of official controls a year, a category B establishment would be subject to fourteen hours and a category C establishment would be subject to twenty-one hours.

61. There is a system for recategorising establishments where appropriate. Although several criteria are listed as being potentially relevant when considering recategorisation, the audit team was informed that not all such criteria are considered in practice and that recategorisation to a lower category (for example, from B to C) occurs almost exclusively where serious non-compliance is detected at an establishment.

5.4.2 *Primary production*

62. The audit team visited one registered fishing vessel whilst it was landing fresh fish. The fishing vessels, production area, tubs and other equipment were in good hygienic condition.

5.4.3 *Landing operations, landing sites and first sale*

63. The audit team visited five landing sites. There was landing activity at three of these sites during the audit team's visit. One was receiving frozen products and two were receiving fresh, chilled fishery products.
64. The audit team noted that the landing sites are not registered by the competent authority as required by Article 10(2) of Regulation (EU) 2017/625 and that official controls of these sites are not carried out, contrary to Article 67(a) of Regulation (EU) 2019/627.
65. According to MAST, some official controls of landing operations are undertaken. However, there exist no written records of such official controls, contrary to Article 13(1) of Regulation (EU) 2017/625.
66. The audit team noted that the landing operations were generally undertaken quickly and tubs with chilled fresh fishery products were transferred onto a truck or into an establishment without delay. Frozen products were moved directly from landing into a covered area and from there directly into freezer containers. However, at one landing site the audit team observed many tubs unloaded from a vessel standing unprotected on a pier, permitting seagulls unhindered access to the fish in the tubs. These practices are contrary to the requirements laid down in Article 4 and Point 4.(f) of Section II. of Part A of Annex I to Regulation (EC) 852/2004 and Article 3 and Point 1(b). of Chapter II of Section VIII of Annex III to Regulation (EC) 853/2004.
67. The audit team visited one auction hall. General hygiene was in good order and fish waiting to be transported to the buyer was kept on ice.

5.4.4 *Facilities handling fishery products, including vessels*

68. The risk-based system for approved land-based establishments and vessels applies the same risk principles to both types of establishment. According to Table 3 (see Section 5.2.3, paragraph 15.), most of the approved establishments are inspected once a year.
69. Inspection reports were available in all of the approved establishments (including vessels) visited and all such establishments had been subject to at least one inspection in the last twelve months. The inspection reports by the competent authority did not in all cases reflect the findings by the audit team.
70. The audit team visited one factory vessel producing frozen fishery products. The vessel had a well-developed HACCP system and could provide evidence of control of their product, temperature in storage area and use of additives for frozen redfish. This had been verified by MAST in previous official controls.
71. The audit team observed that FBOs producing frozen products from species sensitive to histamine formation took samples for analysis pursuant to Article 3 and Chapter 1. of Annex I to Regulation (EC) 2073/2005.
72. In some establishments visited, the audit team observed practices that were not in accordance with Article 4 and Chapter I of Annex II to Regulation (EC) 852/2004.
 - a) In one establishment, hot smoked ready-to-eat products were kept in the same cooler as the relevant raw material with no separation between the

raw material and the finished, unpacked product. This had not been addressed in the approval process for the relevant establishment.

- b) In the same establishment, trays used for unpacked finished products were stored on the floor and the audit team observed that these trays were subsequently stacked upon top of each other with the unprotected product in contact with the bottom of the tray that had been on the floor.
- c) In another establishment, the audit team observed fish that had fallen off the production line onto the floor being picked up and placed directly back on the production line.
- d) In another establishment, rooms filled with packaging material and other material relevant (and not relevant) for the production prevented effective cleaning and pest control of these areas.
- e) In another case, the audit team observed cleaning of the floor of the premises with high-pressure hoses next to unprotected products.

Point b, c, d and e were addressed by the inspectors from MAST at the time of the visits.

- 73. In another establishment producing ready-to-eat food, information concerning the HACCP system was inconsistent, one document describing five Critical Control Points ('CCPs') and another document describing only four. Documentation of controls of the CCPs was not carried out in accordance with the relevant procedures laid out in the HACCP system. This had not been identified by the competent authority and is contrary to the requirement under Article 5(1) and 5(2)(d) of Regulation (EC) 852/2004 that FBOs both establish and implement effective monitoring procedures at CCPs.
- 74. In two establishments visited by the audit team, the hazard analysis underlying the HACCP system did not take into account the risk of injection of brine into the fish muscle with metal needles. Some of the needles in the two injection machines inspected were bent or broken. Neither was the use of additives in the brine used for injecting fish products considered in the hazard analysis. This is contrary to the requirement under Article 5(1) and 5(2)(a) of Regulation (EC) 852/2004 that all relevant hazards be identified. Neither did MAST inspectors consider these hazards during official controls of the relevant HACCP systems.
- 75. In two establishments visited, significant amounts of water on the floor created a cross contamination risk by flowing/splashing into clean tubs used for products. The drainage system had insufficient capacity to drain the excess water from the production area, contrary to Point 3. of Chapter IX of Annex II to Regulation (EC) 852/2004.
- 76. One FBO visited by the audit team did not maintain production records of amounts of sugar and salt used in the production of sugar and salted roes. The relevant FBO was not able to present any hazard analysis of the roe production at the time of the audit. MAST had not identified the lack of hazards analysis during official controls.
- 77. The audit team also visited two establishments using clean seawater for the production of fishery products. Although both establishments were monitoring the microbial quality of the seawater, no monitoring to detect harmful substances or toxic marine plankton in the seawater was undertaken and this had not been

identified by the competent authority in previous inspection reports. This is contrary to both Article 2(1)(h) of Regulation (EC) 852/2004 which defines “*clean seawater*” as “*seawater that does not contain micro-organism, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food*” and Article 4 and Point 1.(b) of Chapter VII of Annex II to Regulation (EC) 852/2004 which provides that, where such water is used in relation to commercial activities after the stage of delivery of whole fish from landing vessel to production establishment, adequate facilities and procedures must be available to ensure that such use is not a source of contamination.

78. The audit team noted that handling of fishery products did not always fulfil the requirements for respecting the cold chain set out at Point 1. of Part A. of Chapter III of Section VIII of Annex III to Regulation (EC) 853/2004. More specifically:
- a) Off cuts of fishery products intended for the production of minced fish products were not kept on ice.
 - b) Fishery products in one auction hall were not kept on ice.

The competent authority addressed these two issues at the time of the audit

79. The audit team observed that handling of by-products not intended for human consumption was not always in line with Chapter VI of Annex II to Regulation (EC) 852/2004 and this has not been identified in previous inspection reports by the competent authority. More specifically:
- a) In three establishments visited, identification of the tubs for storing Category 3 ABPs was neither clear nor permanent.
 - b) Outside one establishment, tubs labelled to be only used for food were being used for Category 3 ABPs.

5.4.5 Establishments producing fish oil intended for human consumption

80. The audit team visited two establishments producing fish oil intended for human consumption after refining. The Authority is handling the requirements for producing fish oil intended for human consumption in a separate case and sent 18 May 2022 a letter of formal notice to Iceland regarding incorrect implementation of EEA food hygiene requirements, and failure to undertake official controls, concerning fish oil.
81. The audit team confirmed that MAST carries out official control of the quality of the raw material used for the production of fish oil intended for human consumption. The production is seasonal and is solely from blue whiting (*Micromesistius poutassou*). The blue whiting is mainly caught during the winter and spring months but is used for production of fish oil for human consumption in November-December.
82. The audit team noted that the blue whiting did not always comply with the upper limit of 60 mg of nitrogen /100 g of whole fishery products for raw material that can be used for the production of fish oil for human consumption as defined in Article 70 and Chapter II (A)(1)(d) of Regulation (EU) 2019/627. This was not addressed/checked/controlled by the competent authority during the official controls.

Conclusions

83. Landing sites are not registered with the competent authority and are not subject to official controls. This increases the prospect of unsafe products passing through such landing sites not being detected.
84. Lack of documentation and planning of official controls of landing operations reduces the effectiveness and consistency of such controls.
85. Full compliance with Article 4 and Annex II to Regulation (EC) 852/2004 and with Article 3 and Annex III to Regulation (EC) 853/2004 was not always ensured, e.g. the storage of fishery products without ice, the incorrect handling of ABP products and process conditions that increase the risk of contaminations. This increases the possibility of unsafe fishery products being placed on the market.
86. HACCP systems visited generally complied with EEA legislation. However, the failure of certain FBOs to meet requirements concerning CCP monitoring procedures and identification of hazards and the absence of effective official controls of such requirements noted by the audit team indicate a lack of understanding of the requirements of Article 5 of Regulation (EC) 852/2004 by MAST staff. Lack of implementation of HACCP principles and insufficient official controls of such increases the possibility of unsafe fishery products being placed on the market.
87. Seawater is used in some establishments visited during the audit and this is common practice in larger pelagic freezing establishments in Iceland. The absence of required controls by FBOs of harmful substances or toxic marine plankton in such seawater increases the possibility of such seawater contaminating fishery products.

5.5 Official controls of fishery products

Legal Requirements

Articles 67 and 70 and Chapters I and II of Annex VI to Regulation (EU) 2019/627

Chapter V of Section VIII of Annex III to Regulation (EC) 853/2004

Findings

88. The audit team observed that official sampling of fishery products included analysis for contaminants (mercury, lead, cadmium, dioxins, PCBs and polycyclic aromatic hydrocarbons) and microbiological analysis (for example, *Listeria monocytogenes*), pursuant to Article 70(d) and (e) and Parts D. and E. of Chapter I of Annex VI to Regulation (EU) 2019/627.
89. The audit team saw no documented evidence that official controls of fishery products at establishments included organoleptic examinations or checks for parasites, contrary to Article 70(a) and (f) and Parts A. and F. of Chapter I and Chapter II of Annex VI of Regulation (EU) 2019/627.
90. Neither was there documented evidence in some of the establishments visited that FBOs were carrying out their own organoleptic checks or checks for parasites,

contrary to by Parts A. and D. of Chapter V of Section VIII of Annex III to Regulation (EC) 853/2004.

91. Official controls of fishery products reviewed by the audit team did include testing for histamine in the relevant fish species, pursuant to Article 70(c) and Part C. of Chapter I of Annex IV of Regulation (EU) 2019/627.
92. The competent authority does not undertake official controls of the requirements imposed on FBOs to ensure that seawater used in production of fishery products is clean and not therefore a source of contamination of such products (see Section 5.4.4, paragraph 76) , contrary to Article 67(b) and (c) of Regulation (EU) 2019/627.

Conclusions

93. The competent authority does not carry out all relevant official controls of fishery products required under Article 67, Article 70 and Chapters I and II of Annex VI to Regulation (EU) 2019/627. Neither do certain FBOs undertake required own organoleptic examinations or checks for parasites of fishery products. Both these factors increase the likelihood of unsafe fishery products being placed on the market.

5.6 Follow up of iRASFF notifications

Articles 50(5) of Regulation (EC) No 178/2002

Regulation (EU) 2019/1715

Findings

94. The competent authority has developed instructions to implement the RASFF system (including in relation to fishery products) established pursuant to Regulation (EC) No 178/2002 and further implemented by Regulation (EU) 2019/1715 laying down rules for the functioning of the information management system for official controls and its system components.
95. The audit team examined two of the RASFF notifications listed in Section 4.3 of this report more closely. RASFF NO 2020.3802 concerned *Listeria monocytogenes* in smoked salmon and RASFF No 2021.2245 concerned *Anisakis* in chilled cod fillets. The audit team found that the handling and follow up of these two cases was in accordance with the EEA requirements.

Conclusions

96. The arrangements developed and implemented by the competent authority for the follow-up of RASFF notifications are sufficient to ensure compliance with relevant EEA legislation.

5.7 Laboratories

Articles 34 and 37 of Regulation (EU) 2017/625

Findings

97. The competent authority has designated official laboratories to carry out the analysis of samples taken during official controls on fishery products, pursuant to Article 37 of Regulation (EU) 2017/625.
98. The official laboratory has an alternative method for histamine analysis compared to the analytical reference method provided in Article 5(1) and Annex I of Regulation (EC) 2073/2005. The method used is the official German method, LMBG L 10,00-5,HPLC (1999-1). This method has been validated in collaborative trial studies, however the audit team did not have the opportunity, during this audit, to verify if the alternative method had been validated against the analytical reference method, EN ISO 19343, pursuant to Article 5(5) of Regulation (EC) 2073/2005.

Conclusions

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| 99. The competent authority has designated official laboratories in accordance with Article 37 of Regulation (EU) 2017/625. |
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6 Final meeting

A final meeting was held on 18 May 2022 at MAST's office in Hafnarfjörður with the audit team and representatives from MAST and the Ministry. At this meeting, the audit team presented its main findings and preliminary conclusions from the audit.

At the meeting, the audit team also explained that, based on a more detailed assessment of the information received during the audit and any further information that the Icelandic Government may provide, additional findings and conclusions may be included in the report.

7 Recommendations

In order to facilitate the follow-up of the recommendations hereunder, Iceland should notify the Authority no later than 5 December 2022, 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. Iceland should also ensure that such corrective actions are designed in line with the outcome of the root cause analysis of the non-compliance.

| No | Recommendation |
|----|----------------|
|----|----------------|

| | |
|---|---|
| 1 | <p>The competent authority should ensure that the approval requirements for relevant establishments stipulated in Article 4 of Regulation (EC) No 853/2004 and Article 148 of Regulation (EU) 2017/625 are followed in all cases.</p> <p><i>Recommendation based on conclusions: paragraphs 56 and 57</i></p> <p><i>Associated findings: paragraphs 45, 46, 48, 49 and 50</i></p> |
| 2 | <p>The competent authority should ensure that it draws up and keeps an up-to-date list of all FBOs, including landing sites and registered vessels, pursuant to Article 10(2) of Regulation (EU) 2017/625.</p> <p><i>Recommendation based on conclusions: paragraphs 58 and 83</i></p> <p><i>Associated findings: paragraphs 51, 52 and 64</i></p> |
| 3 | <p>The competent authority should carry out official controls on a consistent and regular basis of hygiene practices and HACCP-based procedures in order to verify that FBOs observe such practices and apply such procedures properly and continuously, pursuant to Articles 4 and 5 and Annexes I and II to Regulation (EC) 852/2004 and Article 3 and Annex III to Regulation (EC) 853/2004.</p> <p><i>Recommendation based on conclusions: paragraphs 84, 85, 86 and 87</i></p> <p><i>Associated findings: paragraphs 64, 65, 66, 72, 73, 74, 75, 76, 77, 78, 79 and 90</i></p> |
| 4 | <p>The competent authority should ensure that official controls of fishery products include all the relevant elements laid down in Articles 67 and 70 and Chapters I and II of Annex VI to Regulation (EU) 2019/627, especially Points A. Organoleptic examinations and F. Parasites of Chapter I of Annex VI.</p> <p><i>Recommendation based on conclusions: paragraph 93</i></p> <p><i>Associated findings: paragraphs 89 and 92</i></p> |

Annex 1 - List of abbreviations used in the report

| | |
|--------|--|
| ABPs | Animal by-products |
| CCP | Critical Control Point |
| CCQ | Cloud Compliance and Quality |
| EC | European Community |
| EEA | European Economic Area |
| EU | European Union |
| FBO | Food Business Operator |
| HACCP | Hazard Analysis and Critical Control Point |
| iRASFF | Electronic system implementing RASFF |
| MAST | Icelandic Food and Veterinary Authority (Matvælastofnun) |
| MANCP | Multi Annual National Control Plan |
| PCBs | Polychlorinated Biphenyls |
| PSP | Paralytic Shellfish Poisoning |
| RASFF | Rapid Alert System for Food and Feed |
| RSW | Refrigerated Sea Water |

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 specific and the sectoral adaptations referred to in Annex I to that Agreement;
- b) 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 specific and the sectoral adaptations referred to in Annex I to that Agreement;
- c) The Act referred to at Point 13 of Part 7.1 of Chapter I of Annex I to the EEA Agreement, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to that Agreement;
- d) The Act referred to at Point 16 of 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 specific and 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, 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;
- f) The Act referred to at Point 52 of Part 6.2 of Chapter I of Annex I to the EEA Agreement, Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

- g) The Act referred to at Point 11bd. in Part 1.1 of Chapter I of Annex I to the EEA Agreement, Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation), as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to that Agreement.

Annex 3 - Corrective actions and comments to the draft report

TOC – Table of corrective actions ESA audit 2022 to evaluate official controls of fishery products.

| No | Recommendation | Responsible Authority | Corrective action | Date of compliance |
|----|--|-----------------------|--|--|
| 1 | <p>The competent authority should ensure that the approval requirements for relevant establishments stipulated in article 4 of Regulation (EC) No 853/2004 and Article 148 of Regulation (EU) 2017/625 are followed in all cases.</p> <p>Conclusions: 56, 57</p> <p>Associated findings: 45, 46, 48, 49 and 50</p> | MAST | <p>Presentation, review, and discussion of the approval procedure and eventually needs for changes in the procedure will be discussed with control personnel</p> <p>Procedures regarding approval of FBO will be revised if necessary.</p> <p>New chapter; Changes in food business (Breytingar á matvælafyrirtæki) will be added to the website: Stofnun matvælafyrirtækis.</p> <p>The new chapter will be presented for control personnel and on MAST's website.</p> <p>FBO's responsibilities to apply for changes of the approval will be presented to the FBOs during control visits.</p> | <p>30.11.2022</p> <p>31.12.2022</p> <p>30.11.2022</p> <p>31.12.2022</p> <p>From 01.01.2023</p> |
| 2 | <p>The competent authority should ensure that it draws up and keeps an up-to-date list of all FBOs, including landing sites and registered vessels, pursuant to Article 10(2) of Regulation (EU) 2017/625.</p> <p>Conclusions: 58 and 83</p> | MAST | <p>MAST will regularly or as needed get an updated list of registered vessels with fishing licence from the Directorate of Fisheries</p> <p>List of ports is available at https://hafnasamband.is/adildarhafnir/</p> <p>Most of the ports are landing sites. MAST will get overview</p> | 01.11.2022 |

| | | | | |
|----------|---|-------------|--|--|
| | <i>Associated: paragraphs 51, 52 and 64</i> | | of the landing sites by using this list. | |
| 3 | <p>The competent authority should carry out official controls on a consistent and regular basis of hygiene practices and HACCP-based procedures in order to verify that FBOs observe such practices and apply such procedures properly and continuously, pursuant to Articles 4 and 5 and Annexes I and II to Regulation (EC) 852/2004 and Article 3 and Annex III to Regulation (EC) 853/2004.</p> <p><i>Conclusions: paragraphs 84, 85, 86 and 87</i></p> <p><i>Associated findings: paragraphs 64, 65, 66, 72, 73, 74, 75, 76, 77, 78, 79 and 90</i></p> | MAST | <p>The findings made by ESA will discussed, with the control staff and senior officers and methods to improve the control discussed</p> <p>The aim to is to strengthen asap focus on good hygiene practice, temperature control and documentation of FBOs own checks of parasites and organoleptically checks in control visits.</p> <p>Internal HACCP training will be organised</p> | <p>30.09.2022</p> <p>15.12.2022</p> <p>30.01.2023</p> |
| 4 | <p>The competent authority should ensure that official controls of fishery products include all the relevant elements laid down in Articles 67 and 70 and Chapters I and II of Annex VI to Regulation (EU) 2019/627, especially Points A. Organoleptic examinations and F. Parasites of Chapter I of Annex VI.</p> <p><i>Conclusions: 93</i></p> <p><i>Associated findings: 89 and 92</i></p> | MAST | <p>MAST will draw up a plan of official control of fishery products for 2023-2025. The plan will cover official control of organoleptic examinations, freshness indicators, histamine, residues and contaminants, microbiological checks and parasites.</p> <p>Control project regarding checks on the hygiene condition of landing will be organised next year. The aim will be to map the situation during landing and define the responsibilities of the owners of the vessels / the fish and port authorities to ensure safe handling of fishery product during landing. If needed the results will be discussed with the port authorities and associations of FBOs.</p> | <p>31.12.2022</p> <p>31.12.2023</p> |

Comments to the draft report

MAST would like to make the following comment / clarification on point 36 on page 11 of the draft audit report: procedures are in place in case the auditee does not rectify / implement corrective actions within the time frame given. Please find more detailed information on this process in chapter 1.5 of the inspection manual „[Matvæli úr dýrarríkinu](#)“ depending on the nature of the on-compliance and/or lack of corrective actions.