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Final report

EFTA Surveillance Authority's audit to

Norway

from 7 to 16 March 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 Norway, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote. Comments from Norway to the draft report are included in Annex 3 and information on the corrective actions already taken and planned are included in Annex 4.

Executive Summary

This report describes the outcome of an audit carried out by the EFTA Surveillance Authority ('the Authority') in Norway from 7 to 16 March 2022 concerning official controls to verify compliance with requirements of European Economic Area ('EEA') legislation concerning 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 control of fishery products has been established.

In general, the official control system is consistently and adequately implemented and covers the fishery products production chain from catch to final product. However, the official controls are not always carried out in line with the frequencies established by the risk-based system.

Procedures for undertaking official controls of fishery products have been established in most cases, which, in most cases, enable competent authority staff to undertake such controls in a consistent and harmonised manner. However, audit and inspections of some more technical processes are not supported by procedures.

The competent authority has implemented a robust internal audit system to ensure continuous improvement of official controls. However, better defined procedures for follow-up of detected non-compliances would enhance the effectiveness of the internal audits.

Training is available to all relevant staff. However, there is no systematic evaluation of what training is needed. The audit team noted a lack of training staff in audits of HACCP based systems to improve the compliance of food business operators ('FBOs') with Hazard Analysis and Critical Control Point ('HACCP') requirements.

Procedures for approval and enforcement actions were established. However, the audit team observed several examples where the approval procedure was not followed by the officials.

Designation of laboratories in Norway generally meets the requirements of the relevant EEA legislation. The competent authority should, however, make sure that designated official laboratories situated in other EEA Member States have already been designated as an official laboratory by the competent authority in the relevant other EEA State.

The report includes a number of recommendations addressed to the Norwegian 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 Norway from 7 to 16 March 2022 and was undertaken as part of the EFTA Surveillance Authority ('the Authority')'s work programme. The audit team comprised three auditors from the Authority and an observer from the Directorate-General for Health and Food Safety of the European Commission ('DG Health and Food Safety').

A pre-audit questionnaire was sent by the Authority to the Ministry of Agriculture and Food on 5 January 2022. A reply ('the pre-audit document') was provided on 17 February 2022.

The opening meeting was held with representatives of the competent authority on 7 March 2022 at the head office of the Norwegian Food Safety Authority ('NFSA') in Oslo. 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 was presented to the audit team.

Throughout the audit, representatives from the NFSA's head office accompanied the audit team. Representatives of the NFSA from different regions and departments participated during meetings in the regions and visits to the different establishments.

A final meeting was held at the NFSA's head office in Oslo on 16 March 2022 at which the audit team presented its main findings and preliminary conclusion.

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 used 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 FBO site visits during the audit are listed in Table 1.

Table 1. Authorities and sites visited by the audit team

Authorities and site	Number of CA/sites	Details
Competent authorities		
Central level	3	Opening meeting/closing meeting, meeting with internal audit team
Departments	3	Departments in 2 different regions
Land based establishments		
Processing plants	8	Producers of crude fish oil, salted fish, stock fish, fresh and frozen fish products and a fish oil refinery.
Cold stores	1	For frozen fishery products
Landing sites	4	Landing sites connected to FBO visited
Fishing vessels		
Factory vessel	1	Headed and gutted frozen fishery products, cooked crustaceans
Laboratories		
Official control laboratory	1	Official and private samples

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 Norway was carried out between 16 to 25 March 2015. Following that audit, five recommendations were issued to Norway. 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

Norway is one of the largest producers of fishery products in the world. For the last twenty years, the annual catch has been between 2,200,000 and 2,700,000 metric tons. In the year 2021, the total wild catch was 2,566,952 metric tons. The main pelagic species fished are herring, mackerel, capelin and blue whiting. The main demersal species are cod and cod related species such as saithe and haddock.

The biggest export markets for Norwegian fishery products are China and certain Member States of the European Union ('EU'), including Denmark, Poland, Germany and the Netherlands.

The number of establishments and vessels approved and/or registered according to relevant EEA requirements in 2021 is provided in Table 2.

Table 2. Approved establishments and registered vessels

Type of FBO	**Number 2021**
Processing plants	586
Fresh fishery product plants	498
Cold stores	304
Freezer vessels	78
Factory vessels	273
Vessels (all)	5,633

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

From 2019 to the end of 2021, there were ten RASFF notifications concerning fishery products from Norway; five in 2019, two in 2020 and three in 2021. These RASFF notifications concerned the following:

- *Listeria monocytogenes*: three notifications (one each year)
- parasitic infestation (*Anisakis*): three (in 2019)
- PSP toxin: two (one in each of 2019 and 2021)
- heavy metals (arsenic): one (2021); and
- documentation missing: one (2020)

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 by the competent authority in the pre-audit document, the Ministry of Trade, Industry and Fisheries, the Ministry of Agriculture and Food and the Ministry of Health and Care Services are responsible for implementation and application of EEA legislation relating to the production of fishery products, including fish oil.

2. The competent authority provided links in the pre-audit document 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. No national guidelines concerning good practices for hygiene or application of the HACCP principles in relation to fishery products have been developed or implemented by any organisation of fishery products producers in Norway as encouraged by Article 8 of Regulation (EC) No 852/2004.
4. National measures have been established and notified as required by Article 7(3) of Regulation (EC) 2074/2005 to the Authority regarding traditional drying of fish outdoors.

Conclusions

5. The relevant EEA legislation concerning the production and the placing on the market of fishery products has been made part of the Norwegian internal legal order in line with Article 7 of the EEA Agreement.
6. In light of the importance of the Norwegian fishing industry, relevant organisations of fish producers should be encouraged to produce a national guide to good practices for hygiene and/or application of the HACCP principles in relation to fishery products pursuant to Article 8 of Regulation (EC) 852/2004.

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. The NFSA is the designated competent authority responsible for official controls concerning the safety of fishery products, including fish oil for human consumption.
8. The NFSA has recently undergone a reorganisation which became effective on 1 May 2021. The current structure of the NFSA can be seen in the organisational chart in figure 1.

9. The NFSA is organised into two administrative levels, the head office and the regions. The head office carries out directorate and governance tasks, such as interpreting legislation and developing control plans and surveillance programs. The

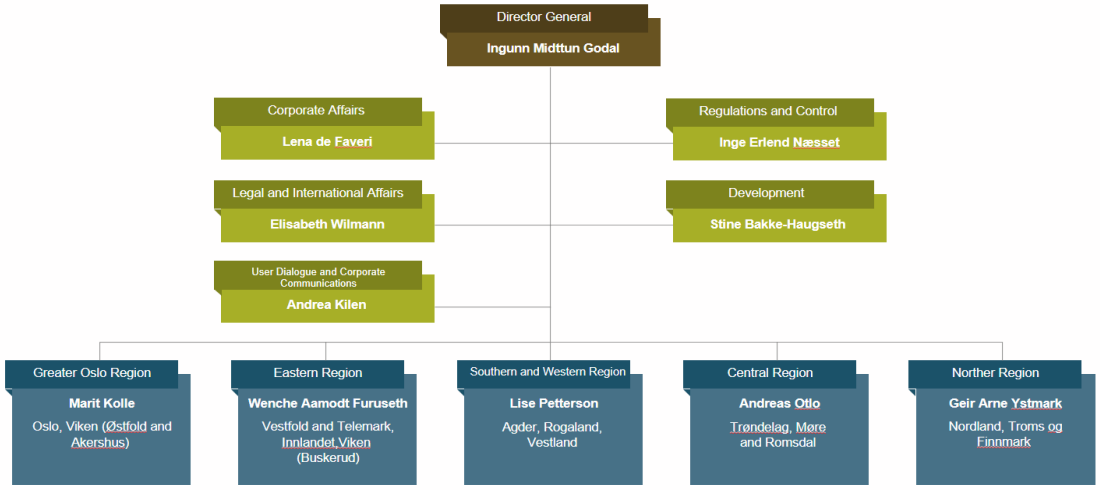

Figure 1. Organisational chart for the Norwegian Food Safety Authority as of 1 May 2021

regional level consists of five regions, with a total of 31 local departments responsible for official control activities and non-compliance decisions. Appeal cases of non-compliance decisions are considered by the head office.

10. There has been no delegation by the competent authority of official control tasks or other official activities to delegated bodies or natural persons concerning fishery products.

5.2.2 Powers, independence and verification of the competent authority

11. The NFSA staff have the necessary powers to enter vessels, establishments and premises to carry out official controls (audits, inspections, sampling) and impose, where necessary, enforcement measures (Matloven, LOV-2003-12-19-124).

12. The independence of staff carrying out official controls is stipulated in the Norwegian Public Administration Act (LOV-1967-01-10). Staff are obliged to inform their management of potential situations of conflict of interest. This is described in the ethical guidelines for NFSA staff.

13. The regions have control verification procedures in place. Inspection reports are reviewed by a team from the regional office established for that purpose. The supervisor will review the report in terms of enforcement measures and correct legal basis among other things. However, the verification procedures[1] failed to identify that the approval procedures had been incorrectly applied, contrary to Article 12(2) of Regulation (EU) 2017/625.

14. The head office has an internal audit unit that carries out internal audits of different NFSA processes and procedures. The last internal audit concerning official controls of fishery products took place in 2017.

[1] In reply to the draft report the Norwegian CA stated that it is not the responsibility of the regional team to identify whether the approval procedures have been applied. The case handler must ensure that relevant guidelines is followed before the inspection report is sent for review by the regional team.

15. The audit team noted that the internal audit reports were detailed and that the internal audit process was well supported by relevant procedures and guidelines.

16. The audit team noted that follow-up of some of the non-compliances identified in the internal audit report from 2017 had been slow and that the non-compliance investigation had taken a long time to close, two of the non-compliances were closed in January and September of 2020. One non-compliance investigation had still not been closed when the Authority began its audit. Article 6 of Regulation (EU) 2017/625 requires that competent authorities take appropriate measures in light of the results of such audits.

5.2.3 Resources

17. In 2021, there were around 37 full-time equivalent inspectors at NFSA carrying out official controls of fish production establishments, fish oil producers and vessels. The total number of establishments and vessels can be seen in table 2 in section 4.2.

18. In the regions visited, the inspectors carrying out official controls of fishery products are organised into teams. The degree of specialisation in each team varies from region to region. In one region, one team carries out all official controls related to fishery products, including import control on such products from third countries. In another region, there is one specialised team for marine ingredients and another for live bivalve molluscs.

19. The risk-based system in use for official controls of fishery products describes the frequency for inspections of relevant establishments (land based and vessels). The head office sets overarching risk classification criteria based on volume and type of production and establishes how to adjust the base frequency for official controls. The local departments further categorise the establishments in their geographical area on a risk basis, including adjustment of the frequency of official controls of establishments based on their compliance history.

20. The audit team noted that there was a different frequency of inspections for land-based establishments and factory vessels carrying out similar operations.

21. The risk-based system for fishery products has been used since 2020. According to the relevant documentation, the system is based on microbiological risk and does not include consideration of chemical risks. An initial risk assessment is used to draft an official control plan. That draft plan is reviewed in light of available resources and a final control plan is subsequently established.

22. The head office has issued guidelines on how official control resources should be allocated to between the different tasks. Approximately fifty percent of resources should be allocated to mandatory tasks (official controls of import/export, approvals and surveillance programs), twenty-five percent allocated for administration and twenty-five percent for risk-based controls.

23. In one department visited, the audit team was informed that sixty-seven percent of their total official control resources were allocated to mandatory tasks, including import control of fishery products (mainly Russian) at border control posts.

24. In one department, the audit team was informed that staff were unable to carry out official controls of factory vessels cooking crustaceans (shrimp) or producers of stock fish in line with the requirements of the risk-based system due to lack of resources.

25. In 2021, the total number of approved factory vessels was two hundred and seventy three (273) and the total number of approved freezer vessels was seventy-eight (78) (see Table 2. in Section 4.2). In 2019, no factory vessels were inspected[2]. In 2020, thirteen (~5%) such vessels were inspected but none in 2021. In 2019, no freezer vessels were inspected. One (~1%) was inspected in 2020 and three (~4%) in 2021. The general frequency of official controls of factory and freezer vessels is once every four years, unless the vessel is cooking crustaceans on board in which case an annual inspection is required.

26. Registered (primary production) vessels are not part of the risk-based approach. These vessels should be inspected at the same time as inspection of the landing site and the selection of vessels for inspection should be random. Registered vessels usually land their catch in the afternoon and evenings. The audit team was told that inspectors are generally not working at these times since it falls outside the office hours of the NFSA.

27. The number of vessels differs between regions. The total number of registered and approved vessels (including freezer and factory vessels) was five thousand six hundred and thirty three (5,633) in 2021. One region informed the audit team that the total number of registered vessels was around three thousand one hundred (3,100) in their region. During 2018 and 2019, there was an official controls campaign to inspect registered vessels in that region and the competent authority inspected three hundred and fifty two (352) vessels and two hundred and thirty-five (235) respectively. In 2020 sixty-eight (~2%) vessels were inspected and twenty-one (~0,7%) in 2021.

28. According to information received in the pre-audit document, the number of approved cold stores for fishery products in Norway was three hundred and four (304) in 2021. The number of official controls of such cold stores was five (~2%) in 2019, one (~0,3%) in 2020 and six (~2%) in 2021. The general frequency of official controls for cold stores according to the risk-based system should be once every four years.

5.2.4 Training and knowledge of staff performing official controls

29. The NFSA has procedures in place for training NFSA staff and to ensure that they are competent to fulfil the NFSA's objectives.

30. Training in the fishery products sector included additional training in relation to planned control-campaigns. The most recent covered relevant control templates, risk-based official controls and official controls of *Listeria monocytogenes* in ready to eat products and raw materials.

31. A system for online training ("RANSEL") containing different modules well suited for initial training is easily accessible to all employees. There was, however, a lack of systematic evaluation of training needs. Line managers discuss training needs with individual staff in their annual performance evaluation but there is no procedure for systematically gathering this information in order to inform the types of training needed more generally.

[2] In the reply to the draft report the Norwegian CA stated that the number of inspections indicated in ESA's draft report correctly reflects the CA´s reply to the pre-audit document, however the actual number of inspections carried out is higher. The numbers are generated from the reporting system (SAS) of NFSA, which has recently been replaced by a new reporting tool.

32. The audit team noted that mandatory trainings focused on general subjects, such as ethics or communication during official controls. Available courses in official control techniques, such as audits and inspections, were not mandatory for staff.

33. In one department visited, the line manager had made a course on the official control regulation (Regulation (EU) 2017/625) in RANSEL mandatory for the departmental staff. In the region, 13 of 20 inspectors involved in official controls of seafood had completed the course.

34. In the same department, the audit team observed that staff had been offered and completed specific training for auditing more technical FBOs, such as those producing marine ingredients.

35. The audit team noted that in some cases the knowledge and experience to carry audits of HACCP systems was insufficient. One of the findings from NFSA internal audits from 2017 was that lack of audits of FBOs contributed to FBOs' failure to establish HACCP based own check systems.

5.2.5 Transparency and confidentiality

36. Results of official controls, surveillance programmes and other official control activities are reported on annually by NFSA. The NFSA, in cooperation with other public health services, manages the website matportalen.no which contains information on various topics, including recall of products and contaminants in food.

37. According to the Norwegian Public Administration Act (LOV-1967-02-10), inspectors are obliged to maintain confidentiality in relation to information obtained through the performance of their duties.

5.2.6 Documented control procedures

38. The NFSA 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 approval procedures. These procedures are kept updated and are available to all inspectors. However, the audit team noted that for more technical and specialised audits (for example, for producers of marine ingredients, such as fish oil for human consumption) no specific guidance documents were available, contrary to Article 5(1)(a) and 12(1) of Regulation (EU) 2017/625.

5.2.7 Control activities, methods and techniques

39. 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 are usually carried out by two inspectors.

40. Fishery product establishments have been classified into different risk classes. Class 1 is the highest risk with a normal inspection frequency of twice a year. No frequency is set for Class 5 establishments (with the lowest risk), which are inspected only where there is suspicion of non-compliance. For each risk class, there are criteria which define the maximum and minimum inspection frequency. Establishments producing prepared and ready to eat fishery products with low risk

are classified into risk Class 2 with a minimum inspection frequency of once a year.

5.2.8 Cooperation and coordination

41. Cooperation and coordination between different parts and administrative levels of the competent authority is organised through procedures, meetings, guidelines and training.

42. The NFSA's head office issues templates for official controls with the aim of coordinating and harmonising official controls undertaken within the different regions.

43. Within each region are teams that work together on specific topics. There are regular meetings to coordinate and harmonise official controls within the regions. The audit team received meeting minutes from a regional forum on seafood and import at which different topics were discussed. Similar fora exist between the regions for the purpose of discussing and harmonising approaches. The NFSA confirmed to the audit team that, there is no overall overview of the topics discussed or conclusion reached in these meetings. Staff would need to consult minutes from meetings for information on past cases.

44. The audit team saw examples of good cooperation between regions. One region carried out an initial approval audit of a new factory vessel on behalf of another region. In another case were products unfit for human consumption had been identified on a transport vessel, effective cooperation between regions enabled coordinated enforcement actions to be carried out in different regions and departments.

45. However, the audit team detected shortcomings in the communication between the regions in both examples mentioned in the previous paragraph. The approval audit of the new factory vessel in the first region identified several shortcomings in relation to the HACCP system and noted that shrimps were processed on board. The second region did not take into account the identified shortcomings or include processing of shrimps within the scope of the approval (see also section 5.3.3). In the second case, a consignment of fishery products unfit for human consumption was identified onboard a transport vessel and the local department ordered it to be destroyed. The audit team saw no evidence of any follow up action towards the establishment of origin.

46. One establishment producing fish oil for human consumption which was subject to inspection by the competent authority in 2009 was not subject to another inspection until 2022 (two weeks before the visit of the audit team). This is contrary to Article 9 of Regulation (EU) 2017/625 which requires that all operators be controlled on a risk basis and with appropriate frequency, taking account of, *inter alia*, identified risks associated with goods, the activities under the control of operators and the use of materials that may influence food safety.

47. The audit team noted that in one case, where a study on contaminants in fish oil identified a product on the market with excessive levels of dioxins and dioxin-like PCBs, communication by the relevant competent authority to the department responsible for the production establishment in question was quick and without delay. However, there was no evidence of communication by the competent authority to the region where the supplier of the fish oil used in the product was based, contrary to Article 5(5) of Regulation (EU) 2017/625.

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5.2.9 Enforcement measures

48. The competent authority has issued guidelines for the use of enforcement measures following official controls which sets out the types of enforcement measures available to inspectors. These include guidance, withdrawal of approval, temporary closure of premises and withdrawal/recall of products.

49. The competent authority has also issued guidance concerning the FBO's duties under relevant legislation. Although it is not obligatory for FBOs to follow this guidance, the competent authority may refer FBOs to it in the case of minor non-compliances or where an FBO breaches the relevant legislation for the first time. In one region the NFSA explained that minor non-compliances may sometimes only be addressed orally and not in the written reports following official controls.

50. 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 measures. The team observed temporary closure of an establishment due to poor hygiene practices. The establishment was not re-opened until an on-site inspection had been carried out. Decisions were issued within specified deadlines and follow-up by the competent authority to ensure that non-compliances had been remedied was observed.

51. The audit team noted that, in the case of contaminants in fish oil, no-follow up at the place of origin had taken place to determine the possible other distribution channels of the oil and no enforcement actions were taken against the producer (or importer) of the raw material, contrary to Article 138 of Regulation (EU) 2017/625. Neither did the audit team see any evidence of enforcement or on-site follow up at the producer of the fish oil in question. Similarly, the audit team saw no evidence of enforcement action towards the establishment of origin of the consignment detained and destroyed (see paragraph 45).

Conclusions

52. The NFSA is designated as the competent authority for official controls throughout the fishery product supply chain. The organisation, powers of control and enforcement, documented procedures, staff training, impartiality and code of ethics permit implementation of official controls in accordance with EEA requirements.

53. The NFSA's internal audit system is a valuable tool for continuous improvement of the official control system and such audits have been carried out in the fishery products sector. However, insufficient follow-up of non-compliances detected during internal audits prevents timely closure of non-compliance investigations and implementation of corrective actions.

54. Cooperation and coordination between the NFSA's head office and its regional offices and between regions and departments was generally good. However, examples of insufficient communication and cooperation were seen where these shortcomings may have resulted in non-compliant products being marketed.

55. There is a training system in place to enable staff to carry out effective controls. However, due to a lack of some elements of the training, certain official controls were not performed consistently by staff. This included audits of HACCP systems which could contribute to the requirement for FBOs to have in place HACCP based own check systems not being met.

56. The risk-based system for official controls of fishery products has defined the frequency of inspections for different categories of establishments and product categories. However, some departments are unable to meet the required

	frequency of inspections due to insufficient allocation of staff resources.
57.	The competent authority has enforcement procedures in place and was able to demonstrate that follow-up action was taken when non-compliances were detected (for example, escalating enforcement measures).
58.	The competent authority applies different official control methods such as verification, inspection, audit, monitoring, surveillance and sampling.

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

Article 24(1)(a) of Regulation (EC) No 1069/2009

Findings

5.3.1 Approval of establishments

59. The competent authority has developed documented procedures for the approval of establishments *("Godkjenning – virksomheter for animalske næringsmidler" (Approval of establishments), case no. 2017/348, 5th edition, last amended 9 March 2022).* The procedures describe the approval process from application to final approval decision.

60. Applications for approval must be submitted electronically and accompanied by blueprints showing flow of production, staff and the position of main production equipment, a draft of the HACCP system, documentation concerning water quality (if own water source) and other relevant documentation (number of employees, production volumes and so on).

61. New establishments generally receive initially a time limited conditional approval. The conditions for obtaining conditional approval are that infrastructure and equipment fulfil applicable regulatory requirements in all main aspects, safe production of food is ensured and that the remaining requirements will be met during the conditional approval period.

62. 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. A list of approved establishments is available on-line and maintained as required by Article 10(2) of Regulation (EU) 2017/625.

63. In one of the regions visited the audit team saw good examples of the approval process, including request for information prior to on site visits and conditional approval being granted.

64. Notwithstanding the above-mentioned procedures, in one case observed by the audit team conditional approval was granted for three months (April-June) following an on-site visit in March (construction was still ongoing). No further official control was carried out within the three months and no prolongation of the initial three-month period was granted. Final approval was granted in September of the same year, in the sixth month after granting of conditional approval, contrary to Article 148(4) of Regulation (EU) 2017/625.

65. In another case observed by the audit team, an establishment was granted a new approval following change of ownership based on the previous owner's compliance record, without any approval application being submitted. The audit team also noted that the same establishment transported products to another unapproved site for freezing and storage. This step was not described in the HACCP system and the competent authority was unaware of it. The establishment also made use of two separate refrigerated sea water ('RSW') units, only one of which was registered by the competent authority.

66. Animal by-products ('ABPs') originating in several establishments were collected for silage production on-site. Notwithstanding their existing approval under Regulation (EC) No 853/2004 as a food business establishment producing fishery products for human consumption, these ABPs processing units were not also approved by the competent authority as required by Article 24(1)(a) of Regulation (EC) No 1069/2009 for the activity of ensilage of fish material, such activity being an alternative processing method pursuant to Point K. of Section 2 of Chapter IV of Annex IV of Regulation (EC) No 142/2011.

67. Major changes (new production facilities, new equipment, new products and new owners) may require a new approval. The competent authority evaluates in each case the need for a new approval and an on-site visit. According to the procedure for approval, new production facilities will always require an on-site visit.

68. In one processing plant observed by the audit team, construction of two new freezer rooms, a blast freezer and rooms for packing and production was being finalised. The representatives from the competent authority informed the audit team that an on-site visit to approve the extension was not required. The competent authority guidance on approval of establishments defines the conditions under which a change should be considered major and therefore requiring approval. A new building would require approval. There was no documented evidence of the assessment undertaken by the CA supporting the conclusion that the changes in the abovementioned facilities visited did not require an on-site visit and/or approval.

5.3.2 Registration of vessels

69. A list of registered vessels is maintained and updated by the Norwegian Directorate of Fisheries (Fiskeridirektoratet). The competent authority has access to that list.

70. The total number of all vessels (registered and approved) in Norway was five thousand six hundred and thirty-three (5,633) in 2021. The majority of the vessels are located in the northern region where around three thousand and one hundred (3,100) are registered or approved.

71. One region visited by the audit team carried out an official controls campaign on

registered vessels in 2018 and 2019. Table 3 below shows the number of inspections carried out in this region over a four-year period. The total number of registered vessels in the relevant region was around three thousand and one hundred (3,100) in 2021.

Table 3. Number of inspections of registered vessels

Year	Number of inspections
2018	352
2019	235
2020	68
2021	21

5.3.3 Approval of freezer and factory vessels

72. Different regions will on some occasions cooperate regarding the approval process for freezer/factory vessels since those vessels may not be available for inspection in the region where the vessels have their home base.

73. One region visited by the audit team carried out the on-site control of a newly built factory vessel and the inspection report was used by the approving department when issuing a conditional approval. The inspection report included reference to the need to position the sea water intake in accordance with relevant requirements. Contrary to Article 148 (4) of Regulation (EU) 2017/625, this issue was not followed up in the final approval, neither was an audit to verify the functioning of the HACCP system on-board undertaken prior to the approval.

74. The initial inspection report indicated that the factory vessel would be producing fresh and frozen headed and gutted fishery products as well as cooked and frozen shrimp. The official list of approved factory vessels places the vessel in category FV (Factory vessel). The NFSA confirmed that this was in line with instructions from the head office that the official list should only indicate FV and not reflect further details of production types onboard factory vessels. However, the department responsible for the approval and related official controls did also not include the cooking of shrimp in the scope of the approval or ensure that the relevant requirements of food law relating to such activities were met by the FBO, contrary to Article 148(3) of Regulation (EU) 2017/625.

75. Staff in the region where the vessel had its home harbour and where relevant official controls were undertaken were not aware of the fact that the vessel was approved for cooking crustaceans and molluscs. This was apparent from interviews and in the risk-based planning for official controls. According to the risk assessment of fishery products, the frequency of checks for a factory vessel cooking shrimp should be once a year but in this case it was once every four years.

Conclusions

76. The competent authority has put in place procedures and guidelines for FBOs to follow when applying for registration or approval of a new establishment or in the case of a major change to an establishment, enabling the NFSA to receive appropriate information to assess the FBO's compliance with relevant requirements.

77. The approval procedure is not always followed, and there is a risk that

establishments are not approved where required, approved establishments and vessels are carrying out operations that they have not been approved for or that operations are being carried out in facilities that do not meet the requirements of the EEA hygiene legislation. This could lead to unsafe products being placed on the market.

5.4 Official control on the production and placing on the market

Legal Requirements

Articles 4 and 5 and Annex II to Regulation (EC) No 852/2004

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

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

Findings

5.4.1 Official control system in place

78. The competent authority has carried out a risk assessment of the fishery sector. The assessment is used as a basis for the Multi Annual National Control Plan ('MANCP'). The NFSA head office issues an annual budget disposal letter based on the MANCP to the regions. The budget disposal letter will contain, *inter alia*, ongoing tasks, special assignments and priorities for the coming year. Based on the budget disposal letter, an annual control plan is then developed which sets targets for official controls in the food sector (see also paragraphs 19-22). The annual control plan is drafted in consultation with the regions and the audit team saw evidence of cooperation between the head office and the regions in this regard.

79. The final annual control plan must take into account the different types of tasks that the regions are required to carry out. The head office of NFSA has issued guidelines on how resources should be allocated. Fifty percent should be used for what has been defined as mandatory official controls. This includes official controls defined in regulations, and includes import/export, approvals, meat control, smiley control and sampling programmes. Twenty-five percent is allocated for administration and twenty-five percent for risk-based official controls. The audit team noted that these values differed in the regions (see paragraph 23).

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5.4.2 Primary production

80. The audit team was able to observe three vessels landing fish at two different landing sites. The fishing vessels, tubs and other equipment used for landing were in good hygienic condition.

5.4.3 Landing operations, landing sites and first sale

81. The audit team visited four landing sites. Three were connected to establishments producing fishery products and one was attached to a cold store. There was landing activity at all sites during the audit team's visit.

82. In one of the sites the operations took a short time and the tubs were transferred into the factory without delay. At one landing site, the operation took place within a closed system, directly from the RSW tanks of the vessel into the factory. At a landing site handling frozen products they were moved directly from landing into a covered cold store.

83. At the fourth landing site visited there was no separation between the landing site and the connected establishment. The gates were kept open, tubs kept on the quay side and parts of the operations took place outdoor contrary to the FBO's HACCP system. The audit team also observed cleaning of tubs with high pressure water and detergent taking place next to tubs with fish. These practices are contrary to the requirements laid down in Point 2. of Chapter 2 of Annex II to Regulation (EC) 852/2004.

5.4.4 Facilities handling fishery products, including vessels

84. A risk-based system for approved vessels has been developed. Factory vessels and freezer vessels are in risk category 3 requiring an inspection every fourth year. Factory vessels that also cook shrimps are in risk category 2 requiring one inspection per year. The competent authority has not been able to respect the frequency for inspections of approved vessels. The competent authority has not established a frequency for official controls of registered vessels (see also paragraph 26).

85. The audit team visited one factory vessel producing fresh and frozen headed and gutted fish. The vessel had a HACCP system that was in electronic form. The vessel had enough capacity to freeze the products and maintain them well below -18C in a storage area. The temperature was registered both automatically as well as manually at regular intervals. The last official control inspection report was the initial approval inspection in February 2020.

86. The same vessel also produced cooked and frozen shrimp (see also section 5.3.3). The approval for the vessel did not indicate that the factory vessel was also carrying out cooking of shrimp. Therefore, the risk-based official control was set to once every four years instead of every year, contrary to the risk-based frequency established by the competent authority.

87. In the HACCP system, the company had identified one critical control point ('CCP'), being the core temperature measurement of the cooked shrimp. An appropriate temperature limit had been set and the temperature was measured every hour during cooking. However, the thermometer used did not have a valid calibration certificate, the validation having expired in January 2021, contrary to the Article 5(2)(d) of Regulation (EC) 852/2004 requirement that FBOs implement effective monitoring procedures for CCPs.

88. Inspection reports were available in all land establishments visited. One establishment visited had structural and maintenance issues which were not reflected in the competent authority inspection reports, contrary to Article 13(1)(c) of Regulation (EU) 2017/625.

89. Unprotected wood was observed in several areas and in some cases this was in contact with fishery products. The wood surface was not in a sound condition and so difficult to clean and disinfect. In one establishment visited by the audit team, wooden planks in the area where the manual heading of fish took place were damaged, leaving splinters sticking out from the planks which risked contaminating the product. The condition of the wood in these cases is contrary to Point 1.(f) Chapter II of Annex II to Regulation (EC) 852/2004. The inspectors from the NFSA did not consider the use of wood in these case to be a non-compliance.

90. In three establishments visited, significant amount of water on the floor created a cross contamination issue 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.

91. Pest control issues were observed in three establishments visited. External doors were left open and other doors were not tightly closed. In one establishment, there was a large open area between the factory and an uncompleted extension. Not all establishments had rodent traps inside and the number and location of fly killers was not always appropriate to be effective, contrary to Point 2.(c) Chapter I of Annex II to Regulation (EC) 852/2004. This had also been pointed out by the competent authority inspector during the internal audit team.

92. Handling of fishery products did not always fulfil the requirements for respecting the cold chain as required by Point 1 of Part A. of Chapter III of Section VIII of Annex III to Regulation (EC) 853/2004.

    a. Fishery products were in some cases stored in tubs of stagnant water with no visible ice. One establishment had permanent tanks to separate catches from different vessels where fish were kept in stagnant water until being processed (sometimes not until the next day). This was neither described in the establishment's HACCP system nor identified by the competent authority.

    b. Fishery products were also kept without ice in other cases, particularly where the products were not part of the main production operations (for example, not fitting size criteria).

93. One establishment had an area with a roof and three walls where clean tubs and other materials were kept. The same area was also used to store unprotected fishery products, contrary to Point 2. of Chapter I of Annex II to Regulation (EC) 852/2004.

94. 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. As an example:

c. In one establishment, it was observed that tubs marked as Category 3 ABPs were being used for products intended for human consumption.

d. In three establishments, identification of the tubs for storing Category 3 and 2 ABPs was not clear or permanent.

e. In one establishment, products for human consumption were kept next to Category 2 and 3 ABPs, creating a risk of cross contamination.

Conclusions

95. Full compliance with Article 4 and Annex II to Regulation (EC) 852/2004 and with Article 3 of Regulation (EC) 853/2004, which requires FBOs to comply with the relevant provisions of Annex III to Regulation (EC) 853/2004, was not always ensured. This was the case, in particular, regarding use of unprotected and damaged wood in production, storage conditions for fishery products and ABPs and waste water on the floor, all of which can cause cross contamination of fishery products.

96. HACCP systems generally complied with EEA legislation. However, problems identified during the audit concerning CCP monitoring procedures indicate a lack of understanding of the requirements of Article 5 of Regulation (EC) 852/2004. Lack of implementation of HACCP principles can reduce controls and the safety of fishery products.

5.5 Official control of fishery products

Legal Requirements

Article 1 and Annex I to Regulation (EC) No 2073/2005

Regulation (EC) No 1881/2006

Article 18(8)(f) of Regulation 2017/625

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

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

Findings

97. The audit team observed that official sampling included analysis of fishery products 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 Chapter I of Annex VI of Regulation (EU) 2019/627.

98. The competent authority stated that organoleptic controls were carried out, however, the audit team saw no documented evidence that official controls of fishery products at establishments included organoleptic or checks for parasites as required under Article 70 and Chapter I of Annex VI of Regulation (EU) 2019/627. The Norwegian rules on how organoleptic checks should be carried out can be found in Kvalitetsforskriften (FOR-2013-06-28-844).

99. There was no documented evidence in many of the establishments visited that FBOs were carrying out their own organoleptic checks or checks for parasites, as required by Parts A and D of Chapter V of Section VIII of Annex IIII to Regulation (EC) 853/2004.

100. Official controls of fishery products reviewed by the audit team did not include testing for histamine in the relevant fish species, as required by Article 70(c) and Chapter I of Annex IV of Regulation (EU) 2019/627. The audit team saw evidence of one sample taken for histamine analysis in 2020.

Conclusions

101. The competent authority does not carry out and document all relevant official controls of fishery products required under Article 70 and Annex VI of Regulation (EU) 2019/627.

5.6 Follow up of iRASFF notifications

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

Regulation (EU) 2019/1715

Findings

102. 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. The instructions describe the duties of the RASFF contact point and the local departments. They contain, for example, information on the operation of the RASFF system in Norway, how to transmit and follow up different RASFF notifications and how to communicate within the competent authority.

103. As described earlier (see Section 4.3), there were 10 RASFF notifications in the period from 2019 to 2021 concerning fishery products. The audit team examined one case in more detail, *Anisakis* in chilled mackerel (RASFF No. 2019-2424) exported to Italy. Follow up by the competent authority was handled according to the relevant procedures and without delay.

Conclusions

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

5.7 Laboratories

Articles 34, 37, 39 of Regulation (EU) 2017/625

Findings

105. The competent authority has designated laboratories to carry out the analysis of samples taken during official controls on fishery products, as required by Article 37 of Regulation (EU) 2017/625.

106. The audit team visited one official laboratory carrying out analysis of official samples of fishery products. The laboratory was well equipped and had suitable training for staff and procedures in place to ensure sufficient analytical capacity.

107. The laboratories designated by the competent authority participate regularly in proficiency testing, with acceptable results.

108. Monitoring/auditing of performance of official laboratories is undertaken on an annual basis as part of the annual tender process, pursuant to Article 39 (1) of Regulation (EU) 2017/625.

109. The official laboratory does not carry out histamine analysis and all samples received are sent for histamine analysis to a laboratory in Sweden. The competent authority had not verified whether the Swedish laboratory was already designated as an official laboratory by the Swedish competent authority, contrary to Article 37(2)(b) of Regulation (EU) 2017/625.

Conclusions

110. The competent authority has access to a network of designated official laboratories.

111. The competent authority had not verified that the laboratory in Sweden that had been subcontracted by the designated official laboratory to carry out histamine analysis had been designated as an official laboratory by the competent authorities of Sweden.

6 Final meeting

A final meeting was held on 16 March 2022 at the head office of the NFSA in Oslo with representatives from the NFSA, the Ministry of Trade, Industry and Fisheries and the Ministry of Health and Care Services. At this meeting, the audit team presented its main findings and preliminary conclusions of 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 Norwegian Government may provide, additional findings and conclusions may be included in the report.

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7 Recommendations

In order to facilitate the follow-up of the recommendations hereunder, Norway should notify the Authority no later than 24 October 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. Norway should also ensure that such corrective actions are designed in line with a root cause analysis of the situation.

No	Recommendation
1	The competent authority should ensure that the approval requirements in Article 4 of Regulation (EC) No 853/2004 for food business operators are followed in all cases and ensure compliance with Article 148 of Regulation (EU) 2017/625. *Recommendation based on conclusions: paragraph 77* *Associated findings: paragraphs 45, 64, 65, 66, 68, 73, 74 and 75*
2	The competent authority should carry out official controls on a consistent and reliable basis regarding good hygiene practices and HACCP-based procedures in order to verify that food business operators observe such practices and apply such procedures continuously and properly, pursuant to Articles 4 and 5 and Annex II to Regulation (EC) 852/2004 and Article 3 and Annex III to Regulation (EC) 853/2004. *Recommendation based on conclusions: paragraphs 95 and 96* *Associated findings: paragraphs 83, 0 88, 89, 90, 91, 92, 93 and 94*
3	The competent authority should ensure that official controls of fishery products include all the relevant elements laid down in Article 70 and Chapter I of Annex VI of Regulation (EU) 2019/627, especially Points A. Organoleptic examinations, C. Histamine and F. Parasites of Chapter I of Annex VI. *Recommendation based on conclusions: paragraph 101* *Associated findings: paragraphs 0, 99 and 100*
4	The competent authority should ensure that sufficient resources and competence are available to carry out official controls of fishery products efficiently and effectively, as required by Articles 5(1)(e) and 78(1) of Regulation (EU) 2017/625. *Recommendation based on conclusions: paragraph 56* *Associated findings: paragraph 23, 24, 0, 26, 27 and 28*
5	The competent authority should ensure that official laboratories that it designates which are situated in other EEA States have already been designated by the competent authority of the other EEA State in question, pursuant to Article 37(2)(b)

	of Regulation (EU) 2017/625. *Recommendation based on conclusions: paragraph 111* *Associated findings: paragraph 109*
6	The competent authority should ensure that staff have the necessary training and experience to carry out official controls, including relating to HACCP systems, in a consistent and harmonised manner, pursuant to Article 5(4) and Point 7. of Chapter I of Annex II of Regulation (EU) 2017/625. *Recommendation based on conclusions: paragraph 55* *Associated findings: paragraph 35*
7	The competent authority should ensure that appropriate enforcement measures are taken in all cases to eliminate or contain risks that might be associated with non-compliant products or establishments, pursuant to Article 138 of Regulation (EU) 2017/625. *Recommendation based on conclusions: paragraph 57* *Associated findings: paragraph 45 and 51*
8	The competent authority should ensure that effective communication, coordination and cooperation is in place between different regions and between the head office and the regions as required by Article 5(5) of Regulation (EU) 2017/625. *Recommendation based on conclusions: paragraph No 54* *Associated findings: paragraphs 45 and 47*
9	The competent authority should ensure that follow up of non-compliances identified during internal audits is carried out within an agreed and reasonable timeframe, as required by Article 6 of Regulation (EU) 2017/625. *Recommendation based on conclusions: paragraph 53* *Associated findings: paragraph 16*

Annex 1 - List of abbreviations used in the report

ABPs	Animal by-products
CCP	Critical Control Point
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
NFSA	Norwegian Food Safety Authority
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 9b of Part 7.1 of Chapter I of Annex I to the EEA Agreement, Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1), 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 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;

e) 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;

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;

g) 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;

h) 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;

i) 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 – Comments from the CA to the draft report

Audit to Norway regarding fishery products 7 to 16 March 2022
– Reply to draft report

We refer to the letter of 25 May 2022, and the draft report from the EFTA Surveillance Authority audit to Norway 7 to 16 March 2022, regarding fishery products.

The Norwegian Food Safety Authority (the NFSA) would like to provide some comments to the factual content of the draft report.

A plan for corrective measures, including a timetable for completion of measures is enclosed. The NFSA will keep the Authority informed of the completion of the measures included in the timetable.

Comments to the factual content of the draft report:

13
The regions have control verification procedures in place. Inspection reports are reviewed by a team from the regional office established for that purpose. The supervisor will review the report in terms of enforcement measures and correct legal basis among other things. However, the verification procedures failed to identify that the approval procedures had been incorrectly applied, contrary to Article 12(2) of Regulation (EU) 2017/625.

Comment:
The guideline "*Preparation, approval and control of inspection reports"* shall ensure that the inspection reports sent out by the NFSA have sufficient administrative quality (See enclosure 4.4.7 to the pre-mission document). According to the guideline, it is not the responsibility of the regional team to identify whether the approval procedures have been applied. The case handler must ensure that relevant guidelines is followed before the inspection report is sent for review by the regional team.

25
In 2021, the total number of approved factory vessels was two hundred and seventy three (273) and the total number of approved freezer vessels was seventy-eight (78) (see Table 2. in Section 4.2). In 2019, no factory vessels were inspected. In 2020, thirteen (~5%) such vessels were inspected but none in 2021. In 2019, no freezer vessels were inspected. One (~1%) was inspected in 2020 and three (~4%)

Comment:
The referred numbers of inspections carried out on freezer vessels and factory vessels in 2019-2021 are in line with the numbers reported to the Authority in the reply to the pre-audit document.
These numbers are generated from the reporting system (SAS) of NFSA, but the actual number of inspections carried out is higher.

The reporting system has recently been replaced by a new reporting tool, PowerBI. Because of the ongoing implementation of a new reporting tool, there are no available exact data now, on number of inspections carried out.

33
In one department visited, the line manager had made a course on the official control regulation (Regulation (EU) 2017/625) in RANSEL mandatory for the departmental staff. The audit team noted that all seafood inspectors in this department had completed that course, while none had done this in the other departments visited.

Comment:
We would like to correct the numbers of inspectors who have completed the mandatory course on the official control regulation: In the region where the two actual departments are located, 20 inspectors are working part-time or full-time with seafood. 13 of these inspectors have completed the course.

59
The competent authority has developed documented procedures for the approval of establishments ("Føre tilsyn" ("Carrying out official control"), case no. 2017/348, 4th edition, last amended 8 December 2020). The procedures describe the approval process from application to final approval decision.

Comment:
The correct name is «*Godkjenning – virksomheter for animalske næringsmidler*» (Approval of establishments), case no. 2017/348, 5th edition, last amended 9 March 2022.

66
Animal by-products ('ABPs') originating in several establishments were collected for silage production on-site. Notwithstanding their existing approval under Regulation (EC) No 853/2004 as a food business establishment producing fishery products for human consumption, these ABPs processing units were not also approved by the competent authority as required by Article 24(1)(a) of Regulation (EC) No 1069/2009 for the activity of ensilage of fish material, such activity being an alternative processing method pursuant to Point K. of Section 2 of Chapter IV of Annex IV of Regulation (EC) No 142/2011.

Comment:
Establishment where ABPs occur, will often be approved in accordance with the food hygiene regulations, and must not at the same time be approved in accordance with animal bioproducts regulations. The establishments in which ABPs occur have an important responsibility to ensure that the material is handled safely and does not pose a threat to the food production that occurs in the establishment or for animal and public health in general. The establishments must ensure to collect the material without undue delay and categorize it correctly. Furthermore, they shall have control over what the containers contain and ensure that information about this is provided to the next part of the value chain in the commercial document that is to accompany the material.

The ABPs can only be delivered to an establishment that is approved under the ABP regulation (processing plant or a storage plant).

With regards to ABPs that are generated in establishments producing fishery products, they are categorized and stabilized using formic acid to pH <4. This product is not fish silage but is delivered to a processing plant which is approved according to the ABP regulation with activity code OEFP and alternative method K for silage production. This is in accordance with the guidance that the NFSA has provided: Plikter for virksomheter der biprodukter oppstår | Mattilsynet

67 and 68
Major changes (new production facilities, new equipment, new products and new owners) may require a new approval. The competent authority evaluates in each case the need for a new approval and an on-site visit. According to the procedure for approval, new production facilities will always require an on-site visit.

In one processing plant observed by the audit team, construction of two new freezer rooms, a blast freezer and rooms for packing and production was being finalised. The representatives from the competent authority informed the audit team that an on-site visit to approve the extension was not required. The competent authority guidance on approval of establishments defines the conditions under which a change should be considered major and therefore requiring approval. A new building would require approval.

Comment:
According to the procedures for approval, the NFSA should assess in each individual case whether the change is considered as new premises (new approval) or an extension that not necessarily require a new approval. In the particular case mentioned in no. 68, the assessment was that the extension did not require a new on-site visit and a new approval.

It appears that ESA does not nuance between extension within existing approval/upgrade (may require) versus new premises (will always require). Extension of existing premises with new facilities/larger premises/upgrading etc., will not always be considered as «new premises» that require new approval and an on-site visit. These changes are considered as major changes, but the need for an on-site visit and a new approval will be evaluated in each individual case. As regards major changes like rebuilding and reconstruction, new equipment etc., the inspector must assess new floor plans and procedures/routines, operations under renovation, etc. Changes like this may require new application, an on-site visit and a new approval.

Recommendation no 1 (page 23):
The competent authority should ensure that the approval requirements in Article 4 of Regulation (EC) No 853/2004 for food business operators are followed in all cases and ensure compliance with Article 148 of Regulation (EU) 2017/625.

Recommendation based on conclusions: paragraph 77

Associated findings: paragraphs 45, 64, 65, 66, 68, 73, 74 and 75

Comment:
The NFSA would like to comment that the recommendation regarding approval requirements in Regulation (EC) No 853/2004, refers to paragraph 66 as one of the associated findings,

even though paragraph 66 refers to the approval requirements in Regulation (EC) No 1069/2009.

Approval under Regulation (EC) No 853/2004 article 4 as a food business establishment, must meet the relevant requirements of Regulation (EC) No 852/2004, those of Annexes II and III of Regulation (EC) No 853/2004 and other relevant requirements of food law, not requirements of Regulation (EC) No 1069/2009.

Yours faithfully,

Inge Erlend Næsset

Head of Department
Regulations and Control Department

Attachments: Annex 1 - Plan for corrective measures

Annex 4 Norway´s action plan for corrective actions

Audit to Norway 7 to 16 March 2022

Production of fishery products, including fish oil for human consumption, and the implementation of official controls thereon

Plan for corrective measures

No	Recommendation from ESA	Action planned	Suggested time aspect
1	The competent authority should ensure that the approval requirements in Article 4 of Regulation (EC) No 853/2004 for food business operators are followed in all cases and ensure compliance with Article 148 of Regulation (EU) 2017/625. *Recommendation based on conclusions: paragraph 77* *Associated findings: paragraphs 45,64, 65, 66, 68, 73, 74 and 75*	a. Procedures for verification of official control activities are in progress, and the NFSA will prioritize this work in 2022. b. The guideline for approval will be verified according to the verification procedures, to ensure that the approval requirements for FBOs are followed, and to ensure compliance with the requirements in Article 148 of Regulation 2017/625. c. Control template specific to the approval of vessels, will be developed.	2022 2023 2022
2	The competent authority should carry out official controls on a consistent and reliable basis regarding good hygiene practices and HACCP-based procedures in order to verify that food business operators observe such practices and apply such procedures continuously and properly, pursuant to Articles 4 and 5 and Annex II to Regulation (EC) 852/2004and Article 3 and Annex III to Regulation (EC) 853/2004.	a. The findings from the Authority will be presented at a seminar for the seafood inspectors of NFSA. b. The NFSA will develop a plan for training of food inspectors on audit of HACCP systems.	2022 2022

	Recommendation based on conclusions: paragraphs 95 and 96 *Associated findings: paragraphs 83, 87, 88, 89, 90, 91, 92, 93 and 94*	c. Training of inspectors regarding audit and HACCP will be carried out. *See also recommendation no 6*	2023
	The competent authority should ensure that official controls of fishery products include all the relevant elements laid down in Article 70 and Chapter I of Annex VI of Regulation (EU) 2019/627, especially Points A. Organoleptic examinations, C. Histamine and F. Parasites of Chapter I of Annex VI. *Recommendation based on conclusions: paragraph 101* *Associated findings: paragraphs 98, 99 and 100*	Organoleptic examination is one of the control points in the control templates for fishery products in 2022. When documentation regarding this control is available, the NFSA will evaluate the results. Based on these results the NFSA will consider further action, to assure that official control of fishery products is carried out in line with Article 70 and Chapter I of Annex VI of Regulation (EU) 2019/627 Point A and F. The NFSA will develop a riskbased plan for official sampling, to ensure that official control on histamine in fishery products is in line with Article 70 and Chapter I of Annex VI of Regulation (EU) 2019/627 Point C.	Mid 2023 2023
4	The competent authority should ensure that sufficient resources and competence are available to carry out official controls of fishery products efficiently and effectively, as required by Articles 5(1)(e) and 78(1) of Regulation (EU) 2017/625. *Recommendation based on conclusions: paragraph 56* *Associated findings: paragraph23, 24, 25, 26, 27 and 28*	a. As part of the further development of an updated governance model, the NFSA aim towards planning the official control more realistically based on available resources and competence and connecting these two aspects more closely. The development of the updated governance model is anchored in this year's annual target and budget letter	Mid/end 2023

		(MDS). The work is ongoing, and improvements are put into practice continuously. The work will be finalized mid/end of 2023. In regard to our ongoing management activities, we are working to connect and align the different governance procedures to get a more comprehensive approach. For instance, after the four-month reports from each region and department is available, we are conducting the internal performance management conversations with each region and department in the head office so we can adjust the course (if necessary). The conversations are based around the MDS and the OTP (operational control plan) for the year and the progress so far.	2023
		b. We are also working with a uniform manual system for all the official controls from risk assessment to a realistic control plan. According to the plan, we will have a more uniform manual system to ensure that sufficient resources and competence are available to carry out official controls from 2024.	2022
		c. In addition, the model for risk assessment of fishery establishments and vessels will be evaluated and revised, based on the	

		concrete feedback from the Authority in the report.	
5	The competent authority should ensure that official laboratories that it designates which are situated in other EEA States have already been designated by the competent authority of the other EEA State in question, pursuant to Article 37(2)(b) of Regulation (EU) 2017/625. *Recommendation based on conclusions: paragraph 111* *Associated findings: paragraph 109*	We will inform the designated laboratories that any subcontractors performing official analysis need to be designated by the EEA state where located. If the laboratory of interest is not designated, we will ask the relevant state about the possibility of designating the specific laboratory, or else the Norwegian designated laboratory needs to find another subcontractor.	Mid/end 2023
6	The competent authority should ensure that staff have the necessary training and experience to carry out official controls, including relating to HACCP systems, in a consistent and harmonised manner, pursuant to Article 5(4)and Point 7.of Chapter I of Annex II of Regulation (EU) 2017/625. *Recommendation based on conclusions: paragraph 55* *Associated findings: paragraph 35*	a. The findings from the Authority will be presented at a seminar for the seafood inspectors of NFSA. b. The NFSA will develop a plan for training of food inspectors on audit of HACCP systems. c. Training of inspectors regarding audit and HACCP will be carried out. *See also recommendation no 2*	2022 2022 2023
7	The competent authority should ensure that appropriate	The NFSA has decided to review the use of measures/sanctions in a broader perspective,	2022

	enforcement measures are taken in all cases to eliminate or contain risks that might be associated with non-compliant products or establishments, pursuant to Article 138 of Regulation (EU) 2017/625. *Recommendation based on conclusions: paragraph 57* *Associated findings: paragraph 45 and 51*	with the aim of ensuring the appropriate enforcement measures in all cases.	
8	The competent authority should ensure that effective communication, coordination and cooperation is in place between different regions and between the head office and the regions as required by Article 5(5) of Regulation (EU) 2017/625. *Recommendation based on conclusions: paragraph No 54* *Associated findings: paragraphs 45 and 47*	The Authority detected some examples of shortcomings in the communication between departments and regions. As mentioned in the report (5.2.8), there is a system in place for cooperation and communication between different parts of the NFSA, including regular meetings to coordinate and harmonise official controls on fishery products, within and between, the regions. The NFSA consider this established system as sufficient to ensure effective communication within and between the regions. Based on the shortcoming detected by the Authority, the NFSA will consider possible measures to facilitate information between departments and regions.	2023
9	The competent authority should ensure that follow up of non-	The management model, mentioned under	

	compliances identified during internal audits is carried out within an agreed and reasonable timeframe, as required by Article 6 of Regulation (EU) 2017/625. *Recommendation based on conclusions: paragraph 53* *Associated findings: paragraph 16*	rec. No 4, is set to cover the issues pointed out in this section.	