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Final Report

EFTA Surveillance Authority's remote audit of

Norway from 12 to 23 October 2020

in order to evaluate official controls related to the production of ready-to-eat food

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 to the report.

Executive Summary

This report describes the outcome of a remote audit carried out by the EFTA Surveillance Authority in Norway from 12 to 23 October 2020.

The objective of the audit was to assess the arrangements put in place by the Norwegian competent authorities (CAs) to verify compliance with European Economic Area (EEA) food hygiene requirements applicable to ready-to-eat (RTE) food.

The mission team found that the Norwegian Food Safety Authority (NFSA) is currently developing a new model for risk based official controls. In the meantime, official controls in establishments producing RTE foods take place regularly and are implemented as planned in the regions reviewed by the audit team. Control reports are available and include evidence of decisions, corrective action and follow-up. However, the approach currently in place is not paying enough attention to HACCP based programmes and the microbiological requirements in Regulation (EC) No 2073/2005. In these areas, there was little evidence of enforcement measures - this may be due in part to some of the competent authorities met not fully understanding the specific and technical microbiological requirements for RTE foods.

A network of official laboratories has been established for microbiological testing purposes related to official samples of RTE foods. This includes the appropriate designation of national reference laboratories (NRLs) and the majority of laboratories used to process official control samples. When responsibilities are shared between more than one NRL, arrangements are in place for co-operation between the NRLs and the relevant European Union reference laboratory (EURL). This provides confidence in the effectiveness of the official laboratory network.

The system in place for registration and approval of establishments is established and generally working satisfactorily. However, relevant guidance is not always followed and has resulted in non-approved establishments placing food on the market.

The approach to product withdrawal / recall involving RTE foods is generally satisfactory and evidence was available that follow up to Rapid Alert System for Food and Feed (RASFF) notifications is handled effectively.

The report includes a number of recommendations addressed to the Norwegian competent authorities aimed at rectifying the identified shortcomings and enhancing the control system in place.

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1 Introduction

The remote audit took place in Norway from 12 to 23 October 2020. The audit team comprised three auditors from the EFTA Surveillance Authority ("the Authority") and an observer from Directorate F, Health and Food Audits and Analysis, DG Health and Food Safety ('DG SANTE') of the European Commission.

A pre-mission questionnaire was sent by the Authority to the Norwegian Ministry of Agriculture and Food on 18 March 2020. A reply ('the pre-mission document') was provided on 18 May 2020.

The opening meeting was held with representatives of the Norwegian Ministry of Agriculture and Food, the Norwegian Ministry of Health and Care Services and the Norwegian Food Safety Authority (NFSA) on 12 October 2020. At the meeting, the audit team confirmed the objectives and scope of the mission and the Norwegian representatives provided additional information to that set out in the pre-mission document.

Throughout the audit, representatives from the head office of NFSA participated in meetings.

A final meeting was held with the relevant competent authorities on 23 October 2020 when the audit team presented its main findings and preliminary conclusions from the audit.

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

2 Objective and scope of the mission

The objective of the mission was to:

- Assess the arrangements put in place by the Norwegian competent authorities (CAs) to verify compliance with European Economic Area (EEA) food hygiene requirements applicable to ready-to-eat (RTE) food[1].

The scope of the mission included:

- Food of animal origin/composite products[2] and the official controls performed by the CAs in registered and approved establishments producing RTE food that according to the data currently available represents the highest microbiological risk[3].

- The organization and implementation of official controls on RTE food and actions/measures taken in case of non-compliance and in relation to food borne outbreaks and food alerts.

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

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[1] 'Ready-to-eat food' means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern (Article 2, point (g) of Regulation (EC) No 2073/2005).

[2] Primary production and associated establishments are excluded from the scope of the audit.

[3] The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2017 - EFSA (European Food Safety Authority) Journal 2018;16(12):5500, the EFSA scientific opinion "*Listeria monocytogenes* contamination of ready-to-eat foods and the risk for human health in the EU" -EFSA Journal 2018;16(1):5134, data from Rapid Alert System for Feed and Food (RASFF) alerts was considered.

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

The meetings with the competent authorities, to discuss the establishments selected for documentary review of official controls during the audit, are listed in Table 1.

Table 1: Competent authorities and establishments reviewed during the mission

	Number	Comments
Central Competent Authorities	2	An initial meeting and a final meeting between the audit team and the Norwegian competent authorities
Regional Competent Authorities	3	7 Departments
Meat products establishments	1	Cured and fermented meats
Fishery products establishments	4	Smoked, cured and fermented products
Dairy establishments	1	Produces cheese from unpasteurised milk
Salad and sandwich producer	1	
Catering establishment	1	Produces RTE meals for in-flight services
Laboratory	1	National Reference Laboratory (NRL) for food pathogens

3 Legal basis for the mission

The legal basis for the mission was:

a) Point 4 of the Introductory Part of Chapter I of Annex I to the EEA Agreement;

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

c) Article 116 of Regulation (EU) 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, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

Legislation relevant to this mission is listed in Annex 2.

4 Background

This was the first remote audit performed by the Authority during the current Covid-19 pandemic with audit team members participating in meetings from two locations in Brussels and one location in Ireland (Directorate F). A programme was arranged with the competent authority (CA) involving central, regional and departmental levels. Interviews at regional and departmental level focussed on specific food business operators (FBOs) selected by the audit team. The findings and conclusions of this remote audit of CA performance are limited in certain aspects where the audit team was, for example, unable to verify fully the CA activities at establishment level. This verification may be necessary at a future date when travel is again permitted.

"The European Union One Health 2018 Zoonoses Report[4]" published by the European Food Safety Authority (EFSA) and European Centre for Disease Prevention and Control (ECDC) highlights that:

- In 2018, campylobacteriosis was the most commonly reported zoonosis and salmonellosis remained the second most commonly reported gastrointestinal infection in humans.

- At processing and retail level, the highest proportion of positive *Listeria* results were reported for 'fish and fishery products.' The case fatality for *Listeria* infections was high (15.6%), which makes listeriosis one of the most serious food-borne diseases under EEA surveillance.

The scientific opinion, "*Listeria monocytogenes* (Lm) contamination of ready-to-eat foods and the risk for human health in the EU[5]" concludes, inter alia, that:

- The RTE food categories typically associated with human listeriosis, i.e. 'meat and meat products,' 'fish and fish products,' and 'milk and milk products' continue to be of significance from a food safety perspective."

4.1 Previous missions

This was the first Authority mission to Norway specifically on RTE foods. However, official controls over the production of different foods, some of them also RTE foods, were covered within the scope of several previous Authority missions. These include a mission to evaluate official controls over the production of meat and milk and their products from 25 November to 4 December 2019 and a mission to evaluate the operation of official controls over the post-slaughter traceability of meat, meat products, meat preparations and composite products from 3 to 12 October 2016. The final reports from these missions can be found on the Authority's website[6].

5 Findings and conclusions

5.1 Legislation and implementing measures

Legal Requirements

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

Findings

1. According to information provided by Norway in its reply to the Authority's pre-mission document, the relevant EEA legislation regarding RTE foods, as listed in Annex 2 to this document, is implemented in the Norwegian legal order.

2. 'Local, marginal and restricted' activity as referred to in Article 1(5)(b)(ii) of Regulation (EC) No 853/2004 is defined in the Norwegian Regulation on special hygiene rules for food of animal origin (Animal Hygiene Regulation) (FOR-2008-12-22-1624) Sections 16 and 17. In summary, 'marginal' activity means weekly delivery of up to 600kg of food of animal origin to other retailers, 'local' relates to delivering

[4] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5926
[5] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5134
[6] https://www.eftasurv.int/internal-market/food-safety/food-safety-missions

food within same county or a distance of 100 km and 'restricted' refers to retailers supplying food of animal origin to other retailers supplying only the final consumer.

3. The CA confirmed that Section 6 of the Food Act (LOV-2003-12-19-124) places a duty on FBOs and laboratories (including private laboratories) to inform CA if they suspect a food may be injurious to health.

Conclusions

4. The relevant EEA legislation related to the production of RTE foods has been implemented into the Norwegian legal order.

5.2 Competent authorities

Legal Requirements

Article 4(1) and 5(4) of Regulation (EU) 2017/625

Findings

5.2.1 Designation of competent authorities

5. The Norwegian Food Safety Authority (NFSA) is designated as the CA for food and feed safety, animal health and animal welfare. Food safety controls in Norway include official controls related to RTE foods.

6. The NFSA is organized into two administrative levels, the head office and the regions. The head office carries out directorate and governance tasks. The regional level consists of five regions which are divided into 31 local departments. The regional level carries out official control activities. The Director in each region is responsible for coordinating the activities of the local departments. During this remote audit, establishments in three regions (seven departments) were reviewed.

7. Part 1 of the country profile[7] describes the organization of the Norwegian CA and their control systems covering the whole chain of animal food production.

5.2.2 Personnel and staff training

8. NFSA staff at regional and department level are responsible for, inter alia, approval of establishments producing RTE foods and the delivery of official controls in these establishments. The CA confirmed staff generally have a third level qualification e.g. food science or similar.

9. According to pre-audit documentation, CA have organised national training on relevant topics including microbiological criteria, Hazard Analysis and Critical Control Points (HACCP) principles and sampling. NFSA staff have also attended "Better Training for Safer Food" (BTSF) courses on relevant topics.

10. Personal training records for staff are held on a centralised system "Ransel" along with training material. The audit team saw evidence related to the delivery of e.g. a two-day training course on microbiology which included the agenda and attendance

[7] https://www.eftasurv.int/cms/sites/default/files/documents/gopro/Country%20Profile%20-%20Part%201%20-%20for%20web%20publishing.pdf

lists which had been rolled out to approximately 200 staff. In addition, the audit team confirmed that new staff accompanied more experienced staff members during audits / inspections of establishments, it was possible for staff to work across departments within a region and that inter-regional forums existed for a variety of issues such as meat and export of seafoods.

11. Staff were generally knowledgeable on the subject of RTE foods but some inspectors had not fully understood some of the specific and quite technical requirements of Regulation (EC) No 2073/2005 e.g. two inspectors considered the requirement for sampling processing areas and equipment for Lm was met if only brine was sampled, not all staff were aware environmental sampling for Lm should take place during production rather than after cleaning of the premises and the food safety criteria in point 1.3; Chapter 1 of Annex I to Regulation (EC) No 2073/2005 still applies to RTE foods with low water activity (aw) unable to support growth of Lm.

5.2.3 Audits and verification / supervisory activities

12. The systems for verification and audit are described in the country profile for Norway and in the Authority audit report[8] on national audit systems.

13. NFSA staff are responsible for performing risk based inspections / audits in establishments producing RTE foods. The CA confirmed that since June 2020, regional teams have been established to review all official control inspection and audit reports. These are then further reviewed by Department Heads of Section prior to issue.

14. The audit team noted some final reports (pre-dating new arrangement) containing errors related to e.g. interpretation of the microbiological criteria (Regulation (EC) No 2073/2005) and reference to the wrong (animal by-products) legislation when describing non-compliances linked to food production.

Conclusions

15. The CA responsible for official controls related to RTE foods have been clearly designated.

16. Procedures for training of staff are in place which should ensure official staff can perform their tasks related to RTE foods competently. However, some inspectors did not fully understand all the specific and quite technical requirements of Regulation (EC) No 2073/2005.

5.3 Registration and Approval of Food Business Operators

Legal Requirements

Article 6 of Regulation (EC) No 852/2004, Article 4 of Regulation (EC) No 853/2004, Article 148 of Regulation (EU) 2017/625.

[8] https://www.eftasurv.int/cms/sites/default/files/documents/Final_Report_-_EFTA_Surveillance_Authority_s_mission_to_Norway_from_2_to_6_October_-888690-.pdf

Findings

17. The organisation of official controls related to approval of food establishments, including RTE foods, is described in the country profile for Norway. In summary, NFSA staff at department level are responsible for approval of meat, dairy and fish processing establishments. In addition, they are responsible for registration of establishments including those where the distribution is on a local, marginal and restricted basis according to national legislation (see paragraph 2).

18. Guidance on FBO approval procedures (dated 02.05.2017) is available to NFSA staff and CA confirmed this guidance is currently being updated. The guidance covers, inter alia, the application process, documentation to be provided by FBOs, conditional approval, issue of approval number and circumstances when an approval number can be re-used.

19. NFSA approved establishments are listed on a public website and lists of registered establishments are maintained by NFSA. This is in accordance with Article 10(2) of Regulation (EU) 2017/625. On the public website, approved food establishments are listed in accordance with categories and activities specified in document SANCO/2179/2005[9]. At the time of audit, all establishments reviewed by the audit team were appropriately approved / registered for the activities taking place.

20. An example of FBO notification to CA of their intention to stop production was reviewed by the audit team. The establishment had been removed from the list of approved establishments. However, there was no formal confirmation to the FBO that this had been done as described in NFSA guidance on FBO approval procedures.

21. The audit team reviewed how one department implemented the approval procedure in relation to a recently approved RTE food establishment. Following FBO application, CA carried out an on-site visit and granted conditional approval for a period of three months. This conditional approval was granted five weeks after production had started. During this period, the establishment placed food on the market with an identification mark. This is not in compliance with Article 4(3)(b) of Regulation (EC) No 853/2004. Towards the end of this initial period of conditional approval, a second approval visit was carried out resulting in full approval being granted.

22. The recently approved RTE establishment was allocated the approval number of the establishment it replaced. However, CA confirmed there was a period when both establishments were operating and using the same identification mark with product transported from one establishment to the other for identification marking. This is not in accordance with Annex II, Section I(A)(1) of Regulation (EC) No 853/2004.

Conclusions

23. The registration and approval procedures for RTE establishments are generally satisfactory and the establishments reviewed were appropriately registered / approved at the time of the remote audit. Notwithstanding, the CA does not always follow procedures for the approval of establishments and this has resulted in non-approved establishments placing food on the market and product being transported between establishments with no identification mark.

[9] *"Technical specifications in relation to the master list and the lists of EU approved food establishments and certain other specified food establishments".*

5.4 Organisation and Implementation of Official Controls

Legal Requirements

Article 17 of Regulation (EC) No 178/2002, Articles 5, 9, 10, 13, 14, 18, 34, 37 and 100 of Regulation (EU) 2017/625, Article 5 of Regulation (EC) No 852/2004 and Regulation (EC) No 2073/2005.

Findings

5.4.1 Risk based official controls

24. According to the pre-mission documents, the CA manages official controls and prioritises certain areas through a long-term plan. Each year, NFSA head office issues a budget disposal letter (BDL) based on the long-term plan to the Regions which contains, inter alia, ongoing tasks, special assignments and prioritisations. Based on BDL, an annual control plan (OTP) is developed which sets targets to control or supervise the food sector. The annual control plan is drafted in consultation with the regions and audit team saw evidence of this taking place. Further details of the risk based prioritisation of official controls is described in the country profile for Norway.

25. The CA confirmed they are currently developing a new model for risk-based official controls for fishery products establishments. They plan to roll this model out to other food sectors in the future.

26. MATS is the NFSA's case processing and decision support tool. All establishments subject to official controls by the NFSA are registered in MATS and all e.g. approval details, control templates, official control reports and guidance for NFSA staff are stored here.

27. In the departments reviewed, risks considered when determining frequency of official controls include e.g. category of food, results of previous controls and non-compliances, local knowledge and the requirements of the annual control plan. However, this did not appear to influence the frequency of official controls as they basically remained the same from one year to the next. For example, in one department there had been no change in the frequency of official controls delivered in any of the dairy establishments in the previous three years. In another department, the majority of RTE establishments were scheduled to have one official control visit / year.

5.4.2 Procedures for official controls

28. The NFSA guidance (ref: 2016/119837) on Supervision of Lm in RTE foods is available for officials and FBOs. This document requires NFSA to verify e.g.:

- Good hygiene practice (GHP)
- The FBOs hazard analysis and application of HACCP-based procedures
- FBOs implementation of sampling and analysis.

In addition, links to other guidance are included e.g. the EURL guidance on sampling food processing areas and equipment for the detection of Lm.

29. The CA confirmed there is currently no stand-alone guidance on microbiological criteria and that the Lm guidance in RTE foods is the main microbiological guidance document for staff.

5.4.3 *Scope / coverage of official controls*

30. The scope and coverage of official control inspections and audits are guided by control templates. If controls are linked to a central NFSA priority, control templates are produced centrally. In the absence of prioritisation from central level, staff can use a general template and select the areas to evaluate. These templates include, inter alia, an overview of the official control to be performed, legislative references and a description of requirements.

31. According to the pre-mission documents, the 2017 BDL prioritised official controls in meat and dairy based RTE foods. Examples of centrally produced control templates were available for these controls and CA confirmed they had performed 48 and 171 inspections in dairy and meat establishments in 2017, respectively.

32. Official control reports were available for all establishments reviewed. One RTE establishment reviewed had an Inspection in 2014 with the next inspection in 2020. The official involved in the most recent inspection confirmed they has spent approximately one and a half hours on-site. The establishment sourced raw materials from many non-EEA countries and distributed the finished product internationally.

33. In a dairy establishment, no centrally produced template had been completed during a period of prioritisation for Lm controls in these establishments. In addition, not all risk factors had been included in determining the frequency of inspections for this establishment as the CA did not consider the use of unpasteurised milk to be a risk factor.

34. In another establishment reviewed, the CA identified that the FBO was not collecting the correct number of units to constitute a sample as required by Annex I, Chapter I of Regulation (EC) 2073/2005. This had not been corrected at a subsequent inspection almost two years later.

5.4.4 Official sampling and laboratory analysis

35. CA confirmed surveillance related to Lm in RTE food was carried out in 2016 (fishery products), 2017 (meat) and 2016 and 2018 (dairy products). The overarching surveillance plans ("OK plans") for 2019 and 2020 include a section on Lm surveillance in RTE foods e.g. dairy, meat and fish / seafood products. Sampling plans for Lm were seen by audit team for this period with distribution of samples, by commodity, to each region.

36. One region has established a separate sampling plan in addition to the OK surveillance plan. In 2019, this plan required e.g. an additional 40 samples to be tested for Lm in fishery products.

37. The Norwegian Veterinary Institute (NVI) is the designated NRL for several food pathogens, including Lm, coagulase positive *Staphylococci* and *Salmonella* in terrestrial animals. A second NRL (Institute of Marine Research) has been designated for Lm and *Salmonella* in seafood and bivalve molluscs respectively. NVI confirmed collaboration between the two NRLs is in place and NVI acts as contact point for the relevant European Union reference laboratory (EURL).

38. The NRL, for food pathogens in terrestrial animals, arranges meetings with official laboratories. Minutes of 2019 meeting were reviewed by the audit team which included agenda and relevant topics e.g. feedback from EURL Lm related to detection / methodology (ISO 11290-1 and ISO 11290-2). The NRL also participates in a national microbiology laboratory platform "MICRO" which the laboratory can use to disseminate information.

39. The NRL participates in EURL inter-laboratory proficiency tests (PT) for e.g. Lm and coagulase positive *Staphylococci*. Results for coagulase positive *Staphylococci* were satisfactory in 2018 with one deviation recorded in 2019. The corrective action proposed by NRL for this deviation was considered satisfactory by EURL.

40. The NRL participated in the last two EURL inter-laboratory proficiency tests for enumeration of *Listeria* in 2017 and 2019. Results in 2017 were satisfactory with two deviations recorded in 2019. Proposed measures to correct these deviations were considered satisfactory by EURL.

41. CA has designated official laboratories to carry out laboratory analysis and tests on samples taken during official controls. NFSA has a framework contract with a service provider that is valid for two years and which can be extended for a further two years - the contract entered into force in 2018. Appropriate written designation for the service provider is available as required by Article 37(3) of Regulation (EU) 2017/625.

42. The NRL for food pathogens related to terrestrial animals relies on a service provider to organise proficiency tests (PT). The service provider is accredited by the Norwegian Accreditation Body to organise PT for food pathogens which it does for the laboratories within its own group. Results of PT are not automatically reported to NRL who confirmed they must request these results. The most recent set of PT results was obtained by NRL in advance of their annual meeting with the designated laboratories. NRL confirmed it is not involved in the follow-up if there has been poor performance during PT.

43. In one RASFF follow up reviewed by the audit team, the relevant Department had taken official samples and sent them to a non-designated laboratory for analysis. This is not in compliance with Article 37(1) of Regulation (EU) 2017/625.

44. The audit team observed a proprietary analysis method for detection of Lm being used as an alternative analytical method to the reference method, EN/ISO 11290-1. A current validation certificate was available for this alternative analytical method. The validation certificate was issued by an independent certification body, using the validation protocol ISO 16140-2 as required by Article 5(5) of Regulation (EC) No 2073/2005.

45. Lm results issued by NRL for one of FBOs reviewed by audit team were assessed. NRL uses an internal method for qualitative testing for Lm. This internal method can be linked to method NMKL 136, 2007 which has been found to give equivalent results to both EN/ISO 11290-1 and EN/ISO 11290-2.

46. Article 6 of the Food Act requires FBOs to notify CAs of the detection of certain notifiable microorganisms in food. CA confirmed that Article 6 also requires laboratories to notify NFSA when they suspect food may be injurious to health.

5.4.5 Measures in case of non-compliance

Legal requirements

Article 138 and Article 139 of Regulation (EU) 2017/625, Article 50 of Regulation (EC) No 178/2002.

47. Enforcement measures are described in the country profile for Norway. In addition, the NFSA's procedures and legal powers in connection with infringements are described in "Virkemiddelbruk ved tilsyn" (administrative rules concerning infringement procedures), last amended on 25 October 2019.

48. The audit team reviewed the actions taken by CA during a product recall and a RASFF notification related to RTE foods.

49. A guidance document on CA procedures for supervision of product recall by FBOs (document 2015/124932-1) is available. The guidance includes a description of the legislative background, how supervision should be performed and what should be verified by supervision e.g. traceability details and verification of quantities of product returned / destroyed.

50. The audit team reviewed CA actions taken during an outbreak of Lm. These included on-site visits to FBO, collection of official samples with same day laboratory confirmation of results and issue of a press release alerting the public to the recall. A log of CA actions was available on MATS.

51. CA confirmed that during this outbreak, no inspection or document control was carried out at retail level as described in the CA guidance on recall and no follow-up inspection was performed to see how much of the product had been returned to the producer despite very high levels of Lm being present in the batch of recalled product.

52. The same FBO failed to inform CA of positive Lm results in brine used for production of the affected batch which had been detected some months earlier (see paragraph 11). No enforcement measures were taken when CA became aware of this information.

53. The audit team reviewed actions taken by CA following a RASFF notification. These included a review of FBO microbiological test results for product and environment, temperature controls and cleaning procedures for the establishment. CA submitted official control samples from the relevant batch for laboratory testing (see paragraph 43).

54. In another establishment reviewed by the audit team, CA had identified a non-compliance related to microbiological sampling where less than five units were used to constitute a sample at the time of inspection contrary to the requirements of Regulation (EC) No 2073/2005. This non-compliance was subsequently closed based on documentary evidence and was not followed up at the next on-site inspection by CA. At the most recent inspection, almost two years after the initial detection of the non-compliance, the correct number of units to constitute a sample were still not being used.

55. In a further establishment reviewed by the audit team, the establishment had been operating for years with no food safety procedures based on HACCP principles. It had only recently been issued a decision to correct this non-compliance within three months (recently extended for a further three months). This is not in accordance with Article 148(3) of Regulation (EU) 2017/625.

Conclusions

56. The risk based system for delivery of official controls in establishments is currently under review. In several departments evaluated, RTE establishments received one official control visit each year, this did not tend to vary from one year to another and not all risk factors are currently considered.

57. An official laboratory network has been established for RTE food microbiological sampling purposes. However, NRL for food pathogens in terrestrial animals is not fully co-ordinating the activities of official laboratories responsible for analysis of official samples in this field. NRL does not have oversight of official laboratory performance to allow timely follow up where necessary. This reduces assurances that official laboratories are performing to the standard required. In addition, CA does not always use this official laboratory network.

58. The methods used by the official laboratories, in the results seen by the audit team, were the methods that have been validated against the reference ISO methods.

59. The approach to product recall / withdrawal involving RTE foods is generally satisfactory. However, guidance is not always followed and in such cases, controls are weakened increasing the risk of unsafe food remaining on the market.

60. The measure taken in relation to some non-compliances reviewed were weak as long periods were given for corrective actions and follow up was not always adequate. This is not in line with CAs guidelines on enforcement which require formal decisions to be taken to ensure shortcomings are rectified and followed up appropriately.

6 Final meeting

A final meeting was held on 23 October 2020 when the audit team presented its main findings and preliminary conclusions. During this meeting, the CA did not express any disagreement with the findings and preliminary conclusions.

7 Recommendations

In order to facilitate the follow-up of the recommendations hereunder, Norway should notify the Authority no later than 5 April 2021 of additional corrective actions planned or already 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 informed of this. The Authority should be kept continuously informed of such changes made to the already notified corrective actions and measures, including changes to the deadlines indicated for completion and also the completion of the measures included in the timetable.

No	Recommendation
1	Norway should ensure that national reference laboratories (NRLs) have timely access to proficiency testing results performed by a third party so they can, where necessary, ensure an appropriate follow up as required by Article 101 point 1(c) of Regulation (EU) 2017/625. Recommendation based on conclusion at paragraph 57. Associated finding: paragraph 42.
2	CA should ensure that laboratory analyses and tests on samples taken during official controls and other official activities are performed in designated official laboratories as required by Article 37(1) of Regulation (EU) 2017/625. Recommendation based on conclusion at paragraph 57. Associated findings: paragraph 43.
3	CA should ensure that an establishment subject to approval does not operate unless the CA has granted the establishment approval to operate as required by article 4(2) and 4(3) of Regulation (EC) No 853/2004. Recommendation based on conclusion at paragraph 23. Associated findings: paragraph 21.
4	CA should ensure that FBOs apply an identification mark before the product leaves the establishment of production as required by Annex II, Section I(A)(1) of Regulation (EC) No 853/2004. Recommendation based on conclusion at paragraph 23. Associated findings: paragraph 22.
5	CA should ensure that when they identify a non-compliance, they take action to ensure that the operator remedies the situation and prevents further occurrences of such non-compliance as required by Article 138(1)(b) of Regulation (EU) 2017/625. Recommendation based on conclusion at paragraph 60. Associated findings: paragraphs 52, 54 and 55.

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

Authority	EFTA Surveillance Authority
aw	Water activity
BDL	Budget Disposal Letter
BTSF	Better Training for Safer Food
CA	Competent Authority
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EFTA	European Free Trade Association
EURL	European Union reference laboratory
FBO	Food business operator
GHP	Good hygiene practice
HACCP	Hazard Analysis and Critical Control Point
Lm	*Listeria monocytogenes*
MATS	NFSA's case processing and decision support tool
NFSA	Norwegian Food Safety Authority
NRL	National reference laboratory
NMKL	Nordic Committee on Food Analysis
PT	Proficiency testing
RASFF	Rapid Alert System for Food and Feed
RTE	Ready to eat

Annex 2 - Relevant legislation

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

a) The Act referred to at Point 11b in Part 1.1 of Chapter I of Annex I to the EEA Agreement, Regulation (EU) 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.

b) The Act referred to at Point 13 in 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 sectoral adaptations referred to in Annex I to that Agreement;

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

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

e) The Act referred to at Point 52 in Part 6.2. of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 2073/2005 of 5 December 2005 on microbiological criteria for foodstuffs*, as amended;

f) The Act referred to at Point 86 of Chapter XII of Annex II to the EEA Agreement, *Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004*, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex II thereto.

Annex 3 - NSFA comments to associated findings and conclusions

Findings in draft report from ESA - case No 84735	NSFA comment to associated findings and conclusions
Associated finding paragraph 11 *«Staff were generally knowledgeable on the subject of RTE foods but some inspectors had not fully understood some of the specific and quite technical requirements of Regulation (EC) No 2073/2005 e.g. environmental testing for Lm and what constitutes processing areas and equipment (two inspectors considered sampling brine as suitable for environmental testing), the fact environmental sampling for Lm should take place during production rather than after cleaning of the premises and that the food safety criteria in point 1.3; Chapter 1 of Annex I to Regulation (EC) No 2073/2005 still apply to RTE foods with low water activity (aw) unable to support growth of Lm.»*	**Comments to associated finding paragraph 11** Sampling of brine: We refer to the NFSA guideance «Official control of Listeria monocytogenes in RTE food» (page 8) regarding alternative sampling methods (Regulation (EC) No 2073/2005 Article 5 point 5): «*Sampling from brine can replace product samples of «rakfish», as an alternative method for sampling of RTE food, if the FBO can provide that these sample procedures provide at least equivalent guarantees. The method must be validated against the reference method.»* Further, we refer to guidelines on sampling the food processing area and equipment for the detection of Listeria monocytogenes (Version 3 – 20/08/2012) from EURL for Listeria monocytogenes. Under 2 Scope, NOTE 1 it is described: *«Surfaces of the processing area and equipment are not the only places to monitor, the sampling scheme should also include processing aids (such as compressed air, ice, brine solution, water, drain water….)» Please see link:* https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_mc_guidelines_on_sampling.pdf RTE foods with low water activity: This finding refer to NFSA`s answer related to brown cheese, "brunost". In the remote audit, NSFA informed that for this type of cheese Chapter 1 of Annex I to Regulation (EC) No 2073/2005, food categori 1.3, footnote 4 applies. We interpretate that regular testing of Listeria monocytogenes against the criterion is not useful for brown cheese «brunost».
Conclusion paragraph 23 *«The registration and approval procedures for RTE establishments are generally satisfactory and the establishments reviewed were appropriately registered / approved at the time of the remote audit. Notwithstanding, the CA does not always follow procedures for the approval of establishments and this has resulted in non-approved establishments placing food on the market and product leaving an establishment with no identification mark.»*	**Comments to conclusion paragraph 23** To avoid misunderstanding, we would like to emphasize that when the products were placed on the market, they did have an identification mark.

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Findings in draft report from ESA- case No 84735	NSFA comment to associated findings and conclusions
Associated finding paragraph 33 *«In a dairy establishment, no centrally produced template had been completed during a period of prioritisation for Lm controls in these establishments. In addition, not all risk factors had been included in determining the frequency of inspections for this establishment as the CA did not consider the use of unpasteurised milk to be a risk factor.»*	**Comment to associated finding paragraph 33** The region that was interviewed report that they do consider unpasteurised milk as risk factors. The department have determined risk-based frequency of inspection for this establishment to once a year. This evaluation is based on activity for dairy products including raw milk, the size of the business, results of the previous official controls and implemented procedures based on HACCP-principles.
Associated finding paragraph 35 *«CA confirmed surveillance related to Lm in RTE food was carried out in 2016 (fishery products) and 2017 (meat and dairy products). The overarching surveillance plans ("OK plans") for 2019 and 2020 include a section on Lm surveillance in RTE foods e.g. dairy, meat and fish / seafood products. Sampling plans for Lm were seen by audit team for this period with distribution of samples, by commodity, to each region.»*	**Comment to associated finding paragraph 35** Please note that surveillance related to Lm in RTE food was carried out in 2016 (fishery products), 2017 (meat) **and 2016 and 2018 (dairy products**).
Associated finding paragraph 42 *«The NRL for food pathogens related to terrestrial animals has delegated certain of its tasks to this service provider. The service provider is accredited by the Norwegian Accreditation Body to organise proficiency tests (PT) for food pathogens which it does for the laboratories within its own group. Results of PT are not automatically reported to NRL who confirmed they must request these results. The most recent set of PT results was obtained by NRL in advance of their annual meeting with the designated laboratories. NRL confirmed it is not involved in the follow-up if there has been poor performance during PT.»*	**Comment to associated finding paragraph 42**: The NRL has not delegated any task to service provider. It is not an OCR requirement to arrange PT if appropriate PTs are available. As the PT provider is accredited for this service, the accreditation body ensures that the organiser of the PT schemes is separated from any laboratories taking part in the PT.

Annex 4 – NSFA action taken and plan for corrective measures and actions

No	Recommendations from ESA in draft report	NSFA action taken and plan for corrective measures and actions	Suggested time
1	*Norway should ensure that national reference laboratories (NRLs) have timely access to proficiency testing results performed by a third party so they can, where necessary, ensure an appropriate follow up as required by Article 101 point 1(c) of Regulation (EU) 2017/625.* *Recommendation based on conclusion at paragraph 57. Associated finding: paragraph 42.*	At the meeting between NRL, official laboratory and NFSA arranged 9 December 2020, the findings and possible routines for collecting and follow-ups of PTs organised by others than the NRL were discussed. NRL establishes routines together with the official laboratory for reporting and follow-ups on PTs. NFSA will be notified if the official laboratory fails in PTs.	November 2021
2	*CA should ensure that laboratory analyses and tests on samples taken during official controls and other official activities are performed in designated official laboratories as required by Article 37(1) of Regulation (EU) 2017/625. Recommendation based on conclusion at paragraph 57. Associated findings: paragraph 43.*	Information about designated laboratories are available at NFSAs Intranet. It is also included in the "*Instruks*" "*Prøvetaking i Mattilsynet*" that analyses are to be carried out only at laboratories NFSA have agreement with.	–
3	*CA should ensure that an establishment subject to approval does not operate unless the CA has granted the establishment approval to operate as required by article 4(2) and 4(3) of Regulation (EC) No 853/2004.* Recommendation based on conclusion at paragraph 23. Associated findings: paragraph 21.	The NSFA Head Office, Hygiene and Drinking Water Section and the Sea Food Section, will present the findings from this ESA remote audit to the Regional level. In this presentation a topic will be requirements for approval. In 2021 NSFA plan to revise the control template for approval of FBOs. This includes a user manual for the approval process in our case handling system «MATS» based on the revision of the NSFA guidance on FBO approval.	April 2021 –
4	*CA should ensure that FBOs apply an identification mark before the product leaves the establishment of production as required by Annex II, Section I(A)(1) of Regulation (EC) No 853/2004.* *Recommendation based on conclusion at paragraph 23. Associated findings: paragraph 22.*	The NSFA Head Office, Hygiene and Drinking Water Section and the Sea Food Section will evaluate the NSFA guidance on FBO approval and consider a closer description for the use of identification mark when an establishment is moving to new premises.	October 2021

No	Recommendations from ESA in draft report	NSFA action taken and plan for corrective measures and actions	Suggested time
5	*CA should ensure that when they identify a non-compliance, they take action to ensure that the operator remedies the situation and prevents further occurrences of such non-compliance as required by Article 138(1)(b) of Regulation (EU) 2017/625.* *Recommendation based on conclusion at paragraph 60. Associated findings: paragraphs 52, 54 and 55.*	The Head Office, the Hygiene and Drinking Water Section and the Sea Food Section, will make a joint presentation to the Regional level of the findings from this ESA remote audit. In this presentation we will emphasize that in the case of non-compliance, it is important to decide proportional measures and time limits. We will also focus on the importance of following up by verifying that the non-compliances are corrected within the set time limits. We would like to inform ESA that there is a central process in the NFSA on our internal control to ensure that the NFSA meets the obligations it has in laws and regulations including the Official Controls Regulation (EU) 2017/625. A relevant part of this process covers official control which includes follow-up of non-compliance until the businesses have complied.	April 2021 –