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Final report

EFTA Surveillance Authority's mission to

Iceland

from 14 to 23 October 2019

on official controls over the production of meat and milk

and their products

In response to information provided by Iceland, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote. Comments from Iceland to the draft report are included in Annex 4 and information on the corrective actions already taken and planned are included in Annex 5 to the report.

Executive Summary

This report describes the outcome of a mission carried out by the EFTA Surveillance Authority (the Authority) in Iceland from 14 to 23 October 2019.

The objective of the mission was to evaluate the official control system implemented by the Icelandic competent authorities related to the hygienic production of meat, milk and their products.

A procedure for the registration of primary producers and the approval of meat and milk establishments has been established. The requirement to keep approval of establishments under review when carrying out official controls does not take into account structural and operational changes which may impact on food safety.

Official controls related to meat and milk production, from primary production through to processing, are carried out on a risk basis though not all identified risks are considered when calculating the frequency of these controls. This may lead to the objectives of the hygiene legislation not being fully met in establishments as insufficient time may be allocated to officials to perform their controls satisfactorily. On farms, this means inspections are performed at a set frequency irrespective of farm size and does not target farms likely to be a higher risk for food safety issues.

Official staff employed on a temporary basis do not have the necessary training and qualifications to perform their duties satisfactorily. Official controls related to certain inspection tasks such as post mortem inspection, where many of the European Economic Area (EEA) inspection tasks are systematically not carried out, and monitoring food business operator (FBO) compliance with the requirement to remove specified risk material (SRM) from cattle are weak. This increases the possibility of unsafe food entering the human food chain and animal diseases not being detected.

An identification system is in place for horses and is working satisfactorily. However, the reliability of animal identification in cattle and sheep is weakened by incomplete compliance with the requirement for ear tags in cattle and sheep to have, inter alia, non-removable inscriptions for all cattle ear tags and for ear tags not to be re-used in sheep.

Microbiological sampling is performed by FBOs but there is limited oversight and understanding of the requirements by many of the officials met. In the meat sector, this will result in limited opportunity for interventions to improve slaughter hygiene and review process controls. In the dairy sector, lack of sampling for food safety criteria, shortcomings in process hygiene criteria sampling and inadequate verification of the pasteurisation process, restricts the opportunity to improve process hygiene and ensure food safety requirements are fully met. Overall, this may increase the risk of unsafe food being placed on the market.

National reference laboratories (NRLs) for Trichinella and microbiology are not fulfilling, inter alia, their roles for co-ordination of activities in official laboratories and organising comparative testing which may result in inaccurate test results.

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

Table of contents

| | |
|--|-----------|
| 1. INTRODUCTION | 4 |
| 2. OBJECTIVE AND SCOPE OF THE MISSION | 4 |
| 3. LEGAL BASIS FOR THE MISSION | 5 |
| 4. BACKGROUND - PREVIOUS MISSIONS..... | 5 |
| 4.1 PREVIOUS MISSIONS | 5 |
| 4.2 INFORMATION ON PRODUCTION | 5 |
| 5. FINDINGS AND CONCLUSIONS..... | 5 |
| 5.1 LEGISLATION AND IMPLEMENTING MEASURES..... | 5 |
| 5.2 COMPETENT AUTHORITIES..... | 6 |
| 5.2.1 Designation of competent authorities and organisation of official controls | 6 |
| 5.2.2 Personnel and training of staff..... | 6 |
| 5.2.3 Ante-mortem inspection..... | 7 |
| 5.2.4 Post-mortem inspection..... | 7 |
| 5.2.5 Animal identification..... | 8 |
| 5.2.6 Risk based controls and documented control procedures | 8 |
| 5.2.7 Verification | 9 |
| 5.2.8 Enforcement measures | 10 |
| 5.3 REGISTRATION AND APPROVAL OF FOOD BUSINESS OPERATORS..... | 10 |
| 5.4 OFFICIAL CONTROLS OVER FOOD BUSINESS OPERATORS' COMPLIANCE WITH HYGIENE RULES AT ESTABLISHMENT LEVEL | 11 |
| 5.4.1 General and specific hygiene rules | 11 |
| 5.4.2 Good hygiene practices..... | 12 |
| 5.4.3 Hazard analysis and critical control point (HACCP) based procedures..... | 12 |
| 5.4.4 Health marking | 14 |
| 5.4.5 Control of milk production holdings | 14 |
| 5.4.6 Control of milk upon collection..... | 15 |
| 5.5 LABORATORIES, SAMPLING AND ANALYSIS | 16 |
| 6. FINAL MEETING..... | 17 |
| 7. RECOMMENDATIONS..... | 17 |
| ANNEX 1 - LIST OF ABBREVIATIONS AND TERMS USED IN THE REPORT | 19 |
| ANNEX 2 - RELEVANT LEGISLATION..... | 20 |
| ANNEX 3 - TOTAL RED MEAT PRODUCTION TRADED WITHIN EEA IN 2017 AND 2018. | 22 |
| ANNEX 4 - COMMENTS FROM ICELAND TO THE DRAFT REPORT | 23 |
| ANNEX 5 - PLAN FOR CORRECTIVE MEASURES PROVIDED BY ICELAND | 25 |

1. Introduction

The mission took place in Iceland from 14 to 23 October 2019. The mission team comprised three auditors from the EFTA Surveillance Authority (the Authority).

A pre-mission questionnaire was sent by the Authority to the Icelandic Ministry of Industries and Innovation on 8 July 2019. A reply ('the pre-mission document') was provided on 20 September 2019.

The opening meeting was held with representatives of the Icelandic Food and Veterinary Authority (MAST) on 14 October 2019 in Selfoss. At the meeting, the mission team confirmed the objectives and the itinerary of the mission and the Icelandic representatives provided additional information to that set out in the pre-mission document. The mission team were accompanied throughout the mission by representatives of MAST.

A final meeting was held at Hafnarfjordur on 23 October 2019 when the mission team presented its main findings and preliminary conclusions from the mission.

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

2. Objective and scope of the mission

The main objective of the mission was to evaluate the official control systems implemented by the Icelandic competent authorities related to the hygienic production of meat, milk and their products.

The main scope of the mission was to assess:

- All stages of meat and milk production and processing, with a particular focus on products of animal origin derived from cattle, sheep, pigs and horses produced in approved establishments;
- Controls over meat, minced meat, meat preparations, meat products and mechanically separated meat;
- Controls over milk and dairy products;
- Assessment of progress made since previous missions on related topics.

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

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

The meetings with the competent authorities and the visits to establishments during the mission are listed in Table 1.

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

| | Number | Comments |
|--------------------------------|--------|--|
| Competent authorities | 2 | An initial meeting and a final meeting between the mission team and the Icelandic competent authorities. |
| MAST Districts | 4 | |
| Dairy farms | 2 | |
| Milk processing establishments | 2 | |
| Slaughterhouses | 4 | 2 sheep, 1 multi-species (cattle and horses) and 1 pig slaughterhouse. In all slaughterhouses visited, co-located cutting / meat preparations / meat products. |
| Laboratory | 3 | Private laboratory providing microbiological services to industry and 2 in-house laboratories. |

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;
- c) Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States;
- d) Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Legislation relevant to this mission is listed in Annex 2.

4. Background - Previous missions

4.1 Previous missions

This Authority carried out a mission to Iceland from 7 to 16 May 2012 regarding controls on meat, minced meat, meat products, meat preparations, milk and dairy products. This was the first mission carried out by the Authority within the framework of the Food Hygiene Package, which was incorporated into the European Economic Area (EEA) Agreement on 1 May 2010 and, following a transitional period of 18 months, entered into force in Iceland on 1 November 2011.

The Authority has since carried out missions on related topics, including a mission from 22 to 26 September 2014 to evaluate the official controls related to processed casings, a mission from 28 November to 7 December 2016 to assess the official controls in Iceland related to post-slaughter traceability and labelling of meat and products thereof, and to use of additives in these products and a mission from 11 to 20 June 2018 on animal by-products not intended for human consumption.

The present mission will allow the Authority to follow-up on the actions taken by the relevant competent authorities to address recommendations issued following these earlier missions. The final report from these missions can be found on the Authority's website (www.eftasurv.int).

4.2 Information on production

Trade in meat within the EEA in 2017 and 2018, as provided by MAST in the pre-mission document, is summarised in Annex 3.

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 Icelandic internal legal order.

Findings

1. According to information provided by Iceland in its reply to the Authority's pre-mission document, the relevant EEA legislation regarding meat, milk and products thereof, as listed in Annex 2 to this document, is implemented in the Icelandic legal order.

Conclusions

2. The relevant EEA requirements related the production of meat and milk and their products have been implemented in the Icelandic legal order.

5.2 Competent authorities

Legal Requirements

Articles 3, 4, 6, 8, 9 and 54 of Regulation (EC) No 882/2004

Article 5 and Section I, Chapter II Points B and D, Section II Chapter III 1-8 and Chapter IV, Section III Chapter IV and Section IV Chapter I-IV of Annex I to Regulation (EC) No 854/2004, Article 2 of Regulation (EU) 2015/1375)

Findings

5.2.1 *Designation of competent authorities and organisation of official controls*

3. According to information provided by Iceland in its reply to the Authority's pre-mission document, part 1 of the country profile describes the organization of the Icelandic authorities and their control systems covering the whole chain of animal food production.
4. Primary production and slaughterhouses are under the control of MAST and these control activities are carried out by the District Veterinary Offices or by the MAST Food Control Team (FCT).
5. There are six MAST districts in Iceland each with a District Veterinary Officer (DVO) responsible for a team of official veterinarians (OVs) and animal welfare officers. DVOs are responsible for primary production and daily supervision of slaughterhouses and a Food Control Team (FCT) carries out regular inspections and audits of slaughterhouses and meat plants and milk processors. There are 10 staff members in the FCT, three of which specialize in meat and milk and the remainder specializing in fish. Establishments retailing meat and distribution centers for milk are under the responsibility of Local Competent Authorities (LCAs) while the DVOs and the FCT are responsible for e.g. small ice-cream producers and cheese producers on farms.
6. MAST has implemented a teamwork procedure in the area of primary production and is in the process of developing this approach for meat and dairy establishments. The primary production procedure involves an inspection team and a decision team. The former is responsible for a range of duties including responding to serious animal welfare incidents, follow-up of non-compliances and performing regular on-farm inspections. The latter is responsible for e.g. decision making in relation to enforcement actions and penalties. The overall objective of the teamwork procedure is to improve the consistency of audits and inspections throughout Iceland. All control staff work according to the existing general documented procedures, which are established in MAST's Quality Manual.
7. According to the pre-mission document, additional staff are employed on a temporary basis during the sheep slaughter season (September – October). Approximately 15 – 20 temporary OVs are employed to deliver official controls in sheep slaughterhouses.

5.2.2 *Personnel and training of staff*

8. All official controls in slaughterhouses, including post mortem examination, are in principle performed by OVs. There are a small number of veterinary auxiliaries /assistants employed by the CA, whose main task is to do on-line inspection work under the supervision of OVs.
9. Official veterinarians employed on a permanent basis by MAST receive training and are examined through e.g. a better training safer food (BTSF) e-learning course and by a Norwegian company specializing in knowledge and expertise in the meat industry.
10. Prior to the start of the 2019 sheep slaughter season, MAST organized a two-day training course for temporary Official Veterinarians working in sheep slaughterhouses. The first day included, inter alia, theoretical training covering relevant legislation, hygiene, animal welfare, ante-mortem and post-mortem inspection and animal by-products. The second day consisted of practical training in a sheep slaughterhouse. CA provided the audit team with an attendance record of the temporary veterinarians who participated on this course.
11. According to pre-mission document, temporary veterinarians working in slaughterhouses should be accompanied by a permanently employed veterinarian or an experienced veterinarian. The CA was unable to demonstrate how temporary veterinarians received practical training for a probationary period of at least 200 hours before starting to work independently as required by Annex I, Section III, Chapter IV(A)(4) of Regulation (EC) No 854/2004.
12. In one Region visited by the audit team, six temporary veterinarians were appointed as official veterinarians to cover the 2019 sheep slaughtering season. Only one of these veterinarians

attended the 2019 training course. Four out of the six temporary staff then went on to form the complete veterinary inspection team in a sheep slaughterhouse¹.

13. The CA confirmed that in one district, a veterinary student was employed by MAST to perform OV duties in a sheep slaughterhouse. Article 6 of the Icelandic Veterinary and Animal Health Services Act No. 66 of 15 June 1998 permits veterinary students that are in the later stages of studies to do certain work on a temporary basis if they are under veterinary supervision and are approved by MAST. This veterinary student had not attended the two-day training course for new official veterinarians before starting work.
14. The CA confirmed that these veterinary students could perform a range of tasks including veterinary ante-mortem examination in slaughterhouses. This is not in compliance with Annex I, Section III, Chapter IV(A)(1) of Regulation (EC) No 854/2004.
15. The training record (document EBL-014) for a new member of the FCT was available and detailed the relevant trainings and supervisions undertaken including visits to establishments accompanied by an experienced FCT member. Neither the training record, nor the training document (LBE-151) sets out the minimum training an inspector must undergo prior to working independently.
16. The DVO is responsible, on a daily basis, for delivery of official controls in slaughterhouses. Throughout the sheep slaughter season, the "Veterinary Officer of Meat Inspection" visits each sheep slaughterhouse to assess if the OVs are working in accordance with the MAST quality manual in relation to daily inspections at slaughterhouses. Veterinary Officer of Meat Inspection fills out document GAT-052.2.0 for each member of staff assessed. Completed documentation was provided to the audit team for the 2019 sheep slaughtering season.

5.2.3 *Ante-mortem inspection*

17. According to the pre-mission document, the official controls system for ante-mortem inspections at slaughterhouses is described in Chapter 4 of the inspections manual for daily inspections at slaughter of sheep, pigs and large animals.
18. Ante-mortem inspection is performed exclusively in slaughterhouses - the CA confirmed that emergency slaughter outside slaughterhouses does not occur in Iceland.
19. Procedures are in place in all slaughterhouses visited to ensure that only animals which have undergone veterinary ante-mortem inspection are slaughtered. Ante-mortem inspection records were available and signed by OVs before lairage staff of food business operators ('FBOs') presented the animals for slaughter. In one slaughterhouse visited, a non-compliance report had been issued for one animal which had been slaughtered without ante-mortem inspection. However, OV had not considered forward tracing of this carcass to ensure meat was withdrawn from the market.
20. Food chain information (FCI) is made available to OVs in a timely manner. The format of the FCI document is determined by FBOs and contains the required information e.g. confirmation that the animals are healthy, the withdrawal period for any veterinary medicinal products administered has been met, the animals are properly identified and there are no animal movement restrictions at the farm of origin. FCI documents reviewed were signed by the presenting farmer, the animal transporter and on arrival at the slaughterhouse, the lairage staff. Official staff met were generally familiar with FCI documentation. FCI was available in all slaughterhouses visited by the audit team.
21. In one slaughterhouse visited, FCI was delivered directly to the OV. The FBO did not evaluate the relevant FCI before making it available to the OV (see paragraph 68).
22. In slaughterhouses visited by the audit team, evidence of official enforcement actions taken at lairage level were available e.g. issuing a non-compliance for holding pens with no drinking water and a centrally issued letter from MAST reminding all slaughterhouse FBOs that animals must be provided with feed if kept in the lairage for prolonged periods. In addition, evidence was available in one slaughterhouse of an animal being declared unfit for human consumption in the lairage based on ante-mortem inspection.

5.2.4 *Post-mortem inspection*

23. According to the pre-mission document, post-mortem inspections are conducted by DVO/OV in compliance with the provisions of Regulation (EC) No 854/2004 and Chapter 12 of LBE-046.

¹ In their response to the draft report the Competent Authority noted that three of the six temporary veterinarians had worked as official veterinarians during previous sheep slaughter seasons.

24. With few exceptions (see paragraph 8), carcasses and accompanying offal are subjected to post-mortem inspection by OVs. The audit team observed the post-mortem inspection of pigs and considered it was performed satisfactorily and in line with legislative requirements. However, this was not the case for sheep, cattle and horse post-mortem inspections observed by the mission team.
25. During post-mortem inspection of sheep, there was no visual inspection of heads despite the majority of lamb heads being harvested for human consumption. In addition, there was routinely no incision of the gastric surface of the liver to examine the bile ducts. The CA confirmed this was the procedure in all sheep slaughterhouses. This is not in compliance with Annex I, Section IV, Chapter II (5) of Regulation (EC) No 854/2004.
26. During post-mortem inspection of cattle, in one slaughterhouse visited, there was no routine incision and examination of the sub-maxillary and parotid lymph nodes nor the bronchial and mediastinal lymph nodes. Furthermore, there was no lengthways incision of the heart so as to open the ventricles nor incision of the gastric surface of the liver and at the base of the caudate lobe to examine the bile ducts. This is not in compliance with Annex I, Section IV, Chapter I(B)(1), (2), (3) and (5) of Regulation (EC) No 854/2004.
27. During post-mortem inspection of horses, in one slaughterhouse visited, there was no lengthways incision of the heart so as to open the ventricles and cut through the interventricular septum. This is not in compliance with Annex I, Section IV, Chapter III(3) of Regulation (EC) No 854/2004.

5.2.5 *Animal identification*

28. Regulation (EU) No 2015/262 (methods for the identification of equidae) does not apply in Iceland. Notwithstanding, a functional horse identification system is in place based on an electronic transponder (microchip) and an equine database – horse passports are not issued in Iceland. Horses presented for slaughter are accompanied by FCI and includes the information outlined in paragraph 20.
29. The horse database has the functionality to highlight horses excluded from the human food chain due to e.g. treatment with certain veterinary medicinal products. The audit team followed an example of a horse excluded from the food chain and could verify it was correctly identified in the database.
30. In one horse slaughterhouse visited, the FBO explained that the livestock haulier scanned all horses for electronic transponders when collecting them from farms. In the slaughterhouse, the electronic transponder was again scanned post slaughter. FBO administrative staff then cross checked this number with incoming FCI and information held on “WorldFengur” the Icelandic horse studbook to ensure they all matched.
31. In one sheep slaughterhouse, both electronic and conventional sheep ear tags were collected by FBO for return to farmers for re-use. In a second sheep slaughterhouse visited, FBO confirmed this was standard practice throughout Iceland and the CA concurred. This is not in compliance with Section A(3) of the Annex to Regulation (EC) No 21/2004.
32. In one bovine slaughterhouse, a batch of approximately fifty ear tags from the previous day’s kill was examined. As a minimum, three of the ear tags had removable inscriptions. This is not in compliance with Article 2(e) of Regulation (EC) No 911/2004.
33. The CA confirmed there is no national pig database and there is no requirement for slaughter pigs to be identified. The national requirement to identify pigs is provided by Article 8 of the Icelandic Regulation 916/2012.

5.2.6 *Risk based controls and documented control procedures*

34. A risk based system has been established by the CA to determine the frequency of official control delivery on farms and in meat and milk establishments. All findings and reports are kept in MAST’s electronic database Ísleyfur.
35. According to information provided in the pre-mission document, the risk assessment for meat and milk establishments takes into account:
 - a) the type of production and raw material
 - b) the size of the operation which can be based on production / throughput or number of staff
 - c) final consumer group for the product in question

The FBOs are allocated a score for each of these variables and additional time is added for controls on labelling and the complexity of production. This total score then determines the number of hours of official controls per year.

36. During audits, the inspector reviews changes in production type and production volume and amends the database Ísleyfur as appropriate. The database then re-calculates the time allocated for official controls.
37. The CA have produced guidance for risk categorization of farms. The latest version is dated 12/01/18. The guidance outlines the weighting for animal welfare and food safety risks and provides a matrix to determine frequency of official controls. This can range from once per annum to once every 5 years. The veterinary officers who performs the on-farm control follows a checklist and the results are kept in the database Ísleyfur.
38. Monitoring official controls is the responsibility of MAST coordination department. Their role is described in the guidance document "Verification of the effectiveness of official controls" and includes the modification of risk based official control systems.
39. The mission team noted that in one dairy processor visited, the complexities of the business were not considered in the calculation of the official control hours e.g. inspection hours allocated are based on the volume of milk in and did not consider the large volume of whey received nor the complexity of production.
40. The primary production risk assessment is not influenced by the number of cattle on a farm i.e. the same weighting is given to a herd with two cattle and a herd with two hundred cattle. In addition, the risk assessment is more developed and weighted to animal welfare rather than food safety issues.
41. The guidance for risk categorization of farms has not been updated for almost two years (see paragraph 92). Consequently, references in the document are outdated e.g. the EU summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks of 2015 is listed rather than the more recent version.
42. The frequency of official controls at farm level was carried out in line with the risk categorization in two out of the three districts visited. In the third district, this was not the case. On the farm visited by the audit team, there had been no official controls related to food safety since at least 2013 (see paragraph 93). Since then, the operation had changed significantly with more cows and a total rebuild of the dairy farm.
43. In another district, there was evidence of poor enforcement at farm level e.g. the same non-compliance related to absence of veterinary medicine records was recorded during official controls in 2014 and 2019 with no follow up. In contrast, a third district demonstrated good corrective action following notification of high somatic cell counts on a farm under their control. This included a farm visit and a comprehensive report.
44. Documented procedures are available for MAST staff performing audit and inspection duties in establishments producing products of animal origin (POAO), for the daily completion of OV checklists in slaughter establishments and for the completion of primary production checklists.
45. However, the audit team noted that the guidance for completion of daily OV checks in slaughterhouses (LBE-046) is only available in Icelandic. MAST currently employ OVs from several European countries e.g. Poland, Spain and Slovakia with no pre-employment language assessment.
46. Microbiological criteria guidance has not been updated recently e.g. the link to the consolidated EEA microbiological legislation shows the last amendment was in 2010 rather than the most recent amendment of 2019. The MAST guidance for sampling frequency of sheep carcasses (aerobic colony count and enterobacteriaceae) permits reductions in sampling frequency based on throughput rather than test results i.e. > 100,000 sheep per annum requires 5 samples /week, 50 000 – 10 0000 sheep per annum requires 5 samples every other week, 10 000 – 50 000 sheep per annum requires 5 samples taken twice during the lamb slaughter season and <10 000 sheep per annum requires no sampling. The guidance applies the same approach to sampling frequency for cattle and horse carcasses i.e. a reduced frequency for aerobic colony count and enterobacteriaceae sampling based on throughput rather than satisfactory results. This is not in accordance with Annex I, Chapter 3.2 of Regulation 2073/2005.

5.2.7 Verification

47. The DVOs and "Veterinary Officers of Meat Inspection" have a role in verifying the performance of OVs (see paragraph 16).

48. The CA confirmed that their 2017 - 2020 programme of internal audits (LEMA) did not include any audits relevant to the scope of this mission.

5.2.8 Enforcement measures

49. According to the pre-mission document, the Icelandic Act No. 93/1995 on Food provides the CA with a range of enforcement measures. The CA has the authority to stop production if foodstuffs are considered e.g. unfit for human consumption or the production is operated without an approval. The CA has also the authority to seize and destroy foodstuffs if a reasonable suspicion exists that Act No. 93/1995 has been breached. Furthermore, the CA can demand improvements and impose daily fines if the demands are not met. The maximum daily fines are 500 000 Icelandic krona per day for hygiene related issues concerning food and feed and 100 000 Icelandic krona per day for animal welfare issues.
50. The CA described the team work approach to primary production (see paragraph 6) and their plans to introduce this for approved food establishments. In the meantime, a hierarchical approach is taken to enforcement in slaughterhouses i.e. verbal warning from OV, written warning from OV, written warning from DVO and finally the case is passed to the Office for Coordination to progress.
51. The mission team noted that certain non-compliances identified by the FCT during audit are not given a time limit for remedial action to be taken. Rather, the non-compliance is followed up at the subsequent audit (which may be many months later). It is only at the subsequent audit, if no corrective action has been taken, that time limits are applied.
52. In one slaughterhouse visited, a comprehensive record of enforcement was maintained by officials. This included nature of non-compliance and dates when oral and written advice was provided by OV and also when written advice was provided by DVO.

Conclusions

53. The training provided to temporary OVs performing official controls in sheep slaughter establishments is weak and does not provide them with adequate knowledge to perform their tasks satisfactorily. This, together with the use of veterinary undergraduates as OVs, may increase the likelihood of unfit food entering the food chain.
54. Official controls related to post-mortem inspection of cattle, sheep and horses are weak. This increases the possibility of unsafe food entering the human food chain and animal diseases not being detected.
55. An identification system is in place for horses and is working satisfactorily. However, the reliability of animal identification in cattle and sheep is weakened by incomplete compliance with the EEA requirements for ear tags in cattle and sheep.
56. Official controls related to meat and milk production, from primary production through to processing, are carried out on a risk basis though not all identified risks are considered when calculating the frequency of these controls. This may lead to the objectives of the hygiene legislation not being fully met in establishments as insufficient time may be allocated to perform the controls adequately.

5.3 Registration and approval of food business operators

Legal Requirements

Article 31 of Regulation (EC) No 882/2004

Article 6 of Regulation (EC) No 852/2004

Article 4 of Regulation (EC) No 853/2004

Article 3 of Regulation (EC) No 854/2004

Findings

57. DVOs are responsible for registration / approval of primary production holdings and the FCT is responsible for approval of meat and milk FBOs.
58. According to the Icelandic Act No 93/1995 on Foodstuffs, primary producers of food of animal origin must be approved following an application and official control visit, except for premises for sheep production and horse farms which should only be registered.

59. Guidance on FBO approval procedures is available to MAST staff via their on-line quality manual. General procedures for FBOs to follow when applying for approval and more specific guidelines for both meat and milk FBOs is available on MAST website. The FBO guidance covers, inter alia, application process and documents which must be submitted, issue of approval number and requirements for certain country specific markets.
60. The mission team noted that the farms / slaughterhouses visited were appropriately registered/approved for the activities carried out. In one dairy visited, the approval document listed milk powder even though the product was not produced. Conversely, the same FBO produced whey protein but this was not listed on the approval document.
61. A national legislative requirement exists (Act No 93/1995, Article 9) which requires FBOs to notify the CA of significant changes to their business. In one slaughterhouse visited by the audit team, FBO confirmed they had not submitted detailed plans regarding a significant expansion of their processing establishment. Similarly, one of the dairies visited was in the process of moving a production line into a new part of the building. Production had started although the new building work had not been completed with e.g. storage of equipment.
62. A recent case (2019) of approval for a slaughterhouse and a dairy were reviewed by the audit team. The FBO's application for approval, the FCT report following an on-site visit and the subsequent conditional approval document were assessed and found to be satisfactory.

Conclusions

63. The registration of farms and the approval procedure for meat and milk establishments is generally satisfactory. The establishments visited were in general, appropriately registered or approved. However, the non- notification by FBOs of significant changes restricts the CA's ability to evaluate the impact of these changes.

5.4 Official controls over Food Business Operators' compliance with hygiene rules at establishment level

Legal requirements

Article 4, 5 and 8, Chapter I and II of Section I of Annex I and Annex IV of Regulation (EC) No 854/2004

Article 4 and 5 of Regulation (EC) No 852/2004

Article 3 and 5 and Section III of Annex II of Regulation (EC) No 853/2004

Article 18 of Regulation (EC) No 178/2002

Regulation (EC) No 2073/2005

Regulation (EC) No 2074/2005

Regulation (EC) No 999/2001

Findings

5.4.1 General and specific hygiene rules

64. Official controls in respect to meat and milk should include audit of good hygiene practices and hazard analysis and critical control point (HACCP) based procedures as required by Article 4(3) of Regulation (EC) No 854/2004. In slaughterhouses, there are three levels of official controls regularly performed to verify FBO compliance with the requirements of Regulation (EC) No 852/2004, Regulation (EC) No 853/2004 and Regulation (EC) No 1069/2009:
 - daily checklist (GAT-019.3.0) completed by OV in slaughterhouse
 - checklist (GAT-052.2.1) completed by Veterinary Officer of Meat Inspection once (or twice) per sheep slaughter season. DVOs have the option to use this during their inspections.
 - risk based audit performed by FCT (see paragraph 34)

In milk processing establishments, official controls are performed on a risk basis by FCT.

65. In all slaughterhouses visited, daily checklists (GAT-019.3.0) were available and completed. In slaughterhouses and milk processing establishments visited, completed FCT audit reports were available. Review of FCT reports for establishments visited demonstrated identification and follow up of non-compliances e.g. use of wooden pallets in production areas. However, in at least three of the districts visited, no checklist (GAT-052.2.1) had been completed by DVOs during the 2019 lamb slaughter season to demonstrate DVO supervisions.

5.4.2 *Good hygiene practices*

66. Audits of good hygiene practices should verify that FBOs apply procedures continuously and properly concerning, inter alia, food chain information, design and maintenance of premises and equipment, operational hygiene and water quality.
67. According to information provided in the pre-mission document, guidance is provided for DVO / OV concerning FCI. This includes the prohibition of slaughter unless the FBO has received and checked relevant FCI.
68. In one slaughterhouse visited by the audit team, the accepted procedure was to present FCI directly to the OV with no prior evaluation by the FBO (see paragraph 21). This does not permit FBO to comply with their obligations to guarantee, inter alia, FCI is presented, animals originate from a holding with no movement restrictions and any animals treated with veterinary medicinal products have fulfilled the necessary withdrawal period prior to slaughter. This is not in compliance with Annex II, Section III (5) of Regulation (EU) No 853/2004 and official controls did not detect this practice as a non-compliance².
69. In the slaughterhouses visited, a number of issues related to the design and maintenance of premises were identified. These included e.g. wash-hand basins blocked and overflowing, sterilizer too small to allow full immersion of implements in water, the requirement to cross the carcass line to dispose of animal by products (ABPs) with concurrent risk of cross contamination of carcasses from dirty ABP container, poor ventilation / extraction in slaughterhall leading to condensation and subsequent drip onto carcasses and the general poor control of waste water including e.g. the carcass splitting saw in one establishment.
70. Similarly, a number of operational hygiene issues were identified by the audit team which had not been noted on recently completed daily OV checklists (GAT-019.3.0). These included e.g. inconsistent sterilization of knives by FBO operatives, the use of sinks as apron washes and the storage of packaging in an operational area leading to its decomposition. In addition, the audit team observed the use of caustic soda in a process to wash sheep heads for human consumption. This is not in accordance with Article 3(2) of Regulation (EC) 853/2004.
71. Official controls should verify that FBOs are continuously and properly applying procedures to ensure water quality. Points 4.1.1 and 4.1.2. of the MAST instruction manual for foods of animal origin provide guidance in relation to water quality. The guidance includes the requirement to check, amongst other things, that FBO carries out at least annual sampling and that certain microbiological parameters are met.
72. In one slaughterhouse visited, there had been no CA overview of water quality results for a period of almost two years. FBO confirmed the water was always sampled at the rising mains (point of entry of water to the establishment) and that samples were not taken from within the establishments water distribution network to verify water quality did not deteriorate therein.
73. In a storage room in one of the dairies visited, the mission team found various products, including products in damaged packaging material, expired products, unlabeled products and products with mould present. According to the operator, these products would be used in the production of spreadable cheese. In the same dairy, clean containers used in production areas, were dried in an unclean storage room. These practices had not been identified by the FCT in their reports.

5.4.3 *Hazard analysis and critical control point (HACCP) based procedures*

74. Audits of HACCP based procedures should verify that FBOs apply such procedures continuously and properly. The audits should have particular regard to, inter alia, guarantees that each animal accepted onto the slaughterhouse premises is properly identified and is accompanied by relevant FCI.
75. The guidelines for official control of products of animal origin (LBE-008) Chapter 6.4 and 6.5 provide guidance to officials on audit of HACCP based procedures and microbiological criteria respectively. The OV guidance document for completion of daily slaughterhouse checklists (LBE-046.1.0), at point 9, states that the method for microbiological sampling, the frequency of sampling and test results must be reviewed, without providing further explanation how this should be done.
76. Not all cattle are being correctly identified (see paragraph 32) and not all FCI is being screened by FBOs prior to making it available to OVs (see paragraph 21). This is not being detected by FBO procedures nor CA audit of these procedures.

² In their response to the draft report the Competent Authority noted that corrective action has been taken regarding FCI in this particular slaughterhouse.

77. OV tasks include, among other things, the requirement to check that operators' procedures guarantee, to the extent possible, that meat does not bear faecal or other contamination. In several slaughterhouses visited by the audit team, health marked carcasses were present in the chillers which were visibly contaminated with e.g. hair and intestinal contents. This deficiency in FBO compliance with hygiene rules had not been detected by official controls and is not in compliance with Annex I, Section I, Chapter I(2)(b) of Regulation (EC) No 854/2004.
78. Iceland is listed in Decision 2007/453/EC *establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk*, as a country with a negligible BSE risk. This means that for cattle, the tissues listed in Annex V, point 1(a)(i) of Regulation (EC) No 999/2001 (skull excluding the mandible and including the brain and eyes and the spinal cord of animals aged over 12 months) are defined as specified risk material (SRM). For sheep and goats, the tissues listed in Annex V, point 1(b) of Regulation (EC) No 999/2001 (skull including the brain and eyes and the spinal cord of animals aged over 12 months or which have a permanent incisor erupted through the gum, or aged over 12 months as estimated by a method approved by the competent authority of the Member State of slaughter) are defined as SRM.
79. In the sheep slaughterhouses visited, SRM controls were in place. The audit team observed sheep carcasses identified by age, sheep carcasses older than 12 months being split to remove spinal cord and sheep heads from sheep older than 12 months being excluded from the human food chain and treated as category 1 ABP. However, in one cattle slaughterhouse visited, the audit team found spinal cord present in a carcass after the final official inspection point and which was health marked. A second carcass, observed in the chills, had not been split symmetrically leaving remnants of SRM present. This is not in accordance with Annex V(4.1)(a) of Regulation (EC) No 999/2001. In addition, the official controls over FBO compliance with hygiene rules did not detect these deficiencies as required by Annex I, Section I, Chapter I(2)(c) of Regulation (EC) No 854/2004.
80. The CA confirmed that SRM is not stained with a dye or otherwise marked immediately on removal. This is the subject of a recent recommendation following an Authority mission to Iceland on animal by-products (ABPs) not intended for human consumption. The recommendation remains un-resolved. This is not in compliance with Annex V, point 3 of Regulation (EC) No 999/2001.
81. Audit of FBOs' HACCP based procedures should determine whether the procedures guarantee, to the extent possible, that products of animal origin comply with microbiological criteria laid down in EEA legislation.
82. In one dairy visited, not all food categories were included in the FBO sampling plan e.g. whey powder was not sampled for Salmonella as required by Annex I, Chapter 1, point 1.12 of Regulation (EC) No 2073/2005. In addition, the FBO was using alternative sampling and testing procedures to fulfill the requirements of process hygiene requirements e.g. the number of units comprising the sample was one rather than the required five. Furthermore, FBO was carrying out analysis for coliforms, mould, Salmonella and Listeria rather than, depending on the product, entero-bacteriaceae, E. coli and coagulase-positive staphylococci as required by Annex I, Chapter 2, point 2.2 of Regulation (EC) No 2073/2005. These shortcomings had not been identified during FCT audit and the CA could not confirm if they had accepted these alternative parameters and methods as equivalent to the requirements of Regulation (EC) No 2073/2005.
83. In one sheep slaughterhouse visited, the OV confirmed they were not aware of the microbiological sampling requirements for carcasses in Regulation (EC) No 2073/2005 and did not know how FBO carried out carcass sampling in the establishment.
84. In a second slaughterhouse, the OV completed the daily checklist (GAT-019.3.0) and marked compliance with sampling according to Regulation (EC) No 2073/2005 as compliant. However, OV confirmed they were unsure what should be checked. In this same slaughterhouse, carcasses were swabbed the day after slaughter and following chilling. This is not in compliance with Annex I, Chapter 2, point 2.1.1 and 2.1.3 of Regulation (EC) No 2073/2005.
85. Entero-bacteriaceae are a group of indicator organisms that are commonly found in the intestines of animals and the environment. In several of the slaughterhouses visited, which used both in-house and external private laboratories, it was common for e.g. entero-bacteriaceae test results to have no colony forming units (CFU) present in successive sampling events. This was never investigated by CA as unusual.
86. One in-house laboratory used proprietary test kits for enumeration of e.g. entero-bacteriaceae on carcasses and Listeria monocytogenes on meat products. The CA could not demonstrate that the proprietary test kits provide at least equivalent guarantees to the analytical reference methods

detailed in Annex I, Chapters 1 and 2 of Regulation (EC) No 2073/2005. This is not in compliance with Article 5(5) of Regulation (EC) No 2073/2005.

87. In one dairy establishment, the audit team observed that FCT audit of FBOs procedures did not identify that pasteurisation treatment involving a high temperature for a short time (at least 72°C for 15 seconds) may not be met as required by Regulation (EC) No 853/2004. Recirculation of milk to pass through the pasteurisation process for a second time was set at 71.9°C. This, together with the temperature probes being calibrated to +/- 0.5 °C and uncertainty whether the “in” or “out” temperature sensor was the one which determined recirculation of milk, introduces the possibility of non-pasteurised milk entering the food chain.
88. In the same dairy establishment, an FBO standard operating procedure (SOP) required the alkaline phosphatase test to be used three times per week to monitor the efficacy of the pasteurisation process. The audit team noted that FBO did not adhere to this frequency and this had not been identified by the CA during audit. In addition, FBO corrective action for a positive alkaline phosphatase test did not address the time period when pasteurisation was not working in order to identify all non-pasteurised products.

5.4.4 Health marking

Legal Requirements

Article 5 and Chapter III, Section I of Annex I to Regulation (EC) No 854/2004

89. According to the pre-mission document: DVO/OV are responsible for health marking of carcasses and products and for the use of health marks; it is only permitted to health mark carcasses of animals that have undergone ante-mortem and post-mortem inspections; it is acceptable to health mark carcasses before results of examination for trichinosis is available provided satisfactory results are available prior to placing the meat on the market; when half carcasses are cut into three pieces, each piece is health marked.
90. The mission team noted that, in principle, health marks were applied correctly to carcasses and identification marks were applied correctly to meat and milk products.

5.4.5 Control of milk production holdings

Legal Requirements

Article 8 and Chapter I of Annex IV to Regulation (EC) No 854/2004.

Regulations (EC) Nos 852/2004 and 853/2004.

91. According to the pre-mission document, the DVOs are responsible for controls on production of milk at primary production level. The controls are risk based since 2018, and according to the risk assessment, dairy holdings should be visited every third year. Veterinary officers use a checklist, and the reports are stored in the database Ísleyfur.
92. The audit team visited two milk production holdings in two different districts. On one of the farms visited, no official controls in relation to food safety had been carried out since at least 2013. In meantime, the operation changed significantly with increased number of animals and a total rebuild of the farm and installation of new equipment, including milk robots. In the second farm, the frequency of the official controls was in line with risk assessment. In a third district, the mission team noted that official controls were carried out in line with risk assessment, as well as in response to notification from a dairy of high somatic cell count.
93. In one farm, the premises for the storage of milk was not protected against vermin or adequately separated from premises where animals are housed, contrary to the requirements laid down in Part II A(2) of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004. The DVO had recently carried out official controls in relation to animal welfare on the farm, and had not addressed this shortcoming in the report pursuant to point 3 of Chapter I of Annex IV to Regulation 854/2004. Other structures and equipment on the farms were largely satisfactory, including temperature control of milk storage tanks. Receipts for collected milk were available and recorded milk temperatures well below 6°C. However, the mission team noted that the outlets of the milk tanks were unprotected at the time of the visit, increasing the risk of contamination during cleaning of the premises. The hygiene of milking could not be evaluated during the visit. Notwithstanding, some of the cows were quite dirty, posing a higher risk of contamination to the milk.
94. None of the farms visited could demonstrate complete records of veterinary medicine used and relied on their private veterinarian to keep records. On one of the farms, this was recorded in the two previous inspection reports (2014 and again in January 2019). The mission team noted that

antibiotics were kept at the farm. According to the farmer, they were used for treating dry cows as no lactating cows had undergone treatment during the last 18 months. Records of antimicrobial resistance (AMR) testing, before treatment, were presented to the mission team.

95. Both herd-owners explained their system for separation of milk not intended for human consumption e.g. colostrum and milk from cows receiving medication and the mission team observed that satisfactory systems were in place.

5.4.6 Control of milk upon collection

Legal Requirements

Article 8 of and Chapter II of Annex IV to Regulation (EC) No 854/2004.

Section IX of Annex III to Regulation (EC) No 853/2004

Regulation (EC) No 852/2004

96. During the opening meeting, the CA confirmed there are no collection centers for milk. Milk is collected directly from dairy farms two or three times per week.
97. The audit team visited two dairy processing plants. Collection and transport of milk is organised by the dairies. The transporter checks the temperature of the milk and takes samples of milk upon collection. The samples are subsequently used to determine somatic cell-count (SCC), total bacterial count (TBC) and tested for the presence of residues of veterinary medicinal products (VMPs).
98. Contrary to the requirements laid down in Chapter I of Section IX of Annex III to Regulation 853/2004, Part B, point 2(a), both dairies accept the collection of milk above 6°C. Based on a case-by-case assessment, such milk may be collected immediately or later the same day, allowing time for further cooling on farm before collection. The dairies did not accept milk above 10°C.
99. A quality manager in the dairies is responsible to evaluate the results for SCC, TBC and VMP residues, as required by Annex III, Section IX, Chapter I, Part III to Regulation (EC) No 853/2004. The FBOs follow up with farmers in case of positive residue samples, but do not always notify MAST in such cases. Both dairies had positive VMP incidents in 2019, which they followed up on farm. The CA was not notified, nor had the CA identified the positive cases during official controls. Consequently, the audit team could not evaluate the actions taken by the CA in such circumstances.
100. Both dairies explained their procedure for cases where the rolling geometric average for SCC exceeded 400 000, which included follow up of the farm in question as well as notifying the CA. The mission team noted that one DVO carried out an official control on the farm in question after receiving such a notification. Regarding SCC, both dairies showed records of the rolling geometric average over a three-month period, with at least one sample per month.
101. One of the dairies confirmed they evaluated the monthly average of TBC. The CA could not confirm during the audit how the dairies calculated the rolling geometric average of TBC and if it was calculated over a two-month period, with at least two samples per month. After the audit, the CA confirmed this was the case following discussion with industry.

Conclusions

102. Microbiological sampling is performed by FBOs but there is limited oversight or understanding of the requirements by many of the officials met. In the meat sector, this will result in limited opportunity for interventions to improve slaughter hygiene and review process controls. Similarly, in the dairy sector, lack of sampling for food safety criteria, shortcomings in process hygiene criteria sampling and inadequate verification of the pasteurisation process restricts the opportunity to improve production hygiene and ensure food safety requirements are fully met. Overall, this may increase the risk of unsafe food being placed on the market.
103. SRM is not stained and official controls related to monitoring FBOs' compliance with the requirement to remove SRMs from cattle are weak. This increases the possibility of unsafe food entering the human food chain.
104. Audits of GHP are not detecting many operational and structural deficiencies in approved food establishments. This limits the opportunity to improve production hygiene and may increase the risk of unsafe food being placed on the market.

105. Official controls related to HACCP based procedures is failing to detect deficiencies related to e.g. traceability of livestock and hygienic production of carcasses. This limits the opportunity for interventions to ensure production of safe food.

5.5 Laboratories, sampling and analysis

Legal requirements

Articles 4, 11 and 12 and 33 of Regulation (EC) No 882/2004

Article 4 of Regulation (EC) No 854/2004

Part III of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004

Regulation (EC) No 2073/2005

Chapter I, Annex VIa of Regulation (EC) No 2074/2005 (ISO methods as required by)

Regulation (EU) 2015/1375

Findings

106. The CA confirmed that laboratories need to be accredited and use accredited methods in order to be on the list of official laboratories permitted to perform analysis within the scope of this audit. There is an exception for in-house laboratories performing examination for Trichinella when designation by the CA is required.
107. The CA provided an example of their designation procedure which included an on-site visit and report along with a letter to FBO confirming designation. However, one of the in-house laboratories visited was not designated by the CA for Trichinella examination and this was not identified during official controls. The laboratory had notified the CA it was performing examination for Trichinella but no action had been taken to designate it. This is not in compliance with Article 2(1) of Implementing Regulation (EU) 2015/1375.
108. According to the pre-mission document, official residue sampling is performed according to a quality manual (document number LBE-010) on monitoring of residues in animal products. Official veterinarians collect samples in meat establishments and at farm level. The number of samples to be collected at each establishment is decided according to the establishment's production numbers the previous year.
109. In one private laboratory visited, an accreditation certificate was available together with the scope of the accreditation listing parameters analyzed and methods used. For many of the microbiological organisms relevant to this mission and analyzed by this laboratory e.g. enterobacteriaceae and aerobic microorganisms, the test methods are listed as a Nordic Committee on Food Analysis (NMKL) standard rather than an International Organization for Standardization (ISO) standard. Documentation was provided on the comparison between NMKL methods and ISO methods to demonstrate equivalence of these different test methods as permitted by Article 5 of Regulation (EC) No 2073/2005.
110. In the same private laboratory, (performing microbiological examination of meat and examination for Trichinella) the operator confirmed they had no contact with the respective national reference laboratories (NRLs). Consequently, NRLs did not provide them with any support in the form of e.g. co-ordination or organize comparative tests. This is not in accordance with Article 33(2)(b) and Article 33(2)(c) of Regulation (EC) No 882/2004.
111. In one slaughterhouse visited, the in-house laboratory used proprietary test-kits for e.g. aerobic colony counts. The CA were unable to confirm if these proprietary test-kits had been validated against the specific reference methods. This is not in accordance with Article 5 of Regulation (EC) No 2073/2005.

Conclusions

112. NRLs for Trichinella and microbiology are not fulfilling their roles for co-ordination of activities in official laboratories and organising comparative testing which may result in unreliable results being produced.
113. Not all laboratories performing official controls for Trichinella have been designated by the CA and not all proprietary test-kits have been validated against the specific reference methods. This increases the likelihood of inaccurate test results being produced.

6. Final meeting

A final meeting was held on 23 October 2019 when the audit team presented the main findings and preliminary conclusions. During this meeting, the CA provided some additional information and clarification and did not express any disagreement with the findings and preliminary conclusions. On 12 November 2019, the CA provided an overview on certain corrective actions taken or planned following the final meeting.

7. Recommendations

In order to facilitate the follow-up of the recommendations hereunder, Iceland should notify the Authority no later than 27 March 2020 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 | <p>The CA should ensure that post-mortem inspection of sheep, cattle and horses is carried out in accordance with the specific requirements of Annex I, Section IV, Chapters I - III of Regulation (EC) No 854/2004.</p> <p>Recommendation based on conclusion at paragraph 54.</p> <p>Associated finding: paragraphs 25, 26 and 27.</p> |
| 2 | <p>The CA should ensure examination for <i>Trichinella</i> only takes place in a laboratory they have designated in accordance with Article 2(1) of Implementing Regulation (EU) 2015/1375.</p> <p>Recommendation based on conclusion at paragraph 113.</p> <p>Associated finding: paragraph 106 and 107.</p> |
| 3 | <p>The CA should ensure that official controls in relation to TSEs take account of the requirements of Regulation (EC) No. 999/2001, which should include controls to ensure FBO removes all specified risk material (SRM) from bovine carcasses in accordance with Annex I, Section IV, Chapter IX(A) and Section I, Chapter I(2)(c) of Regulation (EC) No 854/2004 and Annex V(4.1)(a) of Regulation (EC) No 999/2001.</p> <p>Recommendation based on conclusion at paragraph 103.</p> <p>Associated finding: paragraph 79.</p> |
| 4 | <p>Iceland should ensure that only qualified veterinarians are appointed as official veterinarians and official veterinarians are suitably trained and have undergone practical training for a probationary period of at least 200 hours before starting to work independently, as required by Annex I, Section III, Chapter IV(A) of Regulation (EC) No 854/2004.</p> <p>Recommendation based on conclusion at paragraph 53.</p> <p>Associated finding: paragraph 11, 13, 14, 19, 83 and 84.</p> |
| 5 | <p>The CA should ensure that FBOs do not use any substance other than potable water - or when permitted, clean water - to remove surface contamination from products of animal origin, unless use of the substance has been approved in accordance with Article (3)(2) of Regulation (EC) 853/2004.</p> <p>Recommendation based on conclusion at paragraph 104.</p> <p>Associated finding: paragraph 70.</p> |
| 6 | <p>The CA should ensure that bovine ear tags carry only non-removable inscriptions, as required by Article 2(e) of Regulation (EC) No 911/2004.</p> <p>Recommendation based on conclusion at paragraph 55.</p> <p>Associated finding: paragraph 32.</p> |

| | |
|-----------|---|
| 7 | <p>The CA should ensure that ear tags used for sheep are non-reusable, as required in Section A(3) of the Annex to Council Regulation (EC) No 21/2004.</p> <p>Recommendation based on conclusion at paragraph 55.</p> <p>Associated finding: paragraph 31.</p> |
| 8 | <p>Iceland should ensure that national reference laboratories (NRLs) fulfil their roles to include coordination of the activities of official laboratories responsible for analysis of samples in their area of competence and organise comparative testing between the official national laboratories, as required by Article 33(2) points (b) and (c) of Regulation (EC) No 882/2004.</p> <p>Recommendation based on conclusion at paragraph 112.</p> <p>Associated finding: paragraph 110.</p> |
| 9 | <p>The CA should ensure compliance with the requirements of Regulation (EC) No 2073/2005.</p> <p>Recommendation based on conclusion at paragraph 102 and 113.</p> <p>Associated finding: paragraphs 46, 82, 84, 85, 86 and 111.</p> |
| 10 | <p>The CA should ensure that FBO procedures guarantee, to the extent possible, that meat does not bear faecal or other contamination, as required by point 2(b) of Chapter I of Section I of Annex I to Regulation (EC) No 854/2004.</p> <p>Recommendation based on conclusion at paragraph 105.</p> <p>Associated finding: paragraphs 69, 70 and 77.</p> |

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

| | |
|---------------|--|
| Authority | EFTA Surveillance Authority |
| CA | Competent Authority |
| DVO | District Veterinary Officer |
| EC | European Community |
| EEA | European Economic Area |
| EEA Agreement | Agreement on the European Economic Area |
| FBO | Food business operator |
| FCT | Food control team |
| MANCP | Single integrated multi annual national control plan |
| MAST | Icelandic Food and Veterinary Authority |
| NRL | National reference laboratory |
| OV | Official veterinarian |
| SRM | Specified risk material |
| TSE | Transmissible spongiform encephalopathies |
| VMP | Veterinary medicinal product |

Annex 2 - Relevant legislation

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

- a) The Act referred to at Point 74 in Part 1.2 of Chapter I of Annex I to the EEA Agreement, Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States; as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;
- b) The Act referred to at Point 11 in Part 1.1 of Chapter I of Annex I to the EEA Agreement, Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, as amended, and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;
- c) 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;
- d) The Act referred to at Point 7c in Part 1.1 of Chapter I of Annex I to the EEA Agreement Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97, as amended;
- e) The Act referred to at Point 7b in Part 1.1 of Chapter I of Annex I to the EEA Agreement, Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;
- f) The Act referred to at Point 141 in Part 1.2 of Chapter I of Annex I to the EEA Agreement Commission Regulation (EC) No 911/2004 of 29 April 2004 implementing Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards eartags, passports and holding registers, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;
- g) The Act referred to at Point 9 in Part 1.1. of Chapter I of Annex I to the EEA Agreement, Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;
- h) The Act referred to at Point 16 in Part 6.1. of Chapter I of Annex I to the EEA Agreement, Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, as amended;
- i) 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;
- j) The Act referred to at Point 12 in Part 1.1. of Chapter I of Annex I to the EEA Agreement, Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;
- k) 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;
- l) The Act referred to at Point 53 of Part 6.2. of Chapter I of Annex I to the EEA Agreement, Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European

Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) 854/2004, as amended;

- m) The Act referred to at Point 54 of Part 6.2. of Chapter I of Annex I to the EEA Agreement, Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down specific rules on official controls for *Trichinella* in meat;
- n) The Act referred to at Point 12 of Part 7.1 of Chapter I of Annex I to the EEA Agreement, Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;
- o) The Act referred to at Point 9b of Part 7.1 of Chapter I of Annex I to the EEA Agreement, Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;
- p) The Act referred to at Point 9c of Part 7.1 of Chapter I of Annex I to the EEA Agreement, Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive , as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement.

Annex 3 -Total red meat production traded within EEA in 2017 and 2018.

Information provided by Iceland in the pre-mission document

| Type of product | 2017 (in tonnes) | | 2018 (in tonnes) | |
|------------------------|------------------|--------|------------------|--------|
| | Fresh | Frozen | Fresh | Frozen |
| Meat of bovine origin | | 0,1 | | 27,5 |
| Meat of ovine origin | 48 | 1660 | 104 | 2188 |
| Meat of porcine origin | 0 | 0 | 0 | 0 |
| Meat of equine origin | | 309 | | 284 |

Annex 4 - Comments from Iceland to the draft report



EFTA Surveillance Authority
Rue Belliard 35
B-1040, Bruxelles, Belgium

Selfoss, 20 December 2020
Ref: 1907465

Subject: Cover letter - Iceland's corrective action plan - ESA Mission on Hygiene in milk and meat and their products

Please find attached the Table of corrective actions to the recommendations put forward in the draft report from ESA dated. 22 November 2019 from the ESA mission to Iceland on official controls over the production of meat and milk and their products carried out 14 – 23 October 2019 (attachment #1).

You will also find attachment #2 with further clarification and explanations from MAST inspectors on certain point put forward in the above mentioned draft report which they believe may be based on eventual misunderstanding (see attachment #2, issues of possible misunderstanding).

Please if you have any questions or need further clarification do not hesitate to contact me.

Yours Sincerely
on behalf of MAST

A handwritten signature in blue ink, appearing to read 'Ágústa R. Jónsdóttir', written over a faint circular watermark or background.

Ágústa R. Jónsdóttir
Senior officer
Office of Coordination and Legal Affairs

Attachment #2

Draft report, EFTA Surveillance Authority's mission to Iceland, from 14 to 23 October 2019 , on official controls over the production of meat and milk and their products

Issues of possible misunderstanding

There are few paragraphs that we feel might be based on some misunderstanding and in the following we try, not to correct, but more to explain the basics.

12. In one Region visited by the audit team, six temporary veterinarians were appointed as official veterinarians to cover the 2019 sheep slaughtering season. Only one of these veterinarians attended the 2019 training course. Four out of the six temporary staff then went on to form the complete veterinary inspection team in a sheep slaughterhouse

Because of the number of vets this paragraph can only apply to North-east region. In that region there were 6 temporary veterinarians, all working in sheep slaughterhouses. 3 of them were experienced, it was their third season for two of them and the fourth season for one of them, who has also been working as a permanent veterinarian at MAST for a year. That's the reason those 3 did not attend the 2019 training course. The course was obligated for un-experienced slaughterhouse veterinarians. One of the un-experienced veterinarians did attend the original course as the paragraph states. But another one, who came later, got a private theoretical lesson by one of the tutors from the course, teaching the same lectures. Then this person got 6 hours of practical training with another tutor. The last person came in out of acute necessity. That veterinarian received the lectures on e-mail and was accompanied by an experienced permanent OV for 3 working days.

21. Corrective actions have already been taken in this slaughterhouse regarding FCI.

45. There must be a typo in this finding. The guidance for completion of daily OV checks in slaughterhouses has the code LBE-046 and is only available in Icelandic. GAT-019.4.0 however is the English version of the checklist for daily inspections. The checklist for daily inspections is also available in Icelandic (GAT-011.3.0).

64. and 65. Here has been some misunderstanding. GAT-052 is not meant as a checklist for DVOs weekly inspections at sheep slaughterhouses. The list was made for Veterinary Officer of Meat Inspection to do her inspection once (or twice) per sheep slaughterseason. The DVOs can also use it for bigger inspections but it was not intended for weekly inspections by DVOs. That might explain why the DVOs had not completed GAT-052 once a week at three slaughterhouses visited.

68. Corrective actions have already been taken in this slaughterhouse regarding FCI.

Annex 5 - Plan for corrective measures provided by Iceland

| No | Recommendation | Reaction of Icelandic authorities | Date of compliance |
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| 1 | <p>The CA should ensure that post-mortem inspection of sheep, cattle and horses is carried out in accordance with the specific requirements of Annex I, Section IV, Chapters I - III of Regulation (EC) No 854/2004.</p> <p>Recommendation based on conclusion at paragraph 54.</p> <p>Associated finding: paragraphs 25, 26 and 27.</p> | <p>The CA will reconstruct instructions on post-mortem inspection of sheep, cattle and horses according to the requirements of Section 3 of Regulation (EC) 2019/627.</p> <p>The handbook of daily inspections at slaughterhouses (LBE-046) will be updated and the new instructions on post-mortem inspection will be included in the handbook.</p> <p>OVs at slaughterhouses will be trained to work according to the instructions.</p> | <p>End of May 2020</p> <p>End of June 2020</p> <p>End of October 2020</p> |
| 2 | <p>The CA should ensure examination for Trichinella only takes place in a laboratory they have designated in accordance with Article 2(1) of Implementing Regulation (EU) 2015/1375.</p> <p>Recommendation based on conclusion at paragraph 113.</p> <p>Associated finding: paragraph 106 and 107.</p> | <p>The office of consumer protection, will ensure that all laboratories examining for trichinella will be designated in accordance with Article 2(1) of Implementing Regulation (EU) 2015/1375. The relevant laboratory will be visited and controlled and licensed if criteria are met.</p> <p>Other laboratories will be visited according to date of compliance in recommendation no. 8</p> | <p>End of February 2020</p> <p>End of December 2020</p> |
| 3 | <p>The CA should ensure that official controls in relation to TSEs take account of the requirements of Regulation (EC) No. 999/2001, which should include controls to ensure FBO removes all specified risk material (SRM) from bovine carcasses in accordance with Annex I, Section IV, Chapter IX(A) and Section I, Chapter I(2)(c) of Regulation (EC) No 854/2004 and Annex V(4.1)(a) of</p> | <p>The "slaughter team for big animals and sheep" will inform all OVs at slaughterhouses for cattle and sheep about this finding of ESA and train the OVs to make sure that all SRM is removed correctly in accordance with article 29 of Regulation (EC) 2019/627 and Annex V(4.1)(a) of Regulation (EC) No 999/2001. The slaughter team will also inform the FBOs about this finding and instruct them on what to do, to make sure that SRM is removed correctly.</p> <p>The "ABP team" will instruct the FBOs on how to stain the SRM according to Annex V, point 3 of Regulation (EC) No 999/2001. The "slaughter team for big animals and sheep" will train the OVs to control the FBOs staining of SRM.</p> | <p>End of October 2020</p> <p>End of October 2020</p> |

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| | <p>Regulation (EC) No 999/2001.</p> <p>Recommendation based on conclusion at paragraph 103.</p> <p>Associated finding: paragraph 79.</p> | | |
| 4 | <p>Iceland should ensure that only qualified veterinarians are appointed as official veterinarians and official veterinarians are suitably trained and have undergone practical training for a probationary period of at least 200 hours before starting to work independently, as required by Annex I, Section III, Chapter IV(A) of Regulation (EC) No 854/2004.</p> <p>Recommendation based on conclusion at paragraph 53.</p> <p>Associated finding: paragraph 11, 13, 14, 19, 83 and 84.</p> | <p>Regarding the recommendation that only qualified veterinarians should be appointed as official veterinarians. The Ministry for Industry and Innovation has been informed about this finding since the ministry is accountable for issuance of temporary licenses for veterinary students according to article 6 of the Icelandic Veterinary and Animal Health Services Act No. 66. Matvælastofnun (CA) will make sure that only qualified veterinarians are appointed as official veterinarians from now on.</p> <p>Regarding training of unexperienced official veterinarians and other official control staff, the plan is to</p> <ul style="list-style-type: none"> • Measure the need for training • Make a training framework for each official • Evaluation of training for control work <p>by Annex I, Section III, Chapter IV(A) of Regulation (EC) No 854/2004</p> | <p>End of December 2019</p> <p>End of December 2021</p> |
| 5 | <p>The CA should ensure that FBOs do not use any substance other than potable water - or when permitted, clean water - to remove surface contamination from products of animal origin, unless use of the substance has been approved in accordance with Article (3)(2) of Regulation (EC) 853/2004.</p> <p>Recommendation based on conclusion at paragraph 104.</p> <p>Associated finding: paragraph 70.</p> | <p>A report with a decision of non-compliance about misuse of additive was send to the FBO in intrest, in the end of october 2019</p> <p>Other FBO's in same production will be followed up on the matter.</p> <p>A training course on additives in food production for the control staff in the FCT is planned.</p> | <p>End of January 2020</p> <p>End of June 2020</p> |
| 6 | <p>The CA should ensure that bovine ear tags carry only non-removable inscriptions, as required by Article</p> | <p>Instructions about correct uses of ear tags in bovine animals will be clarified in the instructions manual for OV's; "Skoðunarhandbók nautgripir" (LBE-032) as</p> | <p>End of January 2020</p> |

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| | <p>2(e) of Regulation (EC) No 911/2004.</p> <p>Recommendation based on conclusion at paragraph 55.</p> <p>Associated finding: paragraph 32.</p> | <p>required by Article 2(e) of Regulation (EC) No 911/2004.</p> <p>In regular visit on cattle farms, inspectors will handle the finding of removable inscriptions on bovine ear tags, as a non-compliance.</p> <p>Information regarding correct reaction in slaughterhouses according to the same regulation, will be sent to all FBO's, and a following up on the matter will be taken care of by OV's in daily inspection.</p> <p>Furthermore The FCT will act on the matter in regular audits.</p> | <p>End of January 2020</p> <p>End of March 2020</p> |
| 7 | <p>The CA should ensure that ear tags used for sheep are non-reusable, as required in Section A(3) of the Annex to Council Regulation (EC) No 21/2004.</p> <p>Recommendation based on conclusion at paragraph 55.</p> <p>Associated finding: paragraph 31.</p> | <p>MAST will strengthen it's surveillance so that no sheep ear tags will be reused.</p> <p>It is the understanding of MAST that the electronic ear tags referred to in paragraph 31 of the draft report are not „ear tags“ in the same manner as described in section A(3) of the Annex to regulation 21/2004</p> <p>In recent years increased usage has been evolving with electronic tagging. The electronic tag is mainly intended for the private use of the farmer but not as a replacement for tagging for traceability purposes. The traceability tag is attached to the electronic tag and removed after slaughter and dismissed off permanently.</p> | <p>End of October 2020</p> |
| 8 | <p>Iceland should ensure that national reference laboratories (NRLs) fulfil their roles to include coordination of the activities of official laboratories responsible for analysis of samples in their area of competence and organise comparative testing between the official national laboratories, as required by Article 33(2) points (b) and (c) of Regulation (EC) No 882/2004.</p> <p>Recommendation based on conclusion at paragraph 112.</p> <p>Associated finding: paragraph 110.</p> | <p>Considering this recommendation, the MOII consult and co-ordinate with stakeholders (representatives from NRLs for trichinella and microbiology and the CA) to discuss how the NRLs can better fulfill their role. Simultaneously the MOII will review the agreement with these NRLs to assess if there is a need to re-negotiate the terms. Laboratories are compensated already for the work associated with the NRL role and deliver an annual report to the MOII.</p> | <p>Consultation, review and re-negotiation finalized before the end of October 2020</p> |
| 9 | <p>The CA should ensure compliance with the requirements of Regulation (EC) No 2073/2005.</p> | <p>The guidelines for microbiological criteria will be updated.</p> <p>The control of microbiological criteria in slaughterhouses will be on the responsibility of daily control in slaughterhouses.</p> | <p>End of September 2020</p> <p>End of October 2020</p> |

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| | <p>Recommendation based on conclusion at paragraph 102 and 113.</p> <p>Associated finding: paragraphs 46, 82, 84, 85, 86 and 111.</p> | <p>The “slaughter team for big animals and sheep” will train OV’s at slaughterhouses to control the FBO’s sampling, sampling methods and sampling results at least once a week.</p> | <p>End of October 2020</p> |
| 10 | <p>The CA should ensure that FBO procedures guarantee, to the extent possible, that meat does not bear faecal or other contamination, as required by point 2(b) of Chapter I of Section I of Annex I to Regulation (EC) No 854/2004.</p> <p>Recommendation based on conclusion at paragraph 105.</p> <p>Associated finding: paragraphs 69, 70 and 77.</p> | <p>Instructions on evaluation of cleanliness of cattle will be issued soon. The instructions will be sent to FBOs and OV’s at slaughterhouses to coordinate the evaluation of cleanliness of cattle and to coordinate actions taken when dirty animals arrive at slaughterhouses. OV’s will be trained to work by the instructions. The instructions can also be used for evaluating cleanliness of other species. Enforcement actions will be taken if FBOs do not follow the instructions according to LBE-166.</p> <p>LBE-166 have been translated to English (LBE-173).</p> <p>OV’s at slaughterhouses have been instructed on notifying the DVO team if dirty animals come to a slaughterhouse so that the DVOs can visit the farm, the animals originated from and demand corrective actions.</p> <p>Results from special on-going project called „skimun á markaði“ where STEC is analysed in meat, directly from market, will used to alter the focus in meat production. Extra attendance will be on cross-contamination on slaughterline. Mast will introduce results and possible effects in a letter to FBO about change of risk because of STEC.</p> <p>A follow up on reaction of FBO to this letter. This follow up will be carried out by FCT in regular audits and by the daily inspections of OV’s.</p> | <p>End of January 2020</p> <p>End of June 2020</p> <p>End of December 2020</p> |