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The logo of the EFTA Surveillance Authority, consisting of a dark blue rectangle with the text 'EFTA SURVEILLANCE AUTHORITY' in white, sans-serif capital letters. The text is arranged in two lines: 'EFTA SURVEILLANCE' on the top line and 'AUTHORITY' on the bottom line, with a small white square to the right of the second line.

EFTA SURVEILLANCE
AUTHORITY

Final report

EFTA Surveillance Authority's mission to Iceland

from 15 to 19 January 2018

in order to evaluate the system put in place to implement

Article 4(6) of Regulation (EC) No 882/2004 (National Audit System)

Please note that comments and information from the Icelandic competent authority on the corrective actions already taken and planned are included in Annexes 3 and 4 to the report.

Executive Summary

This report describes the outcome of a mission carried out by the EFTA Surveillance Authority in Iceland from 15 to 19 January 2018. The objective of the mission was to assess the system in place to implement Article 4(6), on audits of competent authorities, of Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. The scope of the mission was limited to the procedures put in place by the Icelandic competent authorities responsible for official controls falling under Regulation (EC) No 882/2004.

Overall, the report concludes that there are audit arrangements in place, supported by a mandate (audit charter), documented procedures and instructions, which follow the requirements for independence, transparency and independent scrutiny of Articles 2(6) and 4(6) of Regulation (EC) No 882/2004 and generally take into account the guidelines of Commission Decision 2006/677/EC.

The national audit system, recently set up and approved by the Icelandic Ministry of Industries and Innovation (MoII), is implemented under the responsibility of the Director General of the Icelandic Food and Veterinary Authority (MAST).

The audit process is systematic and well documented, ensuring that activities are carried out in a consistent manner. However, risk assessment and risk-based prioritisation for developing the audit multi-annual programme and annual plans are not supported by documented procedures and are not well documented, thus undermining the reliability of the audit system.

Responsibilities for carrying out audits on official controls have been allocated, ensuring the proper functioning of the audit system and allowing to provide credible and reliable results, although some aspects are to be developed further. Compliance with planned arrangements is audited in a systematic manner but the effective implementation of planned arrangements is addressed to a lesser extent, and verification of suitability of official controls in achieving objectives is not included yet in the audits' scope.

A mechanism is in place to ensure the auditors' competence and that their competence is maintained and further developed, although selection criteria are not fully documented.

Audit reporting procedures ensure consistent and clear reporting of relevant audit results, and good practices are described in audit reports; however, they are not systematically disseminated and timely reporting was not always ensured.

Measures are in place to ensure that appropriate actions are taken in the light of audit results; however, the audit body has not defined a procedure to deal with failure by auditees to address identified observations and non-compliances, and to take action according to the corrective action plan.

The audit process has not been systematically reviewed yet, which represents a missed opportunity for verifying that the objectives of Article 4(6) are achieved and for ensuring continuous improvements in the audit process.

The report includes recommendations addressed to the Icelandic competent authority aimed at further improving the national audit system.

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1 Introduction

The mission took place in Iceland from 15 to 19 January 2018. The mission team comprised two inspectors from the EFTA Surveillance Authority ('the Authority') and a national expert.

A pre-mission questionnaire was sent by the Authority to the Icelandic Ministry of Industries and Innovation (MoII) on 9 November 2017. A reply ('the pre-mission document') was provided on 18 December 2017.

The opening meeting was held on 15 January 2018 at the Icelandic Food and Veterinary Authority (MAST) office in Reykjavík, with representatives from MAST, MoII and the Municipal Environmental and Public Health Offices (LCAs). 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 reply to the Authority's pre-mission document.

Representatives of MAST attended all meetings taking place during the mission.

A final meeting was held at MAST office in Reykjavík on 19 January 2018, during which 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, scope and criteria for the mission

The objective of the mission was to evaluate the system in place to implement Article 4(6), on audits of competent authorities, of Regulation (EC) No 882/2004¹ of the European Parliament and of the Council, on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (hereafter: 'Regulation (EC) No 882/2004').

The scope of the mission was limited to the procedures put in place by the competent authorities responsible for the official controls falling under Regulation (EC) No 882/2004 to implement Article 4(6). Observing the performance of individual auditors was not included in the scope of this mission.

The criteria used for the evaluation are set out in Article 4(6) of Regulation (EC) No 882/2004:

'Competent authorities shall carry out internal audits or may have external audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of this Regulation. These audits shall be subject to independent scrutiny and shall be carried out in a transparent manner.'

¹ 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, Official Journal L 165, 30.4.2004, pages 1 to 141, corrected and re-published in OJ L 191, 28.5.2004, pages 1 to 52.

This article should be read together with the definition of Article 2(6) laid down in the same Regulation:

“Audit” means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.’

In addition, where applicable, the mission team took into account Commission Decision 2006/677/EC² setting out the guidelines and laying down criteria for the conduct of audits under Regulation (EC) No 882/2004. Where relevant, reference was made to Network Reference Documents produced by the Network of Member States National Experts on National Audit Systems (NAS) (hereafter: ‘the NAS Network’), while recognising that they do not constitute an audit standard and are not legally binding.

At the time of this mission, the NAS Network has produced the following Network Reference Documents:

- Root Cause Analysis - November 2016 - Version 1
- Audit Evidence - October 2015 - Version 1
- Risk-Based Planning for Audits of Official Control Systems - February 2014 - Version 1
- Independence and Independent Scrutiny - February 2014 - Version 1
- Auditing Effectiveness of Official Control Systems - February 2014 - Version 1

The evaluation focused particularly on those elements which the mission team considered essential to ensure that the national audit system allows for adequate coverage of official controls, and to give assurance that the objectives of Regulation (EC) No 882/2004 are being met:

- Responsibilities for the implementation of Article 4(6);
- Measures taken to implement Article 4(6) at central and local level;
- Status and reporting lines of auditing bodies/units;
- Arrangements for independent scrutiny and independence;
- Procedures for the selection of auditors and management of auditor competence;
- Procedures for the development of audit programmes, with particular attention on how an adequate coverage of the audit/risk universe is ensured;
- Planning, conduct and reporting of audits, including the approach to auditing effectiveness and suitability of arrangements in place for official controls to achieve the objectives of the Regulation;
- Follow-up of audit recommendations including the system in place for corrective action in cases where problems are identified during the audit activities; and
- How and to what extent transparency is ensured.

In addition, the audit team gathered information on particular challenges faced by the competent authorities when implementing Article 4(6). The evaluation included the gathering of relevant information, appropriate verification by means of interviews/discussions, and review of documents and records provided by the competent authorities.

² Commission Decision 2006/677/EC of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules. Official Journal L 278, 10.10.2006, pp15 to 23.

The meetings were held in MAST office in Reykjavík and in Selfoss. The mission team met with:

- Representatives from MAST, MoII and LCAs at the opening and closing meeting;
- Representatives from MAST head office involved in the audit process;
- Four auditors and auditees involved in two 2016 audits;
- One auditor who carried out the independent scrutiny in accordance with the Nordic cooperation paper on independent scrutiny of national audit systems; and,
- Two representatives of the MoII chairing the Audit Board and Audit Committee.

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) *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;
- 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*, as corrected, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement.

The main legislation relevant for this mission is listed in Annex 2 of this report.

4 Background - Previous missions

Detailed information on the structure and organisation of the competent authorities can be found in the Country Profile for Iceland³.

The assessment of the national audit system has not been the specific objective of any previous Authority mission in Iceland, although internal audits carried out by the competent authority have been included within the scope of numerous sector-specific missions. Furthermore, a mission to evaluate national procedures in place to verify the effectiveness of import control systems for products of animal origin was carried out in 2015 and covered relevant internal audits for that sector.

Reports from previous missions can be found on the Authority's webpage: www.eftasurv.int.

³http://www.eftasurv.int/media/food-safety/27.01.2017-10-13-00_FINAL-Country-Profile-Iceland-version-2017_-PART-I.pdf

5 Findings and conclusions

5.1 Competent authorities

Legal Requirements

Article 4(1) of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for the purposes and official controls set out in the Regulation.

Article 4(6) of Regulation (EC) No 882/2004 states that competent authorities shall carry out internal audits or may have external audits carried out.

Findings

MoII is the ministry responsible for policy coordination and transposition of legislation related to food and feed safety, animal health and animal welfare. Within the Ministry, the Department of food, agriculture and rural affairs is responsible for policy development/co-ordination and legislation (including the transposition of the EU legislation).

MAST is the central competent authority for food and feed safety, animal health and animal welfare and operates under the auspice of MoII. Details on the organisation of official controls can be found in the Country Profile for Iceland and in the Multi-Annual National Control Plan (MANCP)⁴ available on MAST webpage.

MAST and LCAs have been designated as the competent authorities for food safety controls. The division of responsibilities between the competent authorities is established in the Icelandic Food Act (IS) No 93/1995. MAST supervises and coordinates the work of the LCAs, and ensures that official controls are implemented in the same manner throughout the country.

The audit system has been set up with the audit charter in January 2016 and it was explained to the mission team that it has been operating in a pilot phase since its establishment. The audit system is approved by the MoII and implemented under the responsibility of MAST Director General. MAST Quality Manager is responsible for the audit process as audit supervisor, under the authority of an audit board and an audit committee chaired by MoII.

Conclusions

The competent authority responsible for official controls set out in the Regulation has been designated in compliance with Article 4(1) of Regulation (EC) No 882/2004.

The competent authority has established an audit system intended to achieve the objectives of Article 4(6) of Regulation (EC) No 882/2004. Responsibilities for carrying out audits on official controls have been allocated, ensuring the proper functioning of the audit system.

5.2 Audit arrangements

5.2.1 *Independence*

Legal Requirements

⁴http://mast.is/library/Bodberar/Bodberi_LEMA_LOKASKJAL_UNDIRRITAD_4.10.2017.pdf

Article 2(6) of Regulation (EC) No 882/2004 defines “audit” as an ‘independent examination’.

In section 5.3 of the Annex of Commission Decision 2006/677/EC further guidance is provided on ‘Independence’:

“Audit bodies should be free from any commercial, financial, hierarchical, political or other pressures that might affect their judgment or the outcome of the audit process. The audit system, audit body and auditors should be independent of the activity being audited and free from bias and conflicts of interest. Auditors should not audit areas or activities for which they have direct responsibility.

All relevant competent authorities should introduce safeguards to ensure that responsibility and accountability for audit and control activities, such as the management and supervision of official control systems, are kept sufficiently distinct. [...]

Independent audit bodies should be external to or separate from the management of audited activities. Internal audit bodies should report to the most senior management within the organisational structure.

Where technical expertise required for the audit is available only within a competent authority, measures should be taken to ensure the audit team remains independent. Where control activities are organised on a regional basis, technical specialists could be exchanged in order to ensure they are independent.”

In addition, the NAS Network Reference Document on Independence and Independent Scrutiny of February 2014 provides additional guidance on threats to independence and mitigating measures.

Findings

The audit charter, signed in January 2016 by a representative of MoII, and updated in September 2016, provides the audit body with a written mandate to conduct audits under the responsibility of MAST Director General and ensures its independence within MAST. In this single document, clear legal basis, objectives, scope and process description of the audit system for official controls falling under Regulation (EC) No 882/2004 are detailed together with role and responsibilities of involved parties, independence principles of the system and auditors, and reporting lines. The audit charter also includes audit activities related to MAST’s quality management system as per ISO 9001 standard. For these auditing activities, a specific role is described in the audit charter for the quality council, which comprises MAST Director General, the Head of MAST Consumer Protection Department and the Head of MAST Animal Health and Welfare Department. However, this role is not specifically defined for audits falling under Regulation (EC) No 882/2004 although clearly identified in MAST’s internal documented procedures. The mission team noted that MAST was not currently auditing its quality management system as described in the audit charter in the framework of ISO 9001 audits.

An audit board and audit committee are part of the audit process with a role and responsibilities defined in the audit charter and detailed in documented procedures.

The audit board comprises three members: (i) MoII, chairman; (ii) MAST Director General; and (iii) Icelandic Food and Biotech R&D (MATÍS) Director. The audit board validates the

national audit system and the multi-annual audit programme, and appoints the audit supervisor of whom it has to ensure the competence. The audit board can also request follow-up audits as necessary.

The audit committee comprises four members: (i) MoII, chairman; (ii) The Consumers Association of Iceland; (iii) Farmers Association of Iceland; and, (iv) Confederation of Icelandic Enterprise. The audit committee validates the annual audit plan, evaluates the audit supervisor's independence and can request ad-hoc audit activities and follow-up audits. The audit committee aims at, *inter alia*, ensuring impartiality and independence of auditors, credibility of audits and monitors the audit board follow-up activities.

The audit supervisor has the overall responsibility for ensuring the functioning of the audit process, for organising and managing the audit activities under the authority of the audit board and for approving audit reports. The audit supervisor is MAST's Quality Manager, administratively placed in MAST Legal Affairs and Coordination Department and appointed by the audit board. The audit team noted that the independence of the supervisor might be compromised when an audit covers aspects of MAST quality manuals and also if the audit supervisor is identified as responsible for implementing specific corrective actions falling under his role as MAST Quality Manager.

The audit team is responsible for preparing and conducting the audit. Auditors are selected among MAST specialists by the audit supervisor who is responsible for ensuring their competence and independence. The mission team noted that in practice they are appointed by MAST quality council, although the audit charter indicates that for audits falling under Regulation (EC) No 882/2004 this is the responsibility of the audit supervisor. There are currently six appointed auditors, including the audit supervisor. According to audit charter, the auditors should not audit control systems they are managing or supervising, to ensure their independence.

The auditee, once informed by the audit team of its composition for a specific individual audit, has seven working days to provide written comments on the appointed auditors to avoid any potential conflict of interest. The audit team will then assess these comments, if any, and decide for any change to the audit team. The mission team was informed by the audit supervisor it had not happened to this date.

Audit reports are drafted by the audit team and submitted to the audit supervisor for approval. The final audit report is submitted to both the audit board and audit committee.

The audit charter and documented procedures describe the possibility of using technical experts to provide assistance in the implementation of individual audits, although technical experts have not been part of audit teams to this date. However, there are no specific arrangements in place to ensure independence of technical experts.

Conclusions

The arrangements in place described in documented procedures and in the audit charter, although not fully reflecting the implemented audit process, ensure independence of the audit process as required by Article 2(6) of Regulation (EC) No 882/2004 and as described in section 5.3 of the Annex of Commission Decision 2006/677/EC. The organisational structure contributes to maintaining objectivity and ensuring credibility of the audit outcome.

5.2.2 *Independent scrutiny*

Legal Requirements

Article 4(6) of Regulation (EC) No 882/2004 requires that the audits shall be subject to independent scrutiny.

In Section 5.4 of the Annex of Commission Decision 2006/677/EC further guidance is provided on the ‘Independent Scrutiny of the Audit Process’:

“In order to check whether it is achieving its objectives, the audit process should be subject to scrutiny by an independent person or body. Such independent person or body should have sufficient authority, expertise and resources to carry out this task effectively. The approaches to independent scrutiny may vary, depending on the activity or the competent authority. Where a body or a committee has been established with a view to independent scrutiny of the audit process, one or more independent persons should be members of such body or committee. Such independent persons should have access to the audit process and be empowered to contribute fully to it. Action should be taken to remedy any shortcomings identified in the audit process by the independent person or body.”

Findings

The competent authority has put in place arrangements in cooperation with the other Nordic countries, Denmark, Finland, Iceland, Norway and Sweden, to conduct mutual independent scrutiny of the audit process according to the agreement paper of March 2016 “Nordic cooperation on independent scrutiny of national audit systems”.

This agreement sets the objective of the independent scrutiny as to evaluate the national audit system’s compliance with the requirements laid down in Regulation (EC) No 882/2004 and to assess the set-up and objectives of the national audit system against the guidelines of Commission Decision 2006/677/EC. The agreement clarifies that the scrutiny is not an audit of the national control system.

Each of the mentioned countries should be subject to an independent scrutiny every five years in accordance with a documented procedure. The multi-annual independent scrutiny programme was agreed for the cooperation to start with a pilot phase consisting in a shorter and more intensive cycle, according to which the national audit system of these countries are planned to be scrutinised over a two-and-a-half year period. The scrutiny process will be reviewed after the pilot phase.

According to the commonly agreed independent scrutiny procedure and guidelines for planning and reporting, the independent scrutiny is carried out by two senior auditors responsible for the national audit systems of the Nordic countries involved in this agreement. The independent scrutiny consists in a two-day visit to the scrutinised country, during which documentary review and interviews are performed, and a report is provided on-site with findings, system strengths, good practices, conclusions and recommendations.

In December 2017, the Icelandic audit system was subject to an independent scrutiny by representatives from the national audit systems of Norway and Finland under the Nordic cooperation agreement. The report from this independent scrutiny, provided to MAST, had a clear objective and scope as defined in the procedures. Audit criteria included Article 4(6) of Regulation (EC) No 882/2004, relevant sections of Commission Decision 2006/677/EC and reference documents from the NAS Network. The main aspects covered in the report

were, *inter alia*, the risk-based planning of the audit programme and plan, the independence of the audit units and auditors, the implementation of the audit process and audit documentation, auditors' competence and arrangements for transparency.

The independent scrutiny report for Iceland generally concluded that the national audit system complied with the requirements of Regulation (EC) No 882/2004 and was in line with the guidelines of Commission Decision 2006/677/EC. It added that the national audit system in Iceland had recently been established and was still developing; as a result, some areas of partial compliance had been identified during the scrutiny.

The report also identified good practices and highlighted areas for improvement based on findings related to deficiencies of the national audit system. Findings were generally confirmed by the Authority mission team. However, part of the findings considered as compliant were not totally in agreement with the Authority mission team's assessment, in particular in relation to the risk-based approach when planning. The report also identified a good practice, which consisted in the handbook for auditees (see sections 5.2.5.1. and 5.2.7. of this report).

The mission team noted that the audit body acknowledged the findings and conclusions of the independent scrutiny, which were currently being taken into consideration.

Conclusions

The national audit system is subject to independent scrutiny as required by Article 4(6) of Regulation (EC) No 882/2004.

5.2.3 Auditor competence

Legal Requirements

Articles 2(6) and 4(6) of Regulation (EC) No 882/2004 do not lay down specific requirements regarding the competence of auditors.

Article 6 of the same Regulation requires that staff performing official controls receive, for their area of competence, appropriate training enabling them to undertake their duties competently and keep up-to-date in their area of competence and receive regular additional training as necessary.

Section 6.6 of the Annex of Commission Decision 2006/677/EC provides guidance on auditor competence.

“Auditor competence and selection criteria should be defined under the following headings:

- *generic knowledge and skills — audit principles, procedures and techniques; management/organisational skills,*
- *specific technical knowledge and skills,*
- *personal attributes,*
- *education,*
- *work experience,*
- *auditor training and experience.*

It is essential to put a mechanism in place to ensure auditors are consistent and their competencies are maintained. Competencies required by audit teams will vary depending

on the area they are auditing within the control or supervision systems. As regards the technical knowledge and skills required by auditors, the training requirements for staff performing official controls (Chapter 1 of Annex II to Regulation (EC) No 882/2004) should also be considered.”

Findings

There are currently six auditors who participate in audits on a part-time basis. They are full-time officers with different educational backgrounds, deployed in MAST Departments of Legal Affairs and Coordination, Import and Export, and Consumer Protection. MAST Quality Manager is the audit supervisor and is included as auditor. With the exception of the audit supervisor who dedicates around 50% of his time to the audit process, the other auditors commit to audit activities in accordance with team allocation for individual audits.

According to MAST guidance on auditors, MAST's Quality Manager proposes to the quality council the needed number of auditors and identifies auditor candidates for the quality council to further assess their skills and formally appoint them for a two-year period. The criteria taken into account regarding auditor competence include personal qualities and knowledge of MAST quality manuals and fundamentals of the methodology for carrying out audits on official controls of food, feed, animal health and animal welfare. The audit charter stipulates that the audit team must have sufficient experience and expertise in relation to audit methodology and to the audit scope. The mission team was informed by the audit body that other criteria included educational background and specific and generic technical knowledge and skills. However, the mission team noted that the selection criteria and selection process of auditors are not fully defined and documented.

The quality council is responsible for appointed auditors to receive the necessary training, which should be periodically reviewed. Training is organised by MAST Quality Manager, other MAST employees or external bodies. Training and experience is gained by auditing various sectors and conducting audits on regular basis. Evidence of training of auditors was provided by the competent authority to the mission team. Training included participation in the European commission's Technical Assistance and Information Exchange (TAIEX) workshops, in British Standards Institution (BSI) and European Commission Better Training for Safer Food (BTSF) training courses. One recently appointed auditor had not yet received the necessary training. However, untrained auditors gain experience under the guidance of the audit supervisor, and they do not lead audits. The mission team was informed that specific training for auditors organised by MAST was planned for February 2018.

As described in section 5.2.1. of this report, the audit supervisor may call technical experts to assist in conducting audits. The audit team was informed by the audit body that it considered the auditors, as members of MAST staff, to have sufficient auditing and technical competence relevant to the audited area. Thus, technical experts had not yet participated in audits. The mission team noted that training or qualification criteria were not specifically described for technical experts.

Conclusions

A mechanism is in place to ensure that auditors are competent and that their auditing competence is maintained and further developed as required by Article 6 of Regulation (EC) No 882/2004. However, defined selection criteria for auditors could further enhance their competence.

5.2.4 Development of the audit programme

Legal Requirements

Article 3(1) of Regulation (EC) No 882/2004 requires Member States to ensure that official controls are carried out regularly, on a risk basis and with an appropriate frequency, so as to achieve the objectives of this Regulation.

The definition laid down in Article 2(6) of the same Regulation specifies, *inter alia*, that audits should be ‘systematic’.

In Section 5.1 of the Annex to Commission Decision 2006/677/EC, further guidance is provided on the ‘Systematic Approach’, including:

“A systematic approach should be applied to the planning, conduct, follow-up and management of audits. To that end, the audit process should:

- *be the result of a transparent planning process identifying risk-based priorities in line with the competent authority’s responsibilities under Regulation (EC) No 882/2004,*
- *form part of an audit programme that ensures adequate coverage of all relevant areas of activity and all relevant competent authorities within the sectors covered by Regulation (EC) No 882/2004 at an appropriate risk-based frequency over a period not exceeding five years,*
- *be supported by documented audit procedures and records to ensure consistency between auditors and to demonstrate that a systematic approach is followed”*

The NAS network document "Risk-based planning of audits on official controls" explains the internal audit experts' common understanding of the objectives of risk-based planning and the concept of ‘audit universe’.

Findings

MAST is responsible for the development and review of the multiannual audit programme. According to MAST procedures, an initial proposal for the programme is drafted by the Head of MAST Consumer Protection Department in collaboration with the audit supervisor, and is presented to MAST quality council to be assessed and confirmed. The programme is then submitted to the audit board by the audit supervisor for approval by 30 November each year and published on MAST web-page. The mission team noted that the described process was not fully reflected in the audit charter.

According to the audit charter and MAST documented procedures, an audit universe has been identified with nine areas of official controls falling under Regulation (EC) No 882/2004, based on the competent authorities’ responsibilities: (i) food of animal origin; (ii) food of non-animal origin; (iii) feed; (iv) specific legislation (such as animal by-products, additives and enzymes, flavourings, labelling, etc.); (v) animal welfare; (vi) animal health; (vii) import and export; (viii) laboratory; (ix) retail and distribution. These areas are to be covered by audits at least once within a five-year cycle, with both horizontal (cross-cutting, such as training) and vertical (sector-specific) audits of all relevant competent authorities at all stages of the feed and food production chain. The mission team noted that different levels of the auditees’ hierarchy were included in the audits examined by the mission team.

These documents also specify that the multiannual audit programme shall be risk-based and provide risk-based priorities in a transparent manner in line with the competent authorities' responsibilities, with an appropriate risk-based audit frequency. During the programme preparation, priorities are set on the basis of new legislation, planned Authority's missions and their outcome, and possible impact for consumers in case of official controls failure. However, there is no specific procedure addressing how the risk assessment should be made to ensure a risk-based approach when developing the programme.

The mission team noted that inputs from within MAST are considered in order to prioritise the control areas to be covered, to establish the sequence of audits, and to select the audit scope. However, the development of the programme was mostly based on MAST staff's personal knowledge and experience. Furthermore MAST did not take into account information such as previous results of official controls carried out by MAST and LCAs. The mission team noted that the inputs to the development of the programme are not listed and this part of the process is not documented. The competent authority could not provide evidence of how potential risks are identified, and how emerging risks and topics of EEA relevance are considered to support the required risk assessment and identification of risk-based priorities. Neither was it evident to the mission team on which basis the selection of audit topics was made.

According to the pre-mission document, the audit body within MAST has started to develop a risk assessment model to be used for systematic and documented risk assessment for the development of the audit programme. In addition, two representatives from the audit body participated in a seminar in August 2017, held in the framework of the Nordic collaboration, focusing on risk-based audit programming.

According to the audit charter, the multiannual audit programme shall be reviewed within a three-year period. The audit system has been recently set-up and the first audit programme covering 2016-2020 was developed in 2016, and reviewed at the beginning of 2017 with the issuance of a new 2017-2021 programme.

According to MAST procedures, an annual audit plan is prepared by the audit supervisor on the basis of the multi-annual audit programme. During this process, the audit supervisor may consult with other MAST staff members who have expertise relevant for the audits' scope. The annual plan is presented to MAST quality council to be assessed and approved. It is then submitted to the audit committee by the audit supervisor for final approval by 1 December each year and published on MAST web-page. The mission team noted that this process was not fully reflected in the audit charter.

The mission team was informed that auditors seek for general information within MAST in relation to the importance of operations at different levels and locations. However, in some cases, MAST stated that more direct sources of information from other competent authorities, such as supervision and inspection reports, were generally not considered, and production volumes and data were not analysed. It was not evident to the mission team on which basis decisions were made on the scope and objective of individual audits and selection of authorities to be audited.

MAST explained that despite initial delays in 2016 and 2017, the 2018 annual plan had been timely approved. A total of seven audits have been planned for 2018. The mission team found that the annual plans of 2016, 2017 and 2018 generally corresponded to the multi-annual audit programme. However, the mission team noted that there is no specific procedure or guidance for ensuring a risk-based approach to annual planning and the process is not documented.

Conclusions

The competent authority has developed and implemented processes for establishing multiannual audit programmes and annual audit plans. However, the risk assessment for developing the audit programme/plan and risk-based prioritisation are not supported by a documented procedure and the development process is not sufficiently documented. The selection of sub-areas for the audits and the decision regarding the selection of audit topics, objectives and auditees do not follow a clear risk-based approach, thus undermining the reliability of the audit system.

The planned audits ensured adequate coverage of relevant areas of activity and of competent authorities within the identified areas of activity.

5.2.5 Implementation of the audit process

Legal Requirements

Article 2(6) of Regulation (EC) No 882/2004 defines the audit as a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

In Section 5.1 of the Annex of Commission Decision 2006/677/EC further guidance is provided on the 'Systematic Approach', including:

“A systematic approach should be applied to the planning, conduct, follow-up and management of audits. To that end, the audit process should:

- be supported by documented audit procedures and records to ensure consistency between auditors and to demonstrate that a systematic approach is followed,*
- include procedures for generating audit findings, including the identification of evidence of compliance and non-compliance, as appropriate, and for preparing, approving and distributing audit reports,*
- include procedures to review audit conclusions, in order to identify system-wide strengths and weaknesses in the control system, disseminate best practice and ensure the monitoring of corrective and preventive actions,*
- be monitored and reviewed to ensure the audit programme's objectives have been met and to identify opportunities for improvement.”*

Section 6.1 of the Annex of Commission Decision 2006/677/EC provides guidance on implementation of the audit process. In particular, to comply with the requirements of Article 4(6) of Regulation (EC) No 882/2004, the audit system should include verification of compliance with planned arrangements, verification of the effective implementation of planned arrangements and assessment of the suitability of official controls. Furthermore:

“In order to determine whether the planned arrangements are suitable to achieve the objectives set out, the audit criteria should include strategic objectives stemming from Regulations (EC) No 178/2002 and (EC) No 882/2004 (including the single integrated multi-annual national control plan) and national legislation.”

The Network Reference Documents on auditing effectiveness of official control systems (February 2014 - Version 1) provides additional guidance on how the effective implementation and suitability of official controls in achieving objectives may be evaluated.

Findings

The audit supervisor organises and manages the implementation of audits according to approved annual audit plans. He nominates the audit team for each audit, and ensures consistency between auditors. The audit team comprises two auditors of which one is nominated team leader, responsible for conducting the audit according to the audit plan and agenda. The audit charter foresees the possibility for the auditors to visit the auditee prior to the audit to facilitate its preparation. This option has not been used to this date.

5.2.5.1 Documented procedures

As stated in section 5.2.1 of this report, an audit charter provides the audit body with the mandate to carry out audits. It formally refers to Article 4(6) of Regulation (EC) No 882/2004 and Commission Decision 2006/677/EC and lays down the objectives of the audit system consisting in verification that official controls comply with the relevant legislation, that they are effectively implemented and suitable to achieve the objectives of the legislation. MAST quality system covers most parts of the audit process, including planning, conduct, reporting, follow-up and review. The documented procedures comprise process descriptions, workflows, and guidance documents, which are publicly available on MAST web-page; and checklists and forms (audit plan, opening and closing meeting, report template, corrective action plan, etc.). The mission team was informed that checklists for the collection of information during individual audits are developed *ad hoc* by the auditors. However, the mission team found discrepancies in the audit charter where the described process and roles did not fully reflect MAST documented procedures related to audit activities.

A handbook for auditors, last updated in November 2017, is part of MAST quality system and aims at ensuring consistency between auditors for the audit process implementation. It provides information on the implementation of audits and methods for auditing, such as (i) guidance to assess compliance with planned arrangements, effectiveness and suitability of official controls; (ii) review of auditee's documentation; (iii) implementation of site audits; (iv) handling of auditees' comments; (v) advice for auditors for preparation, implementation, and communication during an audit; and (vi) recording of data. Various methods for collecting evidence are described such as documentary review (desk-top), interviews, analysis of statistical information, and sampling. The mission team also noted that the handbook refers to the use of an evidence collection plan and provides guidance for assessing the non-compliances as opposed to opportunities for improvement. However, the mission team found that in some examples seen, auditors used different approaches for deciding when findings/conclusions required a corrective action by the auditee.

The audit supervisor explained that a handbook for auditees was currently being finalised, aiming at providing detailed information on the audit process to each auditee.

An excel spreadsheet for individual audit planning and conduct is saved in MAST record management system (RMS) under the relevant audit case. At the stage of planning, this document is used as an audit plan and includes the audit name, objective, scope, criteria, team composition, auditee and information requested to the auditee with corresponding deadline. During the audit, findings and conclusions are recorded by the lead auditor within this document, which also contains the preliminary report presented at the closing meeting. The estimated submission date for the final audit report and deadline for the auditee to submit a corrective action plan are also provided. Another excel spreadsheet with an overview of all corrective actions for audits performed is used for following-up the audit process.

The mission team noted that in relation to reporting and follow-up, there was no defined procedure for dealing with failure by auditees to address the identified observations and non-compliances, and to implement their corrective action plan. Good practices may be included in the audit report, however, there is also no documented procedure in place for their dissemination by the audit body. It was explained by the audit supervisor that further updates were needed to relevant procedures to further define the review of the audit process (see section 5.2.5.6 of this report).

According to MAST procedures, all audit-related documents, data and relevant communication, are saved in RMS. For each audit, the audit supervisor creates a case, for which he is responsible and that is only accessible to the audit body. A folder in each case is dedicated to corrective actions and follow-up.

The review of documentation from two 2016 audits and interviews with auditors and auditees from the same audits revealed that audits were generally carried out in accordance with MAST documented procedures and all stages of the audit process were well documented.

5.2.5.2 Compliance with planned arrangements

Verification of compliance with planned arrangements is included in the scope and objectives of the audits according to MAST documented procedures. The audit criteria includes EEA and national legislation, and quality manuals. Based on audit reports evaluated, the mission team confirmed that compliance with planned arrangements is mostly covered.

5.2.5.3 Verification of the effective implementation of planned arrangements and their suitability to achieve objectives

According to the pre-mission document, the main arrangements in place to ensure that audits include verification of effectiveness of official controls and their suitability to achieve objectives are: (i) audit charter; (ii) MANCP, where objectives of official controls are defined; (iii) guidance documents such as the handbook for auditors and the audit plan form; and (iv) training of auditors.

The mission team noted that the verification of effective implementation of official controls is included in the scope and objectives of the audits according to MAST procedures. However, auditing of effective implementation of official controls was not explicit in audit reports. The competent authority explained that the audits went beyond compliance and often included suggestions for improvement which did not necessarily result in corrective actions required from the auditee. The mission team found that there was insufficient information on the audit results related to the evaluation of effective implementation of official controls.

The verification of suitability of official controls was not yet included in the audit's objectives as the audit body was currently evaluating how this could be achieved. The audit body commented on the difficulties related to developing and applying a methodology to verify the effectiveness and suitability of the official controls.

5.2.5.4 Audit reporting

Reports are drafted by the audit team following each individual audit in accordance with documented procedures and a report template. The final report together with the corrective

action plan in annex, is approved by the audit supervisor. The reporting process can be considered finalised only once the final report is presented by the audit supervisor to MAST quality council, to the audit board and audit committee. The report approval procedure includes a provision for the auditees to comment on the findings detailed in the preliminary report presented at the closing meeting. Although not specified in the procedures, the auditees can also comment on the general content of the draft audit report. There are instructions for the subsequent distribution of the report, which is however not publicly available.

The audit reports include clear objectives, scope and criteria. They present positive findings, observations for improvement, non-compliances, significant non-compliances, and good practices, if any. The mission team noted that emphasis is mainly put on compliance with planned arrangements (quality manuals) in the report examples provided at the time of the mission. Auditees' comments are included in annex and/or in the body of the text of the final report.

The mission team noted that based on the files assessed, the planned reporting arrangements are adequately followed. However, the timeline indicated in the procedures was not always followed with prolonged time lapses between the audit and the presentation of the report, in particular for the audits carried out in 2017 for which no report has yet been finalised. The audit body explained that due to the set-up of the system, auditees' inputs and corrective action plan in response to the preliminary draft are required to prepare the draft report. The auditees are invited to comment on the draft report before it is finalised by the audit team and approved by the audit supervisor. However, no actions are taken by the audit body or by MAST in case of failure by auditees to provide a corrective action plan, and to implement it. The audit body added that delays also occurred due to various reasons such as work load, disagreement with the auditee, or when non-compliances required substantial corrective actions such as those involving legal amendments.

5.2.5.5 Review of audit conclusions and dissemination of best practices

According to the annual audit plans, the audit supervisor analyses the overall results of audits and submits to the audit committee an annual analysis of the systemic strengths or weaknesses identified in audits. However, the mission team noted that these arrangements have not been implemented yet.

The audit body stated that annual reports for audits have not been produced yet but a list of audits was published in the 2016 MAST annual report. The competent authority is currently discussing by which means the results of audits will be shared and with whom.

The audit reports describe good practices, if any, identified during the audit. However, the competent authority has not established a systematic approach to disseminating the identified good practices within MAST and between MAST and other competent authorities and stakeholders. According to the pre-mission document, regular meetings within MAST provide the opportunity for sharing useful information. Bi-annual meetings between MAST and LCAs and routine collaboration on food controls between these authorities represent the platform for disseminating good practices. In addition, final reports are distributed to the audit committee which members are stakeholders' representatives.

5.2.5.6 Monitoring and review of audit process

According to the pre-mission document, the audit supervisor meets with all auditors at the end of the year to discuss the audits carried out. The purpose of this discussion is part of a

learning and improvement process. The audit body plans to ask for feedback from the relevant auditees, but this process has not started yet.

Documented procedures are in place for review of the audit process in the general instructions for improvement of MAST as part of MAST quality system. At the time of the mission, a review of the auditing process had not yet been carried out. The competent authority explained that the pilot phase of 2016-2017 for the implementation of the audit process had just been completed and the review was planned to take place soon.

Conclusions

The audit process is generally implemented according to documented procedures and is well documented, ensuring that activities are carried out in a consistent manner, in line with Commission Decision 2006/677/EC and the NAS network documents. However, the audit body has not defined a procedure to deal with failure by auditees to address identified observations and non-compliances, and to take action according to the corrective action plan.

Arrangements have been put in place to ensure that compliance with planned arrangements is audited in a systematic manner. The effective implementation of planned arrangements is addressed to a lesser extent, and verification of suitability of official controls in achieving objectives has not yet been made part of the audits' scope.

Audit reporting procedures ensure consistent and clear reporting of relevant audit results with the exception of reporting on verification of effectiveness and suitability of official controls. Timely reporting is jeopardised by the system set-up in relation to communication with auditees and delays in report finalisation.

The competent authority has not yet analysed the overall results of audits to identify systemic strengths or weaknesses in audits. Good practices are described in audit reports; however, they are not systematically disseminated by the audit body.

The audit process has not been systematically reviewed yet, due to the recent completion of the two-year pilot phase for the implementation of the national audit system.

5.2.6 Follow-up of audit recommendations

Legal Requirements

Article 4(6) of Regulation (EC) No 882/2004 requires, *inter alia*, competent authorities to take appropriate measures in light of the results of internal or external audits.

In section 5.3 of the Annex of Commission Decision 2006/677/EC further guidance is provided on 'Independence', in relation to follow-up of audit recommendations:

“Where the audit team makes recommendations for corrective and preventive action, the auditee should choose the methods to be applied for such action. Active audit team involvement in follow-up should be limited to assessing the suitability of the action plan and the effectiveness of the corrective and preventive action. Auditees should not be in a position to impede the audit programme, findings or conclusions. They should be consulted on the draft report and their comments should be considered by the audit body. Where appropriate, those comments should be taken into account in a transparent manner”

Section 6.3 of the Annex of Commission Decision 2006/677 provides guidance on follow-up of audit outcome:

“Where appropriate, an action plan should be drawn up and delivered by the auditee. It should propose time-bound corrective and preventive action to address any weakness identified by the audit or audit programme. The audit team should assess the suitability of the action plan and may be involved in verifying its subsequent implementation:

- *An Action plan enables the audit team to assess whether the proposed corrective and preventive action is sufficient to address the recommendations of the audit report. Action plans should include risk-based prioritisation and time frames for completion of corrective and preventive action. A wide range of different action plans could be considered satisfactory. It is for the auditee to choose from the various options available,*
- *Corrective and preventive action should not be confined to addressing specific technical requirements but should, where appropriate, include system-wide measures (...). A root cause analysis of any non-compliance should be conducted by the auditee in order to determine the most appropriate corrective and preventive action. Any differences of opinion between the auditee and audit team should be resolved,*
- *Close-out: Mechanisms should be established to ensure that action plans are appropriate and that corrective and preventive actions are effectively completed in a timely manner. Procedures for verifying the close out of the action plan should be agreed between the auditee and the audit team.”*

Findings

MAST procedures lay down the steps to be taken to follow-up audit findings/conclusions. A preliminary draft report is presented during the closing meeting of the audit and includes the deadline for auditees to send a corrective action plan and the corresponding responsible person. This preliminary draft report is signed by representatives of auditors and auditees, unless there is disagreement between parties, in which case it is signed under reserve.

Following the closing meeting, a corrective action plan form containing observations and non-compliances to be addressed is sent by the audit body to the auditee. Only findings and conclusions requiring corrective actions according to the lead auditor's assessment are included in this form. It is the responsibility of the auditee to identify corrective actions together with a deadline for their implementation, and fill in the given form to be sent to the audit body. The mission team noted that in one audit examined, the action plan had been fully drafted by the audit team.

According to information provided to the mission team, the auditee should perform a root-cause analysis for non-compliances identified in the audit reports. It is required for corrective actions under MAST responsibility in the framework of improvement projects, but has not been implemented for all auditees.

The corrective action plan is assessed by the lead auditor who may request the auditee to make amendments. The finalised corrective action plan is then confirmed by the audit supervisor who submits it to the audit board for approval. Following the audit board's approval of the plan, the draft report with the corrective action plan is sent to the auditee, who has ten days to provide comments by email or by letter. The report is then finalised and sent to the audit supervisor for approval within ten days after receipt of the complete report.

The audit supervisor is responsible for the follow-up of the corrective action plans according to MAST procedures, although this is not indicated in the audit charter. For this purpose, all corrective actions deriving from audits are recorded, regardless of the responsible competent authority, and their status is monitored with the use of a comprehensive excel spreadsheet. The audit supervisor notifies the responsible person for the corrective action if the deadline for its implementation has passed and no further information has been received. All documents are placed in RMS with access limited to the audit body. Corrective actions placed under MAST responsibility are dealt with in the framework of improvement projects managed by MAST Quality Manager according to detailed procedures in MAST quality manual.

The audit board informed the mission team that although it recognised the importance of its role for ensuring that necessary corrective actions are implemented in accordance with the approved corrective action plan, this had not yet been achieved. Similarly, the audit committee should monitor that the audit board ensures follow-up on the corrective action plans but it is not yet fulfilling this role.

According to MAST procedures, only the audit supervisor can close out the action plan and consequently the audit case once the implementation of all corrective actions has been verified. Verification may be achieved either by documentary check, or on the spot, during a follow-up audit carried out by a special audit team nominated by the audit supervisor, or during the next planned audit of the same auditee. The audit body supervisor confirms the positive outcome of the verification by signing each form used for each corrective action, placed in RMS under the case of the initial audit. Finally, the audit supervisor closes the case in RMS, which indicates that the follow-up process has been successfully completed. However, no action is taken when the auditee does not meet the deadlines for drafting the action plan (with consequent delays) and for implementing the plan, and MAST cannot ensure that auditees from other competent authorities take corrective action, where such action is needed. Furthermore, the auditee's failure to meet its obligations is not communicated by the supervisor to top management.

Conclusions

There is a system in place ensuring that the competent authority takes appropriate corrective actions to address the results of the audits carried out, as required by Article 4(6) of Regulation (EC) No 882/2004. However, not all arrangements have been implemented yet.

Furthermore, the competent authority does not have any arrangements for dealing with auditees' failure to meet deadlines and to follow up on corrective actions.

5.2.7 Transparency

Legal Requirements

Article 4(6) of Regulation (EC) No 882/2004 requires, *inter alia*, that audits shall be carried out in a transparent manner.

Section 5.2 of the Annex of Commission Decision 2006/677/EC provides guidance on transparency, including the following:

“In order to demonstrate the audit process is transparent, documented procedures should, in particular, include a clearly defined audit planning process, audit criteria and audit report approval and distribution mechanisms.

Management and implementation of the audit process should be transparent to all relevant stakeholders. In particular, there should be full transparency between the audit body and the auditee. Ensuring the audit process is transparent in the eyes of other stakeholders will assist in the dissemination of information, and in particular in the sharing of best practice within and between competent authorities.

The Member States should adopt the appropriate measures to ensure their audit systems are transparent, taking national legal and other requirements into account. To that end, the Member States should consider encouraging practices that improve the transparency of the process.”

Findings

The arrangements in place in relation to the audit planning process and definition of audit scope and objectives ensure transparency. These include public access to the MANCP, audit charter, national multi-annual audit programmes, annual audit plans, and the audit process descriptions, which are published on MAST website. MAST staff has access through its intranet to all documented procedures related to audits, but access to each audit case is restricted to the audit body.

According to the charter and procedures, the audit board validates the multi-annual audit programme and the audit committee approves the annual audit plans. However, the mission team noted that not all audited services have an active involvement during planning.

MAST documented process descriptions establish that the audit supervisor shall formally inform the auditee of the planned audit and the audit team leader shall send the audit plan to the auditee at least one month before the audit. The auditee has seven days to comment on the audit team composition. At least seven days before the audit, the audit team leader shall send the auditee a final version of the audit agenda which has been developed in collaboration with the auditee. The mission team was informed that a handbook for auditees had been drafted and was soon to be finalised to be provided to the auditees before the planned audit.

A preliminary draft report, prepared by the audit team, is presented at the time of the closing meeting (or shortly after in examples seen by the mission team) during which it is signed by representatives of the auditor and auditee. It is foreseen that in case of disagreement, notice shall be given at the time of the signature and formal comments may be sent by the auditee. Auditees have the opportunity to comment on the preliminary draft report and on the draft report before it is finalised.

The final report, with the auditee's action plan in annex, and auditees' comments in its contents and/or in annex, is distributed to auditee representatives, the quality council, the Head of MAST Coordination and Legal Affairs Department, the audit committee and the audit board. The audit committee includes stakeholders such as consumers and farmers associations, to which the final report is made available according to the charter; however, not all competent authorities involved in official controls under Regulation (EC) No 882/2004 have access to this document.

MAST publishes general information on its audit activities in the annual report available on its webpage. No other systematic arrangement to provide assurance to external stakeholders and other competent authorities was in place during the 2016-2017 pilot phase. Audit reports or their summary have not been published, and no specific annual report on audits' outcome

has been prepared. The mission team was informed that the audit body is currently discussing how to approach this issue.

Conclusions

Appropriate arrangements are in place to ensure transparency of the audit process within MAST as foreseen in Article 4(6) of Regulation (EC) No 882/2004. Final reports are provided to some external stakeholders through the audit committee; however, audit results are not publicly available and are not distributed to all competent authorities involved in official controls under Regulation (EC) No 882/2004, which is considered a missed opportunity to promote confidence in official controls.

5.3 Challenges reported by the competent authority

The audit body informed the mission team of challenges it experienced in planning and implementing the national audit system. In general the identified challenges mirrored the findings of the mission team. In particular, the need for a systematic approach for assessing risks when developing the audit programme/plan (see section 5.2.4 of this report), the verification of effective implementation of official controls and their suitability to achieve objectives (see section 5.2.5.3 of this report) and audit follow-up (see section 5.2.6 of this report) had been identified. Time, resources and independence of auditors in a small competent authority, and appropriate training of auditors were also found challenging. Furthermore, the difficulties related to setting up an audit system considering that MAST and ten LCAs have official control responsibilities were discussed with the mission team.

6 Final meeting

A final meeting was held on 19 January 2018 at MAST office in Reykjavík with representatives from MAST, MoII and LCAs. At this meeting, the mission team presented its main findings and preliminary conclusions of the mission, which were generally acknowledged by the attending representatives.

7 Recommendations

In order to facilitate the follow-up of the recommendations hereunder, Iceland should notify the Authority no later than 6 June 2018, by way of written evidence, of additional corrective actions planned or taken other than those already indicated in the reply to the draft report of the Authority. A timetable for completion of outstanding measures, relevant to the recommendations hereunder, should be included. In case no additional corrective actions have been planned, the Authority should be advised. The Authority should be kept continuously informed of changes made to the already notified corrective actions and measures, including changes of deadlines for completion, and completion of the measures included in the timetable.

No	Recommendation
1	The competent authority should ensure that there is a systematic risk-based approach for the development of the audit programme and the review of the audit process to better achieve the objectives of Article 4(6) of Regulation (EC) No 882/2004.
2	The competent authority should ensure that the audits assess whether activities and related results are implemented effectively and are suitable to achieve objectives in line with Article 2(6) of Regulation (EC) No 882/2004.

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

Authority	EFTA Surveillance Authority
BTSF	Better Training for Safer Food
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
LCA	Municipal Environmental and Public Health Office
MANCP	Single integrated multi annual national control plan
MAST	Icelandic Food and Veterinary Authority
MoII	Ministry of Industry and Innovation
NAS Network	The NAS Network is a network of officials (auditors) from competent authorities of the EEA, responsible for the performance of audits of official control systems as provided for by Article 4(6) of Regulation (EC) No 882/2004. The Network meets regularly, under the chairmanship of, and facilitated by, Directorate-General for Health and Food Safety (DG SANTE) to exchange experiences in implementing national audit systems on official control activities. During the course of these exchanges; discussions, workshops etc. good principles and practices are identified and agreed by the network. To enable dissemination of information the Network, working in plenary session and through subgroups, and facilitated by DG SANTE, consolidates agreed principles and good practices on specific topics into Network Reference Documents.
RMS	MAST record management system
TAIEX	Technical Assistance and Information Exchange

Annex 2 - Relevant legislation

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

- a) The Act referred to at Point 1.1.11 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;
- b) The Act referred to at Point 1.2.74 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;
- c) The Act referred to at Point 1.2.136 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2006/677/EC of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules*.

Annex 3 - Iceland's response to the draft report



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

Selfoss, 27 March 2018
Ref: 1711333
Your ref: 81340/327426

Subject: Iceland's response to draft report on EFTA Surveillance Authority's mission on the national audit system in Iceland in January 2018.

Please find enclosed the table of corrective actions prepared by the Icelandic Food and Veterinary Authority in order to react to recommendations made by the EFTA Surveillance Authority in the above mentioned report.

No general comments or corrections are otherwise made to the draft report.

Respectfully
on behalf of MAST

Ástfríður Sigurðardóttir
Senior officer
Office of legal affairs

Annex 4 - Iceland's action plan for corrective actions

No	Recommendation	Reaction of Icelandic authorities	Date of Compliance
1	The competent authority should ensure that there is a systematic risk-based approach for the development of the audit programme and the review of the audit process to better achieve the objectives of Article 4(6) of Regulation (EC) No 882/2004.	The documented process, VLY-010 Internal Audit Programs – MANAP and Yearly programme, will be reviewed where a systematic risk-based approach of the audit programs will be added in the document. Furthermore, a risk model will be developed which will be used for systematic evaluation of risk when developing Audit Programmes. The risk-based approach will be documented before 1 September 2018 and the model fully developed before 1 February 2019. The review of the audit process will be ensured by necessary revision of the documented guideline, LBE-035 Improvements – holistic process, followed by effective implementation. The revision will be carried out before 1 September 2018 and the necessary implementation will be finished before 1 February 2019.	01.02.2019
2	The competent authority should ensure that the audits assess whether activities and related results are implemented effectively and are suitable to achieve objectives in line with Article 2(6) of Regulation (EC) No 882/2004.	In-house training for internal auditors will be conducted 9 to 11 April 2018. Auditing effectiveness and suitability will be included in the training followed by necessary guidelines revision/development. This year and 2019 the aim is to regard them as a pilot phase for auditing effectiveness and suitability. Audits which are planned 2018 will all be focused both on compliance and effectiveness. The year after, 2019, audits will also cover suitability together with compliance and effectiveness. The 2020 will therefore be the first year to conduct satisfactory audits which fully meet the requirement of Article 2(6) of Regulation (EC) No 882/2004.	31.12.2020