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Final report

EFTA Surveillance Authority mission to Iceland

from 10 to 14 September 2012

regarding application of EEA legislation

related to

the monitoring and control of zoonotic agents in live animals and products of animal origin with emphasis on *Salmonella*

Please note that comments from the Icelandic competent authorities to the draft report and information on the corrective actions already taken and planned by the Icelandic competent authorities are included in Annex 5 and referred to in footnotes in *underlined italic print*.

Executive Summary

This report describes the outcome of a mission carried out by the EFTA Surveillance Authority in Iceland from 10 to 14 September 2012. The objective of the mission was to verify that official controls related to the monitoring and control of zoonotic agents in live animals and products of animal origin, with emphasis on Salmonella, were carried out in compliance with the European Economic Area (EEA) legislation. The mission team found that the epidemiological situation in Iceland concerning zoonotic agents was satisfactory. However reporting on zoonotic agents and the monitoring of antimicrobial resistance for Campylobacter spp. has not yet been fully addressed by the Icelandic competent authorities. The fact that no national reference laboratory is designated for Salmonella and for the zoonotic agents falling within the scope of this mission was also pointed out.

The control programmes for Salmonella in poultry and pigs are in line with the EEA legislation with only minor remarks to be addressed. The control measures taken in the event of groups of poultry infected with Salmonella or Campylobacter are even stricter than the EEA requirements. The mission team was pleased to verify the level of competence and commitment demonstrated by the personnel of the Icelandic Food and Veterinary Authority (MAST) involved in the programmes. Some shortcomings concerning the programmes have been identified by the mission team such as the fact that MAST has not yet submitted the national control programmes for Salmonella to the Authority for official approval and that the official controls on Salmonella in feed are not yet implemented in the mentioned programmes.

The laboratories visited by the mission team were all accredited but the method of analysis to detect Salmonella was not in conformity with the relevant requirements.

The mission team detected serious shortcomings in the official controls in particular in the coordination between MAST and the Local Municipal Environmental Health and Protection Offices (LCA) and relevant enforcement. Limited immediate actions on the spot were taken in a hospital kitchen with regard to unsatisfactory cleaning procedures and unidentifiable, expired and untraceable products stored in a cooler and in a freezer. One establishment visited was providing supplies to the hospital kitchen, but was neither registered nor approved. The company had been distributing frozen products with the knowledge of the LCA for over two years.

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

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1 Introduction

The mission took place in Iceland from 10 to 14 September 2012. The mission team comprised three inspectors from the EFTA Surveillance Authority (the Authority) and a national expert.

This was the second mission to Iceland focusing on monitoring and control of zoonoses. A preparatory mission was carried out by the Authority in September 2008. At that time the relevant European Economic Area (EEA) legislation was not yet applicable to Iceland. This legislation entered into force for Iceland on 1 November 2011.

The opening meeting was held with representatives of the Icelandic Food and Veterinary Authority (MAST) and a representative of a Local Municipal Environmental Health and Protection Office (LCA) on Monday 10 September 2012 at MAST's offices in Reykjavik.

At the meeting, the mission team confirmed the objectives and the itinerary of the mission. The Icelandic representatives provided additional information to that set out in the reply to the Authority's pre-mission document.

Throughout the mission, the mission team was accompanied by a representative of MAST head office together with representatives of the relevant district offices and/or the LCA in charge of official control in the facilities visited.

A final meeting was held in Reykjavik on 14 September 2012 with representatives of MAST, the Ministry of Industries and Innovation, an LCA and the Chief Epidemiologist.

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

2 Scope and objective of the mission

The following main EEA Acts and related EEA legislation fall within the scope of the mission:

a) *Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents* (as amended) and

b) *Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 (as amended) on the control of Salmonella and other specified food-borne zoonotic agents* (as amended).

The objective of the mission was to assess the Icelandic competent authority's application of the above mentioned legislation and relevant additional legislation. All legislation referred to in this report is listed in Annex 2 to this document.

A particular focus was put on the Icelandic control and monitoring of *Salmonella* at the level of primary production of poultry but also at other stages of the food chain, including animal products and feed.

The assessment was based on the following main issues:

- the national legislation, policy and operating procedures regarding the objective of this mission;

- the compliance action and procedures, reporting and competence of personnel; and
- the uniformity in national implementation.

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 inspections, to verify the normal control procedures adopted and enforcement measures in place to ensure that corrective actions will be taken when necessary.

The meetings with the competent authorities and the visits 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
	1	Local Municipal Environmental Health and Protection Office (LCA)
Public health institutions	2	A representative of the Chief Epidemiologist and a local Chief Physician (district Epidemiologist)
Laboratories	3	Two designated laboratories analysing official samples and own-checks samples taken within the *Salmonella* control programme in poultry and one designated laboratory analysing own-checks samples for feed
Establishments	4	A catering facility providing meals to hospitalised people, an establishment placing fishery products on the market, a slaughterhouse for poultry and a feed mill
Farms	1	A poultry farm (laying hens)

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*; and

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*.

4 Background

A mission to Iceland focusing on monitoring and control of zoonotic agents in live animals and products of animal origin with emphasis on *Salmonella* was carried out by the Authority in September 2008. At that time the relevant European Economic Area legislation was not applicable to Iceland and the mission was considered as "preparatory" therefore the report was not published on the Authority's website.

Relevant information on production and trade with EEA countries of products subject to controls on zoonotic agents for the recent years is available in Annex 3.

5 Main findings and conclusions

5.1 Legislation and implementing measures

Legal requirements

Article 7 of the EEA Agreement states that acts referred to or contained in the Annexes to the Agreement are binding upon the Contracting Parties and shall be, or be made, part of their internal legal order.

Findings

According to information received from Iceland, the majority of the EEA legislation falling within the scope of this mission has been implemented within national regulations that have been in force since November 2011. Some regulations (e.g. Regulation (EC) No 584/2008 as regards a Community target for the reduction of the prevalence of *Salmonella Enteritidis* and *Salmonella Typhimurium* in turkeys, Regulation (EC) No 199/2009 laying down a transitional measure as regards direct supply of small quantities of fresh meat derived from flocks of broilers and turkeys and Regulation (EU) No 200/2010 as regards a Union target for the reduction of the prevalence of *Salmonella* serotypes in adult breeding flocks of *Gallus gallus*) was implemented later, in March 2012. Regulation (EU) No 517/2011 as regards a Union target for the reduction of the prevalence of certain *Salmonella* serotypes in laying hens of *Gallus gallus* has been implemented from May 2012.

The Icelandic legislation provides for stricter national measures regarding monitoring and control of *Salmonella* in poultry and pigs and *Campylobacter* in poultry than those laid down in EEA legislation. These measures were initially adopted for broilers in 2002 with Regulation (IS) 688/2002 implementing restrictions on marketing products from *Salmonella* and *Campylobacter* positive flocks. The controls have been further developed with latest amendments laid out in Regulations (IS) 783/2011 concerning *Salmonella* and in Regulation (IS) 562/2012 concerning *Campylobacter*. In addition, concerning stricter measures in Iceland, according to Regulation (IS) 1011/2011 implementing Regulation (EC) 2160/2003, there is no distinction made in relation to *Salmonella* serotypes with or without public health significance. This is further stated concerning broilers in Regulation (IS) 1014/2011 implementing Regulation (EC) 646/2007 as regards a Community target for the reduction of the prevalence of *Salmonella Enteritidis* and *Salmonella Typhimurium* in broilers and laying hens in Regulation (IS) No 369/2012 implementing Regulation (EU) No 517/2011. Furthermore, according to Regulation (IS) No 211/2012 implementing

Regulation (EC) 199/2009 Iceland applies the same monitoring and control procedures concerning broilers and turkeys irrespective of flock size (see chapter 5.8).

Salmonella in pigs has been monitored in farms and slaughterhouses by an official control programme since October 2006. Farmers and food business operators are obliged to comply with the control programme which has its legal basis in a general clause in Article 13 in the Act on the Raising and Health of Slaughter Animals, Slaughtering, Processing, Health Inspection and Quality Grading of Slaughter Products No. 1997/96. The current official control programme includes annual faecal sampling at farm level and muscle biopsies taken from carcasses at slaughter from every farm. Additionally carcass swabs are taken from each farm at every slaughter to monitor cross contamination.

Conclusions

The relevant EEA legislation concerning the zoonotic agents included in the scope of this mission has been made part of the Icelandic legal order. For some zoonotic agents (*Salmonella* in poultry and pigs and *Campylobacter* in poultry) the Icelandic legislation implements stricter requirements than those laid down in the EEA legislation.

5.2 Competent authorities

Legal Requirements

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

Article 4(2)(c) of Regulation (EC) No 882/2004 states that the competent authorities shall ensure that they have, or have access to a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively.

Article 4(3) of Regulation (EC) No 882/2004 requires that efficient and effective coordination and cooperation shall be ensured between all the competent authorities involved in official controls;

Article 54 of Regulation (EC) No 882/2004 lays down the action in case of non-compliance and in particularly states that when the competent authority identifies non-compliance, it shall take action to ensure that the operator remedies the situation. When deciding what action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance.

Findings[1]

According to information provided by MAST in its reply to the pre-mission document of the Authority, the Ministry of Fisheries and Agriculture is the highest administration body and is responsible for legislation and implementation and application of EEA acts regarding monitoring and control of zoonotic agents in live animals and products of animal origin. However, at the initial meeting, MAST informed the mission team that since 1 September 2012 the newly created Ministry of Industries and Innovation has taken over the responsibilities of the Ministry of Fisheries and Agriculture. MAST is the competent authority for the purpose of the legislative acts falling within the scope of this mission. Following the amendment of Act No 66/1998 on Veterinarians and Animal

[1] *See Annex 5 for comments received from the visited Local Municipal Environmental Health and Protection Office on paragraphs 16 and 20, Section 5.2. and paragraph 12, Section 5.9.*

Health Services, major changes have been made to the districts served by district veterinarians belonging to MAST and the number of districts has been reduced from 14 to six.

The mission team asked MAST to explain how district veterinarians can comply with their duties where the number of staff (apart from the district veterinarian himself) is none (West and East districts). MAST explained that private veterinarians are hired on a temporary basis to perform official controls in those districts and officers from the headquarters could also provide additional help. For fishery establishments only, four inspectors plus a central coordinator from the headquarters are responsible for the official controls of the approved establishments. The mission team had the possibility to verify the level of skills and expertise demonstrated by MAST personnel dealing with the *Salmonella* control programmes in poultry.

According to the Food Act No. 93/1995, the LCAs, under the supervision of MAST, shall inspect foodstuffs production and distribution on the consumer market. Iceland is divided into 10 local authorities. All staff carrying out official food control has a university degree in natural sciences, mainly food science, biology or veterinary medicine.

According to information provided by MAST in its reply to the pre-mission questionnaire from the Authority, MAST has not formulated any specific procedures or criteria to evaluate the harmonisation of the controls carried out by the LCAs. However, MAST indicated several indirect means for such evaluation, i.e. the annual control plans prepared by the LCAs and the annual reports from the LCAs on the results of official controls. Furthermore formal venues for contacts between MAST and LCAs each year exist in the form of meetings, visits and conferences.

At the initial meeting the mission team was informed by a representative of an LCA that starting from 1 January 2014 the LCAs will apply the same risk classification system as the one implemented by MAST assuring the same approach for the whole food chain. The system is going to take into consideration the number of hours that should be spent in an establishment to perform official controls. The LCA explained to the mission team the system in use today in its jurisdiction: a form containing various information on the activities carried out by a food business operator is filled in by the LCA providing a final risk category for that establishment (high, medium or low). The system was conceived in 2002 and was issued as a guideline for LCAs by the Food and Environment Agency. MAST has also issued guidelines concerning classification of food business operators but the mission team did not have the possibility to verify whether the same system is implemented in all LCA districts.

Following this risk categorisation, out of around 800 establishments under control of the mentioned LCA, only 10-20 belong to the high risk category and they should according to the guidelines be visited at least two times a year. The mission team visited one of those establishments (a hospital kitchen) and found that the last visit was carried out in December 2011.

A control manual, for food surveillance carried out by the LCAs to fulfil the Icelandic legislation on food, is available on MAST's website. It is dated 2005 and is designed to harmonise the activities of the LCAs. However, it is not updated (names of responsible persons and authorities, reference to legal acts out of date or not applicable, etc). According to the same LCA the control manual is unsatisfactory as a harmonisation tool.

At the initial meeting MAST informed the mission team about the intention to audit its own districts and the LCAs in 2013. Internal audit at the central level of MAST is planned

for end of 2012. MAST also indicated to the mission team they have no legal power to control the competence of the LCAs' inspectors and that MAST does not control nor has any overview on need for relevant training in the LCAs.

According to information provided by MAST, MAST or LCAs under the supervision of MAST should always be responsible for the investigation of a suspected food-borne outbreak and responsible for the coordination if the outbreak involves more than one LCA.

A contingency plan to manage foodborne outbreaks was issued in 2005 by involved parties. Investigation of outbreaks is carried out according to the plan from 2005. An updated contingency plan has been drafted. It describes the contact and the cooperation between the authorities involved in food borne outbreaks. The draft plan was, according to the Chief Epidemiologist representative, not yet applicable, however, MAST considers the draft to be applicable to the involved parties.

The mission team observed the lack of formalized notification between MAST and the Chief Epidemiologist during a foodborne outbreak that occurred in 2011 (see chapter 5.6).

The mission team noted the limited immediate corrective actions taken on the spot by the LCA in a hospital kitchen regarding unsatisfactory cleaning procedures and unidentifiable, expired and untraceable products stored in a cooler/freezer. Furthermore evidence of inadequate follow-up by an LCA in an establishment found in operation without any formal registration and/or approval was noted (see chapter 5.9).

Conclusions

Iceland has designated competent authorities responsible for the official controls concerning the zoonotic agents falling within the scope of this mission in line with the requirements laid down in the Article 4(1) of Regulation (EC) No 882/2004.

Good competence and commitment was demonstrated by MAST personnel involved in the control programmes for *Salmonella* in poultry. However, problems concerning official controls and control duties not carried out efficiently and effectively, including problems regarding the effective harmonisation and supervision carried out by MAST with regard to the visited LCA, were observed. This is not in compliance with Articles 4(2) (c) and 4(3) of Regulation (EC) No 882/2004.

Cooperation and coordination between competent authorities involved in the management of foodborne outbreaks did not meet the requirements related to effectiveness in Article 4(3) of Regulation (EC) No 882/2004.

The action taken by the LCA in the cases of non-compliance identified during the mission was not sufficient to comply with the measures detailed in Article 54 of Regulation (EC) No 882/2004.

5.3 Laboratory services

Legal Requirements

Article 12(1) of Regulation (EC) No 882/2004 states that the competent authority shall designate laboratories that may carry out the analysis of samples taken during official controls. Article 12(2) states that the competent authority may only designate laboratories that operate and are assessed and accredited in accordance with the European standards; in Article 12(3) it is mentioned that accreditation and assessment of testing laboratories may relate to individual test or groups of tests.

Article 33(2) of Regulation (EC) No 882/2004 lays down the responsibilities of the national reference laboratories.

Article 10 of Directive 2003/99/EC and Chapter VI of Regulation (EC) No 2160/2003 laid down provisions on the reference laboratories for zoonoses and zoonotic agents. Article 3 and Annex II to Commission Decision 2004/564/EC set out the responsibilities and tasks of the national reference laboratories for *Salmonella*, pursuant to Directive 2003/99/EC and Regulation (EC) No 2160/2003.

Findings

MAST has designated four laboratories that carry out the analysis of samples taken during official controls. The mission team visited three of the four designated laboratories, all three analysing samples collected within the *Salmonella* control programmes in poultry and pigs by MAST (official controls) and by the food business operators (own-check controls). Some discrepancies were noted by the mission team regarding the type of matrices for which each laboratory has been designated (as detailed in the list published on MAST website) and the matrices effectively analysed by the laboratories visited.

All the laboratories visited were assessed and accredited in accordance with the ISO Standard 17025. Another laboratory (not visited during the mission) performs analysis of human samples and is also used by the other laboratories for *Salmonella* identification of the serovars isolated in controls of animals, animal products and other materials (e.g. faeces and environmental samples). However, this laboratory is not accredited for the relevant method of analysis.

No National Reference Laboratories (NRL) dealing with the zoonoses falling within the scope of this mission, including *Salmonella*, have been appointed according to information provided by MAST. However, during the visit to one of the designated laboratories, the mission team was provided with copy of a letter addressed by MAST to the Ministry of Agriculture and Fisheries, dated 31 October 2011, requesting the Ministry to proceed with the appointment of several NRLs in conformity with the EEA legislative requirements. At the final meeting, a representative of the above mentioned Ministry (now, the Ministry of Industries and Innovation), informed the mission team that lack of funding is the reason why the Ministry has not yet designated any NRL.

In the three laboratories visited it was observed that the analytical activities of official and own-checks samples are not separated and are performed by the same employees using the same spaces, instruments and reagents; moreover as far as costs for the official samples are concerned, both the sampling and the analytical tests are covered by the food business operators.

All the laboratories visited had quality control systems in place which was properly implemented. Representatives of the laboratories confirmed to the mission team the good relationship with the other designated laboratories. Moreover all three laboratories participated regularly in inter-laboratories comparison studies organized by relevant laboratories abroad. The Icelandic laboratories demonstrated good performances in these studies.

All the laboratories visited used the method NMKL No 71 5th Edition, 1999 that has been demonstrated to be equivalent to the ISO 6579:2002/Corr 1:2004 for the isolation of *Salmonella* in foodstuffs. However, this was also the method used for analyzing animal

faeces and environmental samples from the primary production as part of the *Salmonella* control programmes; these laboratories were not using the method ISO 6579:2002/Amd.1:2007 which include the use of the MSRV (Modified Semisolid Rappaport Vassiliadis) as non-selective enrichment medium. This medium is not used in the NMKL No 71 5th Edition, 1999.

Both in case of negative and positive results the laboratory is obliged to send by e-mail a copy of the report to the client and MAST. On a monthly basis a detailed report summarising the analytical results related to *Salmonella* and *Campylobacter spp*. is also sent to MAST.

Conclusions

The Icelandic competent authorities have designated laboratories that may carry out the analysis of samples taken during official controls in accordance with Article 12(1), (2) and (3) of Regulation (EC) No 882/2004. All the laboratories visited showed good organization.

However no NRLs have been designated in Iceland as required by Article 33(2) of Regulation (EC) No 882/2004, Article 10 of Directive 2003/99/EC, Article 11 of Regulation (EC) No 2160/2003 and Article 3 and Annex II to Decision 2004/564/EC.

The detection of relevant *Salmonella* serotypes shall be carried out according to Amendment 1 of ENI/ISO 6579-2002/Amd 1:2007 as laid down in Annex 3.2 to Commission Regulations (EU) No 200/2010, Commission Regulation (EU) No 517/2011, Commission Regulation (EC) No 213/2009; Commission Regulation (EC) No 584/2008 and Commission Regulation (EC) No 646/2007. The analytical method NMKL No 71 5th Edition, 1999 used in Iceland to detect *Salmonella* in animal faeces and environmental samples from the primary production stage is not in compliance with the relevant EEA legislation mentioned above.

5.4 Monitoring of zoonosis and zoonotic agents

Legal Requirements

Article 3(1) of Directive 2003/99/EC requires the Member States to ensure that data on the occurrence of zoonoses and zoonotic agents and antimicrobial resistance related thereto are collected, analysed and published without delay in accordance with the requirements of this Directive and of any provisions adopted pursuant to it. Article 3(3) requires the Member States to ensure that effective and continuous cooperation based on free exchange of general information and, where necessary, of specific data, is established between the competent authorities or authorities designated for the purposes of this Directive.

Chapter II of Directive 2003/99/EC lays down the general rules on monitoring of zoonoses and zoonotic agents (Article 4), the establishment of coordinated monitoring programmes (Article 5) and the food business operators' duties (Article 6). Annex I (A) to the same Directive lists zoonoses and zoonotic agents to be included in the monitoring while Annex I (B) lists zoonosis and zoonotic agents to be monitored according to the epidemiological situation. Finally Annex IV to the above mentioned Directive lays down the requirements for the reports to be submitted annually to the Authority and made publicly available pursuant to Article 9(1) of the Directive.

Findings

Data on monitoring/control programmes of zoonotic agents referred to in Annex I of Directive 2003/99/EC and the number of outbreaks/identifications of zoonotic agents in production animals in Iceland (2009, 2010 and 2011) have been provided to the mission team in the reply to the pre-mission questionnaire and are included in Annex 4 to this report. According to information provided by MAST in its reply to the pre-mission questionnaire from the Authority, no outbreaks of *Salmonella* in production animals have occurred in Iceland in the past three years.

Iceland has submitted to the European Food Safety Authority (EFSA) a report on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance concerning the year 2011. However, the information available in the above mentioned report does not include, amongst others, data on Salmonellosis and Campylobacteriosis in humans, *Salmonella* in feed, Listeriosis, *E. coli* infections and a full antimicrobial resistance study (see chapter 5.5). Furthermore, information e.g. on the relevant susceptible animal population and food-borne outbreak data have not been provided in the report.

The above mentioned report has not been submitted to the Authority. Furthermore, the report has not been made publicly available.

Conclusions

Iceland is collecting and analysing data on the occurrence of various zoonoses and zoonotic agents and measuring to some extent antimicrobial resistance. However these data are not covering all the zoonoses and zoonotic agents and antimicrobial resistance in accordance with Article 3(1) of Directive 2003/99/EC. A report was also prepared and distributed to EFSA, however the report does not meet all the requirements in Annex IV to Directive 2003/99/EC; the report has not been submitted to the Authority nor made publicly available as required by Article 9(1) of the same directive.

5.5 Antimicrobial resistance

Legal Requirements

Annex II to Directive 2003/99/EC lays down the requirements for monitoring of antimicrobial resistance pursuant to Article 7 of the same Directive. Annex II (B) states that Member States must ensure that the monitoring system provides relevant information at least with regard to a representative number of isolates of *Salmonella* spp., *Campylobacter jejuni* and *Campylobacter coli* from cattle, pigs and poultry and food of animal origin derived from those species.

Findings

Regulation (IS) 1048/2011 implements the relevant provisions concerning monitoring and reporting on antimicrobial resistance. Specific provisions are stipulated further in Regulation (IS) 714/2012. According to information provided by MAST, antimicrobial resistance monitoring in zoonotic agents is carried out for *Salmonella*. However, antimicrobial resistance monitoring is done on human *Campylobacter* spp. samples only but the intention to monitor antimicrobial resistance for *Campylobacter* spp. in the relevant animal species and products was stated by MAST.

Conclusions

The monitoring of antimicrobial resistance in Iceland does not meet the requirements in Annex II (B) to Directive 2003/99/EC as regards *Campylobacter jejuni* and *Campylobacter coli* from cattle, pigs and poultry and food of animal origin derived from those species.

5.6 Food-borne zoonoses in humans

Legal Requirements

Article 8 of Directive 2003/99/EC outlines the rules for the competent authority's epidemiological investigation of foodborne outbreaks. Paragraph 4 of the same article makes reference to paragraphs 1 and 2 of this article stating that both paragraphs shall apply without prejudice to EEA provisions on product safety, early warning and response systems for the prevention and control of communicable human diseases, food hygiene and the general requirements of food law, in particular those concerning emergency measures and procedures for withdrawing food and feed from the market.

Article 50 of Regulation (EC) No 178/2002 establishes a rapid alert system network for the notification of a direct or indirect risk to human health deriving from food and feed (RASSF). Pursuant to Article 50(2) of the Regulation, where a Member State has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall immediately be notified to the network. Regulation (EC) No 178/2002 entered into force under the EEA Agreement on 1 May 2010, and has been applicable to Iceland from this date.

Findings

According to information provided by MAST in its reply to the pre-mission document of the Authority and in conformity with Article 11 in the Act on Health Security and Communicable diseases No. 1997/19, LCAs, veterinarians and MAST shall inform the Chief Epidemiologist immediately if they become aware of a risk of food poisoning outbreaks in consumers. The Chief Epidemiologist has the same obligation to these authorities. The Chief Epidemiologist and MAST provide necessary information, advice and supervise the LCAs.

The Chief Epidemiologist is responsible for surveillance of notifiable diseases and diseases subject to registration according to Article 3 in the Act on Health Security and Communicable diseases No. 1997/19. Outbreaks are often first detected or suspected at laboratory level and reported to the Chief Epidemiologist who is responsible for the epidemiological investigation. The Chief Physicians can take care of the epidemiological investigation in their area. The Chief Epidemiologist supervises the Chief Physicians and assists when needed. The Chief Epidemiologist is responsible for the coordination if the human outbreak involves more than one area.

According to the reply to the pre-mission questionnaire, outbreaks can also be reported, by the public, to the Chief Epidemiologist, MAST or the LCAs. MAST or the LCAs can, in selected cases, do the epidemiological investigation after consultation with the Chief Epidemiologist and if the outbreak meets the following description: the outbreak is reported to MAST or LCA, is limited to five-ten persons, is confined to a limited area (not widely spread) and no serious pathogen has been detected. Nevertheless, during the initial meeting representatives of MAST stated that the definition of serious pathogen was still unclear.

A foodborne outbreak occurred in Iceland in September 2011 (i.e. prior to the entry into force for Iceland of the EEA legislation on zoonoses). The outbreak affected eight persons and was caused by a strain of *Salmonella* with significance impact on human health (*S. Enteritidis*). The origin of the outbreak was correlated with the consumption of duck breasts illegally imported from an EU Member State. The Chief Epidemiologist representative explained to the mission team that, due to reasons of confidentiality, MAST was not involved at the beginning of the epidemiological enquiries (including collection of

supposed contaminated food of animal origin and its submission to the relevant laboratory) which was carried out by personnel of the Chief Epidemiologist.

MAST was responsible for the RASFF notification concerning the identification of *S. Enteritidis* in duck breasts. The notification was sent three weeks after the isolation of the zoonotic agent in the foodstuffs concerned.

Conclusions

Information relating to the existence of a serious direct or indirect risk to human health deriving from food was not immediately notified under the rapid alert system as required by Article 50(2) of Regulation (EC) No 178/2002.

5.7 *Salmonella* national control programmes

Legal Requirements

General

Article 5 of Regulation (EC) No 2160/2003 lays down the requirements concerning the national control programmes. Article 5(7) states that Member States shall submit their national control programmes to the Authority and Article 6 details the procedures concerning the approval of their national control programmes by the Authority.

Point 1.6 of Part A (d) of Annex II to Regulation (EC) No 2160/2003 specifies that official controls (including sampling schemes) should be carried out at feed, flock and/or herd level.

Sampling protocol requirements for broilers are laid down at point 2 of the Annex to Regulation (EC) No 646/2007. The competent authority shall supervise education of the food business operators to guarantee the correct application of the sampling protocol.

For laying hens

Regulation (EC) No 2160/2003 and Regulation (EU) No 517/2011 lay down rules for the *Salmonella* national control programme in the laying hens' population of the Member States. Point 2.2 of the Annex to Regulation (EU) No 517/2011 requires the competent authority or the food business operator to ensure that sampling is carried out by trained persons. Point 2.2.2 of the same Annex requires that, in addition to sampling carried out by the food business operator, the competent authority shall take at least one additional sample.

Findings

The *Salmonella* control programmes are publicly available on the MAST website, however, it has not been submitted to the Authority for approval.

Information on the *Salmonella* control programme in pigs has been given in chapter 5.1.

MAST informed that feed is not yet part of the Icelandic national control programme for *Salmonella.* Very few official samples from feed had been taken in 2012 (one in 2011 and three in 2010 according to information available in the reply to the Authority's pre-mission questionnaire). At the time of the mission the system of sampling feed to check for *Salmonella* was carried out at the feed mills by the private operators themselves as part of their HACCP based own-check systems. At the initial meeting MAST informed that there was a proposal in the Parliament to amend the Act of Feedingstuffs regarding these own-check samples to ensure clearer obligations for food and feed business operators to notify the *Salmonella* positive samples to MAST.

The sampling schemes implemented in Iceland and observed by the mission team on the spot were adapted from the relevant EEA regulations. Sampling materials are not provided by MAST but acquired directly by the food business operator.

A form designed by MAST to be filled in when sampling at farm level was available, however, the use of alternative forms is allowed as well. The same form may be used both by MAST and the food business operator. The mission team noted that the name of the person performing the sampling is not clearly requested in the form.

The handling of samples that are identified as not in conformity by the laboratory differed between the laboratories visited. In one of the three laboratories visited by the mission team, the samples were nevertheless analyzed and MAST would contact the operator and give instructions on how to take samples properly. In another laboratory the samples were rejected by the laboratory and not registered and a laboratory employee would contact the operator to ask for new samples.

In June 2012 a letter was sent by MAST to district veterinarians pointing out the importance of taking samples according to the legal requirements.

No training is provided by MAST to food business operators at primary level on how to take correct samples; MAST informed the mission team that a practical demonstration was given on occasion of official sampling by the official veterinarian. Nevertheless, detailed instructions were publicly available on MAST's website and they were also provided by MAST to the farmers.

During the visit to the poultry slaughterhouse the mission team noted that the quality manager also responsible for breeding flocks was aware of the sampling scheme to be applied at farm level. All flocks are sampled for *Salmonella* prior to slaughter.

During the visit to the laying hens farm, the mission team noted that both own-checks samples and official samples had been taken regularly and in line with the national control programme; however, the mission team was informed by the representative of MAST that no additional sample for laying hens was collected by the competent authorities and that the interpretation of the relevant legislation was unclear. The farmer had the instructions on how to take samples available and a document provided by MAST stating the sampling frequency.

Conclusions

The control programmes implemented in Iceland in relation to *Salmonella* in poultry are in line with the requirements laid down in the EEA legislation and only minor remarks have been pointed out by the mission team.

Iceland has not submitted to the Authority its national control programme as required by Article 5(7) of Regulation (EC) No 2160/2003.

Official control on feed is not implemented as required by point 1.6 of Part A (d) of Annex II to Regulation (EC) No 2160/2003.

The supervision by the competent authority of the education of food business operators to guarantee the correct application of the sampling protocol is not fully in compliance with point 2 of the Annex to Regulation (EC) No 646/2007.

The competent authorities or the food business operators did not ensure that samples are taken by trained persons as required by point 2.2 of the Annex to Regulation (EU) No 517/2011.

No additional sample for laying hens had been collected by the competent authorities as required by point 2.2.2 of the Annex to Regulation (EU) No 517/2011.

5.8 Control measures taken in the event of groups of animals infected with *Salmonella*

Legal Requirements
According to Article 5(3) (c) of Regulation (EC) No 2160/2003, national control programmes shall specify the control measures to be taken following the detection of zoonoses and zoonotic agents, in particular to protect public health, including implementation of the specific measures laid down in Annex II to that Regulation.

Findings
The Icelandic *Salmonella* control programmes in poultry do not distinguish between *Salmonella* with or without significance impact on human health; all the *Salmonella* serovars are considered as relevant and sanitary measures are taken irrespective of the type of *Salmonella* detected. This was confirmed in the meetings between the competent authorities and the mission team and also with the food business operator.

The mission team was informed that in case of suspicion of *Salmonella* in samples taken at farm level measures are taken at the holding in order to avoid spreading the infection. The suspicion is considered confirmed after the serotyping. Additional samples are then taken at the farm and only in case of a second positive sample is the flock of broilers considered infected. At that stage stamping out is applied in addition to other sanitary measures concerning equipments, house and litter. In case of first sampling positive and second sampling negative a third confirmatory sampling at farm level, performed in this case by MAST, is carried out and the results of this third sampling are considered as definitive.

Whenever a negative flock enters the slaughterhouse but neck skin samples taken at this level are *Salmonella* positive, MAST is immediately informed by the laboratory, meat products are withdrawn from the market and the press is informed as well.

The laying hens' farm visited by the mission team had experienced a *Salmonella* positive finding. MAST had applied stringent sanitary control measures since the notification of the suspicion and had conducted an epidemiological investigation in order to identify the source of the infection.

Conclusions
The control measures to be taken following the detection of *Salmonella* in poultry flocks in Iceland are even stricter than those laid down in Article 5(3) (c) of Regulation (EC) No 2160/2003 and Annex II to that Regulation.

5.9 Food and feed safety

Legal Requirements

Article 3 of Regulation (EC) No 882/2004 requires Member States to carry out regularly, on a risk basis and with appropriate frequency, controls on feed and food businesses.

Article 5 of Regulation (EC) No 852/2004 requires food business operators to put in place implement and maintain a permanent procedure or procedures based on the hazard analysis and critical control points (HACCP) principles. Annex II to the same Regulation lays down the general hygiene provisions for all food business operators.

Article 6(2) of Regulation (EC) No 852/2004 requires all food business operators to notify their activity to the competent authority with a view to be registered.

Article 4(2) of Regulation (EC) No 853/2004 requires food business operators handling food of animal origin to be approved by the competent authority.

Chapter II of Regulation (EC) No 854/2004 contains provisions on the official controls in relation to EEA establishments. Article 3 of the Regulation concerns the approval of establishments and Article 4 specifies that the competent authority shall carry out official controls in respect of products of animal origin to verify food business operators' compliance with the requirements of *inter alia* Regulations (EC) No 852/2004 and 853/2004.

According to Article 18 of Regulation (EC) No 178/2002 the food business operators shall have in place systems and procedures to identify from whom they have been supplied and the other businesses to which their products have been supplied. Article 4(6) of Regulation (EC) No 854/2004 requires the competent authority to verify compliance with traceability requirements.

Findings[2]

The mission team visited a feed mill. The facility had two production lines and produced feed for fish, horses and dogs (line 1) and dairy cattle, poultry and pigs (line 2). The feed was produced in a continuous flow including a heat treatment over 80˚C for a time between 10 and 15 seconds. The mission team confirmed that a own sampling plan for *Salmonella* was in place for imported feedstuffs and final products and that samples were taken by the establishment's staff as part of the own-checks (no official samples had been taken at all). In addition, the suppliers of raw material had to provide negative *Salmonella* laboratory certificates.

The senior officer of MAST responsible for feed surveillance had performed audits of the HACCP, last time in May 2012. The audit report was issued pointing out several non-compliances detected, in particular as regards written procedures in the existing Quality Manual System. In the report a date was mentioned (1 August 2012). According to the MAST official this was the dead-line for the feed business operator to address the non-compliances. However, the feed mill had not understood this date as a deadline and consequently the non-compliances had not been corrected. During the visit to the facilities the mission team noted unclear separation between dirty and clean working clothes in the changing facilities. A computerised system was used to survey the process, however, it

[2] *See Annex 5 for LCA Reykjavík comments on paragraphs 9, 10, 12 and 13.*

was noted that there was not a built-in alarm system in case the temperature went under the required 80˚C.

The mission team visited the kitchen of a hospital preparing meals for around 600 patients. From the risk categorisation used by the LCA responsible for the official control of this establishment, it was considered as a high risk category and therefore should have been visited twice a year. The last inspection report was however dated December 2011 and no inspections had so far been carried out in 2012. The LCA representative explained that the inspector in charge left the LCA and that a new inspector was on training at the time of the mission. No major remarks were identified in the reports of the inspections carried out by the LCA in December 2011, March 2011 and October 2010. Because of the absence of serious shortcomings the LCA explained to the mission team that the establishment was not obliged to provide the LCA with information on the corrective actions implemented by the management of the establishments. The non-conformities were identified as minor and were to be checked during future inspections in the establishment.

A HACCP plan was available but biological hazards were not identified. Three critical control points were defined (incoming materials, heat treatment and outgoing food with specific composition). Internal provisions excluded the use of several products such as unpasteurised milk products (even though unpasteurised milk and milk products are not for sale in Iceland), smoked fish etc. No sampling of products had been done by the LCA nor by the food business operator but the management took environmental samples to verify cleaning procedures four times/year using a rapid kit.

During the visit to the facilities several shortcomings were identified by the mission team:

- In a freezer, products were checked and showed a temperature above minus 18˚C (the explanation from the management was that those products were taken out the freezer at room temperature for a period of time and then, when not used, placed back in the freezer);
- In a chiller room several products were placed for thawing. The mission team noted the following shortcomings relating to the labelling: products with expired use by date; products for which the labelling indicated storage temperature between 0˚-4˚C (i.e. not to be frozen); labels of frozen products without mentioning “to be kept frozen”, unlabelled packed products and incomplete labelling with regard to traceability;
- Poor housekeeping was observed where the placing of fridges and freezers made adequate cleaning impossible;
- Accumulation of dust in structures (including electric cables) above areas used for preparation of food, allowing contamination of prepared meals;
- Wooden utensils were found in use;
- Inadequate protection of neon bulbs above the food preparation chain was noted;
- Unidentifiable products was detected in the cold store without any labelling; the representative of the kitchen explained that the products had been frozen by them;
- Several units of expired lamb fat in the cold store were also found.

Limited immediate actions on-the-spot were taken: they included the removal of wooden utensils and part of the non-complaint food found in the chiller.

After the visit to the hospital kitchen the mission team, in agreement with the LCA, decided to carry on an unannounced visit to the establishment supplying the above mentioned kitchen with fishery products with unsatisfactory labelling. The establishment

was visited together with the LCA representatives. The establishments had not been registered, nor approved although the LCA was aware of its operation as a distributor of frozen fish products. The LCA had on two earlier occasions inspected the establishment, visiting the cold store of the company which at that time was a stand alone freezer container stationed on the parkinglot. The mission team noted that the establishment was equipped to process fishery products in addition to storing such products. During the preparation of this report, MAST notified to the Authority that:

1. an inspector of MAST inspected the premises of the food business operator on the morning of 14 September 2012;
2. the company was operating without an approval and consequently breaching the Act on Foodstuffs;
3. as a result MAST decided to prohibit the production and distribution of foodstuffs from the establishment.

Conclusions

The Icelandic competent authorities carried out official controls on a risk basis, in accordance with Article 3 of Regulation (EC) No 882/2004. However, serious infringements of the general hygiene provisions laid down in Annex II to Regulation (EC) No 852/2004 were observed by the mission team during the visit to the hospital kitchen.

Serious shortcomings related to the approval of a food business operator and the official controls of such establishment were found. This is not in line with the requirements in Article 6(2) of Regulation (EC) No 852/2004, Article 4(2) of Regulation (EC) No 853/2004 and Articles 3 and 4 of Regulation (EC) No 854/2004.

Traceability systems and procedures were not always in place to identify from whom certain products have been supplied, as required by Article 18 of Regulation (EC) No 178/2002. Furthermore, compliance with traceability requirements had not been verified by the competent authority in line with Article 4(6) of Regulation (EC) No 854/2004.

6 Final meeting

The final meeting was held on Friday 14 September 2012 at MAST's offices in Reykjavik with representatives from MAST, a representative of the Ministry of Industries and Innovation, a representative of the Local Municipal Environmental Health and Protection Office (LCA) visited and a representative of the Chief Epidemiologist.

At this meeting, the mission team presented its main findings and some preliminary conclusions of the mission. At the meeting the mission team also explained that, based on a more detailed assessment of the information received during the mission, additional conclusions and recommendations could be included in the report.

MAST did not have any objections to the observations made and the preliminary conclusions presented. In particular, MAST informed the mission team that corrective actions taken with regards to the serious shortcomings identified during the visit to the non-approved establishment providing foodstuffs to the hospital kitchen would follow as soon as possible. The Authority received the announced information immediately after returning to the office (see chapter 5.9).

7 Recommendations

Iceland should inform the Authority in its reply to the draft report, by way of written evidence, of the corrective actions taken and a plan for corrective measures and actions, including a timetable for completion of measures still outstanding, relevant to all the recommendations hereunder. This information will be annexed to the final report. The Authority should also be kept informed of the completion of the measures included in the timetable.

No	Recommendation
Competent Authorities	
1	Iceland should ensure compliance with Articles 4(2) (c) and 4(3) of Regulation (EC) No 882/2004 regarding official controls, control duties and harmonisation of supervision concerning the different authorities in charge of official controls.
2	Iceland should ensure that efficient and effective coordination and cooperation between the different competent authorities dealing with food borne outbreaks is assured in accordance with Article 4(3) of Regulation (EC) No 882/2004.
3	Iceland should ensure that appropriate enforcement measures in cases of non-compliance as detailed in Article 54 of Regulation (EC) No 882/2004 are taken.
Laboratory services	
4	Iceland should ensure that NRLs are designated in compliance with the provisions laid down in Article 33(2) of Regulation (EC) No 882/2004, Article 10 of Directive 2003/99/EC, Article 11 of Regulation (EC) No 2160/2003, and Article 3 and Annex II of Decision 2004/564/EC.
5	The Icelandic competent authorities should ensure that the analytical method used in Iceland to detect *Salmonella* in animal faeces and environmental samples from the primary production stage is in compliance with Amendment 1 of ENI/ISO 6579-2002/Amd 1:2007 as laid down in Annex 3.2 to Commission Regulations (EU) No 200/2010, Commission Regulation (EU) No 517/2011, Commission Regulation (EC) No 213/2009; Commission Regulation (EC) No 584/2008 and Commission Regulation (EC) No 646/2007.
Monitoring of zoonosis and zoonotic agents	
6	The Icelandic competent authorities should ensure that the report on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance is drawn up in accordance with Article 9(1) and Annex IV to Directive 2003/99/EC and is submitted to the Authority and made publicly available as required by Article 9(1).
Antimicrobial resistance	
7	The Icelandic competent authorities should ensure that the monitoring of antimicrobial resistance in Iceland covers *Campylobacter jejuni* and *Campylobacter coli* as required by Annex II (B) to Directive 2003/99/EC.
Food-borne zoonoses in humans	
8	The Icelandic competent authorities should ensure that information relating to the existence of a serious direct or indirect risk to human health deriving from food is immediately notified under the rapid alert system as required by Article 50(2) of Regulation (EC) No 178/2002.
Salmonella national control programmes	

9	The Icelandic competent authorities should submit to the Authority the national control programmes for *Salmonella* as required by Article 5(7) of Regulation (EC) No 2160/2003.
10	The Icelandic competent authorities should implement official control of *Salmonella* in feed as required by point 1.6 of Part A (d) of the Annex Regulation (EC) No 2160/2003.
11	The Icelandic competent authorities should supervise education of food business operators to guarantee the correct application of the sampling protocol in compliance with Annex, 2 to Regulation (EC) No 646/2007; they should also ensure that samples are taken by trained persons in compliance with point 2.2. of the Annex to Regulation (EU) No 517/2011.
12	The Icelandic competent authorities ensure that an additional sample for laying hens is collected as required by point 2.2.2 of the Annex to Regulation (EU) No 517/2011.
Food and feed safety issues	
13	The Icelandic competent authorities should ensure that food business operators comply with the general hygiene provisions as laid down in Annex II to Regulation (EC) No 852/2004.
14	The Icelandic competent authorities should ensure that registration and approval of food business operators and its official controls of such establishments are in line with the requirements laid down in Article 6(2) of Regulation (EC) No 852/2004, Article 4(2) of Regulation (EC) No 853/2004 and Articles 3 and 4 of Regulation (EC) No 854/2004.
15	The Icelandic competent authorities should ensure that food business operators have traceability systems and procedures in place to identify from whom certain products have been supplied, as required by Article 18 of Regulation (EC) No 178/2002. Furthermore, the competent authorities should verify compliance with traceability requirements as required by Article 4(6) of Regulation (EC) No 854/2004.

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

Authority	EFTA Surveillance Authority
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EFSA	European Food Safety Agency
HACCP	Hazards Analysis Critical Control Points
ISO	International Organization for Standardization
LCA	Local Municipal Environmental Health and Protection Office
MAST	*Matvælastofnun* (The Icelandic Food and Veterinary Authority)
RASFF	Rapid Alert System for Food and Feed The Rapid Alert System for Food and Feed (RASFF) was put in place to provide food and feed control authorities with an effective tool to exchange information about measures taken responding to serious risks detected in relation to food or feed. This exchange of information helps Member States to act more rapidly and in a coordinated manner in response to a health threat caused by food or feed.

Annex 2 - Other relevant legislation

The following EEA legislation was also 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 corrected, and amended ;

b) The Act referred to at Point 1.1.12 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption*, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I thereto;

c) the Act referred to at Point 1.2.74 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 98/139/EC laying down certain detailed rules concerning on-the-spot checks in the veterinary field*;

d) The Act referred to at Point 6.1.16 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;

e) The Act referred to at Point 6.1.17 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin*, as corrected and amended;

f) The Act referred to at Point 7.1.8a of Chapter I of Annex I to the EEA Agreement, *Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC*, as amended;

g) The Act referred to at Point 7.1.8b of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents*, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I thereto;

h) The Act referred to at Point 7.1.18 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 adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I thereto;

i) The Act referred to at Point 7.2.23 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2004/564/EC of 20 July 2004 concerning Community reference laboratories for the epidemiology of zoonoses and for salmonella and national reference laboratories for salmonella*;

j) The Act referred to at Point 7.2.47 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 646/2007 of 12 June 2007 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Community target for the reduction of the prevalence of Salmonella Enteritidis and Salmonella Typhimurium in broilers* and repealing Regulation (EC) No 1091/2005, as amended;

k) The Act referred to at Point 7.2.51 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 584/2008 of 20 June 2008 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Community target for the reduction of the prevalence of Salmonella Enteritidis and Salmonella Typhimurium in turkeys*;

l) Act referred to at Point 7.2.52 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 199/2009 of 13 March 2009 laying down a transitional measure derogating from Regulation (EC) No 2160/2003 of the European Parliament and of the Council, as regards direct supply of small quantities of fresh meat derived from flocks of broilers and turkeys;*

m) The Act referred to at Point 7.2.53 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EU) No 200/2010 of 10 March 2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of Salmonella serotypes in adult breeding flocks of Gallus gallus*, as amended;

n) The Act referred to at Point 7.2.55 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EU) No 517/2011 of 25 May 2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of certain Salmonella serotypes in laying hens of Gallus gallus and amending Regulation (EC) No 2160/2003 and Commission Regulation (EU) No 200/2010*.

Annex 3 – Information on production and trade[3]

	Slaughtering in tons (rounded)		
	2009	**2010**	**2011**
Pigs	6,375	6,158	6,044
Poultry	7,146	6,905	7,241
Bovines	3,761	3,895	3,858
Sheep	8,841	9,166	9,587
Equidae	1,018	799	878
Goats	0	0	0

Trade with EU Member States 2010-2011. Countries of destination (tons)

Species	Country	Product	2010	2011
Bovine	Norway	w/ bone	1.067	
Horsemeat	Denmark	undefined	25.960	
	Switzerland	undefined	49.088	44.369
Total horsemeat			**75.048**	**44.369**
Lamb	Belgium	processed, >60% meat	99	196
	Denmark	boneless	28.933	20.101
		processed, >60% meat	364	
		w/ bone	10.319	12.231
	England	boneless	130.717	144.625
		w/ bone	807.915	252.344
	Finland	processed, >60% meat	39	
		w/ bone	8.183	
	France	boneless	525	483
	Germany	boneless	129	183
		processed, >60% meat	67	46
		w/ bone	3.757	45.157
	Holland	boneless	31.645	9.801
		w/ bone	312.574	324.437
	Ireland	w/ bone		13.300
	Italy	boneless	23	
		w/ bone	37.061	92.903
	Latvia	w/ bone		3.851
	Norway	boneless	28	46
		processed, >60% meat	111	149
		w/ bone	600.440	619.639
	Spain	boneless	3.125	
		w/ bone	566.163	95.767
	Sweden	boneless	3.533	2.364
		processed, >60% meat	165	48
		w/ bone	108.466	38.262
	Switzerland	boneless	48	326
		w/ bone	28	709
Total lamb			**2.654.457**	**1.676.968**
Other meat	Holland	undefined		22.400
Porcine	Norway	w/ bone	1.100	
Reindeer meat	Denmark	w/ bone	271	
Whale meat	Latvia	boneless	250	
Total meat			**2.732.193**	**1.743.737**

[3] Source: MAST

Annex 4 – Results of the monitoring/control programmes of zoonotic agents referred to in Annex I of Directive 2003/99/EC - years 2009, 2010 and 2011[4]

2009	No Flocks No samples	No Farms	No Pos Flocks No Pos samples	No of Pos Farms	Prevalence	Source of Infection*
Salmonella						
Swine, faecal		17		3	17,6%	Feed/farm
Pigs, swabs	3.472		389		11,2%	Farm
Pigs, meat juice	1.641		204		12,4%	Farm
Broiler, flocks	599		5		0,8%	Farm/feed
Broiler, batch	702		1		0,1%	Farm
Turkeys, flocks	24		1		4,2%	Feed
Turkeys, batch	43		0		0%	
Ducks, flocks	14		0		0%	
Ducks, batch	12		0		0%	
Breeder flocks	306		0		0%	
Breeding flocks, turkeys	10		0		0%	
Laying hens	6		0		0%	
Cattle		1		1		
Campylobacter						
Broiler, flocks	625		26		4,2%	Environment
Broiler, batch	702		53		7,5%	Farm
Turkeys, flocks	24		2		8,3%	Environment
Turkeys, batch	44		7		15,9%	Farm
Ducks, flocks	14		14		100%	Environment
Ducks, batch	12		12		100%	Farm
Listeria						
Sheep						
EHEC						
Cattle						
Trichinella						
Swine						
Horses						
Brucella						
Sheep						
Cattle		15		0	0%	
M. bovis						
Cattle						
Echinococcus						
Pet anim. Q***	125		0			
Salmonella						
	No Industrial samples	**No Pos**	**Prevalence**	**No Official samples**	**No Pos**	**Prevalence**
Feed	467	6	1,3%	13	0	0%
Fishmeal**	424	2	0,5%			

[4] Source: MAST

2010	No Flocks No samples	No Farms	No Pos Flocks No Pos samples	No of Pos Farms	Prevalence	Source of Infection*
Salmonella						
Swine, faecal		16		9	56,2%	Farm/feed
Pigs, swabs	3.301		89		2,7%	Farm
Pigs, meat juice	1.233		288		23,4%	
Broiler, flocks	620		32		5,2%	Feed/farm
Broiler, batch	668		24		3,6%	Farm
Turkeys, flocks	38		1		2,6%	Farm/feed
Turkeys, batch	57		0		0%	
Ducks, flocks	14		0		0%	
Ducks, batch	14		0		0%	
Breeding flocks – meat production	372		0		0%	
Breeding flocks – laying hens	23		0		0%	
Breeding flocks - turkeys	16		0		0%	
Laying hens	20		1		5%	?
Cattle		169		0	0%	
Campylobacter						
Broiler, flocks	586		41		7%	Environment
Broiler, batch	668		88		13,2%	Farm
Turkeys, flocks	28		3		10,7%	Environment
Turkeys, batch	59		14		23,7%	Farm
Ducks, flocks	15		14		93,3%	Environment
Ducks, batch	14		14		100%	Farm
Listeria						
Sheep						
EHEC						
Cattle		169		0	0%	
Trichinella						
Swine						
Horses						
Brucella						
Sheep		19		0	%	
Cattle		18		0	%	
M. bovis						
Cattle						
Echinococcus						
Pet anim. Q***	145		0			
Salmonella						
	No Industrial samples	**No Pos**	**Prevalence**	**No Official samples**	**No Pos**	**Prevalence**
Feed	427	9	2,1%	3	0	0%
Fishmeal	547	1	0,2%			

2011	No Flocks No samples	No Farms	No Pos Flocks No Pos samples	No of Pos Farms	Pre-valence	Source of Infection*
Salmonella						
Swine, faecal		16		6	37,5%	Farm
Pigs, swabs	2.522		32		1,3%	Farm
Pigs, meat juice	1.437		243		16,9%	Farm
Broilers, flocks	637		14		2,2%	Farm
Broilers, batch	695		8		1,2%	Farm
Turkeys, flocks	22		0		0%	
Turkeys, batch	63		0		0%	
Ducks, flocks	27		0		0%	
Ducks, batch	1		24		4,2%	Farm
Breeding flocks – meat production	395		1		0,2%	Farm
Breeding flocks – laying hens	25		0		0%	
Breeding flocks - turkeys	19		0		0%	
Laying hens	27		1		3,7%	Farm/feed
Cattle						
Campylobacter						
Broilers, flocks	631		32		5,1%	Environment
Broilers, batch	695		60		8,6%	Farm
Turkeys, flocks	22		0		0%	Environment
Turkeys, batch	62		1		1,6%	Farm
Ducks, flocks	25		24		96%	Environment
Ducks, batch	25		25		100%	Farm
Listeria						
Sheep						
EHEC						
Cattle						
Trichinella						
Swine						
Horses						
Brucella						
Sheep						
Cattle		16		0	0%	
M. bovis						
Cattle						
Echinococcus						
Pet anim. Q***	151		0			
Salmonella						
	No Industrial samples	**No Pos**	**Prevalence**	**No Official samples**	**No Pos**	**Prevalence**
Feed	359	7	1,9%	1	1	100%
Fishmeal	609	2	0,3%			

* Most likely.
** Jun – Dec 2009.
*** Q =Quarantine.

Annex 5 Reply from competent authorities to the draft report

ESA mission on zoonotic agents in 2012				
No	**Recommendations**	**Reaction of the Competent Authority**	**Date of compliance**	**Comment / attachment**
Competent Authorities				
1	Iceland should ensure compliance with Articles 4(2) (c) and 4(3) of Regulation (EC) No 882/2004 regarding official controls, control duties and harmonisation of supervision concerning the different authorities in charge of official controls.	MAST will in 2013 write an inspection manual in cooperation with the LCAs. Risk classification system similar to the system MAST has implemented to determine the frequency of inspection will be implemented by the LCAs latest 1 of January 2014. The inspection manual should be finalised 2013. The overall aim is to ensure harmonisation between the LCAs. The need for further guidelines will be analysed when the inspection manual has been finalised. MAST is planning audits of the LCA in 2013.	01.09.2013	
2	Iceland should ensure that efficient and effective coordination and cooperation between the different competent authorities dealing with food borne outbreaks is assured in accordance with Article 4(3) of Regulation (EC) No 882/2004.	MAST, in cooperation with the Chief epidemiologist, is working on a revision of the contingency plan. The cooperation and coordination has been discussed between MAST and Chief epidemiologist and it was presented in a joint LCA/MAST meeting in the Food Group on 29 October and in a meeting with the directors of all the LCAs on 31 October 2012. The contingency plan will be finalised in	1.4.2013	

ESA mission on zoonotic agents in 2012				
No	**Recommendations**	**Reaction of the Competent Authority**	**Date of compliance**	**Comment / attachment**
		January 2013 and followed-up with a desktop exercise.		
3	Iceland should ensure that appropriate enforcement measures in cases of non-compliance as detailed in Article 54 of Regulation (EC) No 882/2004 are taken.	Reaction of LCA inspectors in case of non-compliance will be described in the inspection manual. See also recommendation No 1 above. On behalf of the LCA, certain action was taken immediately in the premises, followed-up with an inspection on the spot and a report with request for corrective measures. It has been confirmed that actions were taken by the establishment.	1.9.2013 Completed	
Laboratory services				
4	Iceland should ensure that NRLs are designated in compliance with the provisions laid down in Article 33(2) of Regulation (EC) No 882/2004, Article 10 of Directive 2003/99/EC, Article 11 of Regulation (EC) No 2160/2003, and Article 3 and Annex II of Decision 2004/564/EC.	ANR (the Ministry of Industries and Innovation) and MAST have held meetings with two laboratories, Keldur and Matis regarding designation of NRLs, not only for zoonoses but NRLs in general. The last meeting was on November 5 and hopefully ANR and the laboratories will have a draft agreement for NRL services before the end of this year. ANR will work to designate NRLs and notify EFTA of the designation before the end of the first quarter of	1.4.2013	

ESA mission on zoonotic agents in 2012				
No	**Recommendations**	**Reaction of the Competent Authority**	**Date of compliance**	**Comment / attachment**
		2013.		
5	The Icelandic competent authorities should ensure that the analytical method used in Iceland to detect *Salmonella* in animal faeces and environmental samples from the primary production stage is in compliance with Amendment 1 of ENI/ISO 6579-2002/Amd 1:2007 as laid down in Annex 3.2 to Commission Regulations (EU) No 200/2010, Commission Regulation (EU) No 517/2011, Commission Regulation (EC) No 213/2009, Commission Regulation (EC) No 584/2008 and Commission Regulation (EC) No 646/2007.	Following the mission, MAST contacted the laboratories involved and requested that they change their method for analyzing salmonella in faeces and environmental samples to comply with ENI/ISO 6579-2002/Amd.1:2007 including the use of MSRV medium. The laboratories responded positively and are expected to be in compliance in early 2013.	1.1.2013	Email to labs.doc
Monitoring of zoonosis and zoonotic agents				
6	The Icelandic competent authorities should ensure that the report on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance is drawn up in accordance with Article 9(1) and Annex IV to Directive 2003/99/EC and is submitted to the Authority and made publicly available as required by Article 9(1).	1) A complete report (2012) will be drawn up in accordance with Directive 2003/99 and will be sent to the Authority. 2) The report for 2011 was sent to the Authority on October 24, 2012. 3) The report (2012) will be made available on the MAST website.	1) 31.5.2013 2) Completed. 3) 1.8.2013	
Antimicrobial resistance				
7	The Icelandic competent authorities should ensure that the monitoring of antimicrobial resistance in Iceland covers *Campylobacter jejuni* and *Campylobacter coli* as required by Annex II (B) to Directive 2003/99/EC.	Ongoing	31.12.2013	

ESA mission on zoonotic agents in 2012				
No	**Recommendations**	**Reaction of the Competent Authority**	**Date of compliance**	**Comment / attachment**
Food-borne zoonoses in humans				
8	The Icelandic competent authorities should ensure that information relating to the existence of a serious direct or indirect risk to human health deriving from food is immediately notified under the rapid alert system as required by Article 50(2) of Regulation (EC) No 178/2002.	MAST will take notice of this recommendation		
Salmonella national control programmes				
9	The Icelandic competent authorities should submit to the Authority the national control programmes for *Salmonella* as required by Article 5(7) of Regulation (EC) No 2160/2003.	Ongoing	1.3.2013	
10	The Icelandic competent authorities should implement official control of *Salmonella* in feed as required by point 1.6 of Part A (d) of the Annex Regulation (EC) No 2160/2003.	MAST will in 2013 prepare a control plan for 3-5 years for Salmonella in feed. The plan will include sampling for Salmonella analyses at the critical places in the most important feed business establishments. It will also include sampling for Salmonella in case there is a special risk for Salmonella contamination.		
11	The Icelandic competent authorities should supervise education of food business operators to guarantee the correct application of the sampling protocol in compliance with Annex 2 to Regulation (EC) No 646/2007; they should also ensure that samples are taken by trained	Description of the responsibility of the CA regarding supervision, coordination and training of FBOs will be described in the NCP for salmonella. The NCP also includes a description of correct sampling. It will	1.3.2013 and continuing training.	

ESA mission on zoonotic agents in 2012				
No	**Recommendations**	**Reaction of the Competent Authority**	**Date of compliance**	**Comment / attachment**
	persons in compliance with point 2.2. of the Annex to Regulation (EU) No 517/2011.	be ensured that only trained staff takes samples at farms. A training seminar for official veterinarians is planned in December 2012.	31.12.2012	
12	The Icelandic competent authorities ensure that an additional sample for laying hens is collected as required by point 2.2.2 of the Annex to Regulation (EU) No 517/2011.	Additional sampling requirements will be described in the NCP for Salmonella.	1.3.2013	
Food and feed safety issues				
13	The Icelandic competent authorities should ensure that food business operators comply with the general hygiene provisions as laid down in Annex II to Regulation (EC) No 852/2004.	MAST and the LCA-Rvk have taken notice of the remarks made in the establishments and those remarks will be addressed in the inspection of the establishments concerned as well as in other establishments. In a meeting in the joint LCA/MAST Food Group on 29 October MAST presented the draft report on Zonoosis. The LCAs were encouraged to read the final report in order to learn from the remarks made in some establishments. An Inspection manual will be issued 2013. The need for further guidelines will be analysed. See also recommendation No 1.	1.9.2013	

ESA mission on zoonotic agents in 2012				
No	**Recommendations**	**Reaction of the Competent Authority**	**Date of compliance**	**Comment / attachment**
		MAST is in cooperation with TAIEX organising two HACCP audit workshops for LCA and MAST inspectors. The workshops will be in the beginning of 2013.		
14	The Icelandic competent authorities should ensure that registration and approval of food business operators and its official controls of such establishments are in line with the requirements laid down in Article 6(2) of Regulation (EC) No 852/2004, Article 4(2) of Regulation (EC) No 853/2004 and Articles 3 and 4 of Regulation (EC) No 854/2004.	MAST has collected information on establishments that should be approved. The work is ongoing and the establishments concerned will be inspected and approved when they have fulfilled the requirements of 852/2004 and 852/2004. As written in the draft report page 19, MAST took action against the cold store concerned. The establishment will get approval in week 46 as a cold store and rewrapping establishment.		
15	The Icelandic competent authorities should ensure that food business operators have traceability systems and procedures in place to identify from whom certain products have been supplied, as required by Article 18 of Regulation (EC) No 178/2002. Furthermore, the competent authorities should verify compliance with traceability requirements as required by Article 4(6) of Regulation (EC) No 854/2004.	A joint LCA/MAST control project on traceability is ongoing for 2012. The LCAs have, in several e-mails, been encouraged to participate. Description of the project is in attachment. A report will be issued.	1.3.2013	Rekjanleiki og innköllun_lokaútgáfa :

General comments by LCA RVK (LCA) about the draft report by ESA relating to the monitoring and control of zoonotic agents in Iceland, 10-14 September 2012. LCA emphasizes that the following only addresses the monitoring and activities by LCA.

LCA has viewed ESA's monitoring missions with a positive mind and expectation, and deems it as important to receive criticism of LCA's monitoring and thereby as being an opportunity to improve work procedures.

Hence it is important that monitoring is well defined and that all parties to whom such monitoring pertains are well informed and know their roles. This applies not least to food businesses (FBO's) that are visited during control missions. LCA has regarded it as its role to assist ESA in its monitoring in order to facilitate the mission team receiving as clear image as possible of the work procedures and controls by LCA in the relevant area of monitoring and control or of the matters being monitored at any given time. Additionally, LCA has emphasized clarifying matters when a misunderstanding has arisen between the mission team and LCA's FBO under control.

Referring to the comments in the draft report by ESA after visiting a catering establishment (FBO) on 11 September 2012, LCA wishes to state the following:

Referring to ESA's assessment, cf. paragraphs 16 and 20, Section 5.2. and paragraph 12, Section 5.9., that there was an absence of LCA making observations on the spot, LCA emphasizes, as materialized at the last meeting during the mission visit on 14 September last, that LCA was not carrying out food control at the relevant undertaking; instead that it was only represented there to assist ESA and to correct misunderstanding if occurring between ESA and the FBO under control. LCA does not agree with this opinion of ESA because LCA made oral requirements to the FBO's employees for improvements on the spot and recorded observations made during the mission visit. It is pointed out that the nature of requirements and demands for improvements are always made on grounds of gravity and proportionality under the auspices of the Administrative Procedures Act.

The following day the first comments and requirements for improvement were sent, followed by more detailed comments the day after. Additionally, LCA personnel were in telephone contact with the FBO and it materialized, among other things, that improvements had already been launched. The following day LCA went on its regular control visit to the FBO and also continued its inspection of other elements that materialized during the visit, for example, of the origin of food products from producers who are subject to control by other inspection bodies than LCA.

The aforementioned comments and other data, including information on inadequate labeling of food products in the FBO's freezer and were manufactured in an FBO that was licensed to do so, were submitted to ESA at the final meeting.

There is a misunderstanding by ESA, cf. paragraph 10, Section 5.2. and paragraph 9, Section 5.9, regarding the frequency of control not having conformed to LCA's risk assessment of the FBO. The probable reason for this is lack of detail in LCA's submission of information to ESA. According to the risk assessment (coordinated by Environmental and food agency of Iceland, food div./now part of MAST), it is assumed that the frequency of regular control of this company is one visit per year as a minimum. LCA intended, however, to go to the FBO for two food control missions during the year and the schedule will be followed as a minimum.

There is furthermore a misunderstanding by ESA, cf. paragraph 1, Section 5.9, to the effect that the FBO has special rules prohibiting the use of unpasteurized dairy products. According to information from the FBO, ESA's representatives misunderstood when it was explained to them that in Iceland distributing dairy products from unpasteurized milk is prohibited.

Referring to another FBO, cf. paragraph 13 of Section 5.9., which ESA mentions as having been visited after the visit to the catering establishment, it is incorrect that the FBO was not on record. The FBO was registered with LCA; however, its application for an operating license was being processed. This pertains to an FBO that has an office in Reykjavík, i.e. it is a wholesale enterprise trading in fish products. The majority of its activities is export of fish products and their dispatch directly from producers to the buyers. According to Act no. 7 on Environmental and Food Control, the relevant FBO should have an operating license from LCA in respect of the activities' pollution elements; however, it should have an operating license from MAST, not LCA.

During ESA's mission visit to the aforementioned FBO, accompanied by personnel of LCA to assist ESA, it materialized that the FBO had rented facilities whose interior had been arranged without a license from the relevant building authorities, for example, a freezer had been installed, as well as a small production kitchen. It could not be proved that the FBO had produced foodstuffs in the kitchen; however, items from other producers were found which the FBO was unable to sufficiently explain. LCA stopped distribution of said foodstuffs on the spot.

Referring to the work procedures of the ESA mission team, LCA criticizes its approach at the catering establishment. Its employees experienced the visit as if ESA were conducting food control at the FBO as opposed to the visit pertaining to an inspection of LCA's monitoring. The FBO did not object to improvements being required, however, would have seen to other personnel being present during the visit, i.e. personnel who were better equipped to answer ESA's questions had the FBO received information about this practice of inspection beforehand. LCA criticizes ESA for not informing LCA about this arrangement prior to going to this FBO at the detailed and informative meeting held prior

to the visit. LCA agrees with the FBO's impression that ESA was conducting food control at the site.

The inspection was to pertain to monitoring of zoonotic agents in food and sampling among FBO's; hence there existed some anticipation when notification was made that ESA requested to examine these elements in catering establishments (ranging from restaurants to institutional kitchens). LCA therefore viewed the mission visit and its inspection in a positive manner, as sampling for zoonotic agents has not been a focal point in the monitoring of such food enterprises.

In its report ESA does not submit extensive observations about the execution of the monitoring of zoonotic agents at catering establishments and the mission team's questions upon its inspection did not reflect zoonotic agents and sampling of them as being the principal objective of the visit; hence LCA does not see much as being aimed at LCA.

LCA appreciates any justifiable criticism and will strive to change work procedures accordingly where needed.