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# Final report

# EFTA Surveillance Authority's mission to Iceland

# from 10 to 13 September 2018

# in order to

# evaluate the monitoring and reporting of antimicrobial resistance

# in zoonotic and commensal bacteria

# in certain food-producing animal populations and food

*Please note that comments from Iceland to factual errors in the draft report are referred to in footnotes and/or have been included in the body of the report using underlined italic print. Please note that comments and information from the Icelandic competent authority on the corrective actions already taken and planned are included in Annex 4, 5 and 6 to the report.*

***Executive Summary***

*This report describes the outcome of a mission carried out by the EFTA Surveillance Authority in Iceland from 10 to 13 September 2018.*

*The objective of the mission was to evaluate the implementation of the legislation of the European Economic Area (EEA) on harmonised monitoring and reporting of antimicrobial resistance (AMR) in bacteria obtained from certain food and food-producing animal populations, including the specific monitoring and reporting of extended-spectrum β-lactamases (ESBL), AmpC β-lactamases (AmpC) and carbapenemase-producing bacteria. The mission also aimed at gathering information on good practices on AMR monitoring and reporting.*

*Overall, the report concludes that the Icelandic competent authority has developed a framework for the official monitoring of AMR, supported by documented procedures and by well performing official laboratories, that generally follows the EEA requirements. Further improvements are needed to ensure the effective implementation of the AMR monitoring programme, in particular in relation to specific monitoring of ESBL-producing* E. coli*, and representativeness of samples.*

*Some good practices were identified regarding voluntary monitoring that goes beyond EEA requirements.*

*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.*

## Table of contents

# 1 Introduction

The mission took place in Iceland from 10 to 13 September 2018. The mission team comprised two auditors 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 1 June 2018. A reply (the pre-mission document) was provided on 23 August 2018.

The opening meeting was held on 10 September 2018 at the Icelandic Food and Veterinary Authority (MAST) office in Selfoss, with representatives from MAST, MoII, the Municipal Environmental and Public Health Offices (LCAs) and the National Reference Laboratory (NRL) for antimicrobial resistance (AMR). At the meeting, the mission team confirmed the objectives and the itinerary of the mission, and the Icelandic representatives provided additional information to that set out in the pre-mission document.

A representative of MAST accompanied the mission team throughout the mission.

A final meeting was held at MAST's office in Reykjavík on 13 September 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 Scope and objective of the mission

The main objectives of the mission were to:

- evaluate the implementation of the legislation of the European Economic Area (EEA) on harmonised monitoring and reporting of AMR in bacteria obtained from certain food and food-producing animal populations, including the specific monitoring and reporting of extended-spectrum β-lactamases (ESBL), AmpC β-lactamases (AmpC) and carbapenemase-producing bacteria; and,

- gather information on good practices on AMR monitoring and reporting, and on the implementation of voluntary monitoring systems, as well as to identify new initiatives for improving awareness and understanding of AMR in order to mitigate its development.

The main legal requirements, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement, and related EEA legislation, are included in:

a) *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*;

b) *Commission Implementing Decision 2013/652/EU of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria.*

The scope of the mission included national legislation and policies, organisation and performance of competent authorities, the measures in place to implement relevant monitoring requirements, in particular sampling strategy and design, laboratory performance and reporting procedures.

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

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.

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 opening meeting in Selfoss and a closing meeting in Reykjavík between the mission team and the Icelandic competent authority. |
| | 2 | One meeting with two LCAs and one meeting with MAST's Veterinary Officer of Zoonoses. |
| **Slaughterhouses** | 3 | Two poultry slaughterhouses in two different districts and one pig slaughterhouse. |
| **Laboratories** | 2 | NRL for *Campylobacter* and AMR, also performing ESBL selective isolation and Methicillin-resistant *Staphylococcus aureus* (MRSA) monitoring;<br>One official laboratory, also NRL for *Salmonella*. |

## 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 amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement.

Legislation relevant to this mission is listed in Annex 2.

# 4 Background - Previous missions

## 4.1. Background information

Directive 2003/99/EC requires EEA States to ensure that AMR monitoring provides comparable data on the occurrence of AMR in zoonotic agents and other agents presenting a threat to public health. Decision 2013/652/EU lays down detailed rules for the harmonised monitoring and reporting of the most relevant combinations of bacterial species in food-producing animal populations and food from a public health perspective. It also sets out specific requirements for the monitoring and reporting of ESBL-, AmpC- and carbapenemase-producing bacteria. Reliable and comparable data are essential for the evaluation of the trends and sources of AMR across the EEA, for the risk assessment process as well as for the evaluation of any measures put in place to mitigate the development of AMR.

Iceland produces less than 100,000 tonnes of broiler and pig meat slaughtered annually. On that basis, 85 isolates shall be tested for each combination of bacteria in poultry and pig, in accordance with Point 2.2 of part A of the Annex to Decision 2013/652/EU.

Given that the production of turkeys and bovines under 1 year of age is less than 10,000 tonnes slaughtered annually, no caecal samples are required at slaughterhouse from these populations in accordance with Point 1 of Part A of the Annex to Decision 2013/652/EU.

With regard to samples taken for the specific monitoring of ESBL-, or AmpC- or carbapenemase-producing indicator commensal *Escherichia coli* (*E. coli)*, 150 caecal samples should be gathered from broilers and pigs at slaughterhouses, and 150 samples of broiler, pig and bovine fresh meat at retail are required.

## 4.2.Previous missions

The Authority carried out a mission regarding the 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* in Iceland from 10 to 14 September 2012. The final report from this mission can be found on the Authority's website (www.eftasurv.int).

# 5 Findings and conclusions

## 5.1. Legislative and implementing measures

Legal Requirements

Article 3 of the EEA Agreement requires the Contracting Parties to take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Agreement.

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

Findings

1. Regulation (IS) No 1048/2011[1] implementing Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents includes relevant provisions concerning AMR monitoring and reporting. Regulation (IS) No 714/2012[2] sets out detailed rules for AMR monitoring and reporting for the period from 2012 to 2015 and states that MAST may decide to plan AMR monitoring of a certain number of antimicrobials in samples (animals, food, etc.).
2. Commission Implementing Decision 2013/652/EU of 12 November 2013 on the monitoring and reporting of AMR in zoonotic and commensal bacteria was not implemented in the Icelandic legal order at the time of the mission.

Conclusions

3. At the time of the mission, Commission Implementing Decision 2013/652/EU of 12 November 2013 on the monitoring and reporting of AMR in zoonotic and commensal bacteria had not been made part of the Icelandic legal order, contrary to Articles 3 and 7 of the EEA Agreement[3].

## 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 also lays down operational criteria for the competent authorities.

Article 3(2) of Directive 2003/99/EC requires Member States to designate a competent authority or competent authorities for the purposes of that Directive.

[1] https://www.reglugerd.is/reglugerdir/allar/nr/1048-2011
[2] https://www.reglugerd.is/reglugerdir/allar/nr/714-2012
[3] Reference is made to Annex 6 – action plan: Regulation (IS) No 1000/2018, published on 15 November 2018 - https://www.stjornartidindi.is/Advert.aspx?RecordID=e03027d8-2741-47e5-b4c6-4210119c2daf

Article 4(2)(e) of Regulation (EC) No 882/2004 requires the competent authorities to ensure that they have the legal powers to carry out official controls and to take the measures provided for in this Regulation.

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 3(3) of Directive 2003/99/EC requires each Member State 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 authority or authorities designated for the purposes of this Directive and other relevant competent authorities.

Article 6 of Regulation (EC) No 882/2004 sets out general requirements for training of staff from the competent authority.

Article 3(4) of Directive 2003/99/EC requires each Member State to ensure that the relevant officials of the competent authority or competent authorities referred to in paragraph 2 undertake suitable initial and ongoing training in veterinary science, microbiology or epidemiology, as necessary.

Findings

4. Detailed information on the structure and organisation of the competent authorities can be found in the Country Profile for Iceland[4].
5. According to the pre-mission document, MAST is the competent authority for monitoring and reporting of AMR under the auspices of the MoII. According to Article 8 of Regulation (IS) No 1048/2011, MAST is responsible for planning and implementation of the AMR monitoring programme. More specifically, the responsibility for design and coordination of the AMR monitoring programme pertains to the office of animal health and welfare. The programme is developed by the Veterinary Officer of zoonoses, in consultation with the Veterinary Officer of poultry diseases. Both Veterinary Officers are responsible for reporting monitoring data on AMR to the European Food Safety Authority (EFSA). MAST official veterinarians are responsible for taking samples in pig slaughterhouses, and LCAs are responsible for sampling at retail level in accordance with MAST's instructions and under MAST supervision. Most of the isolates are obtained from food business operators' sampling at farm and slaughterhouses.
6. Samples are sent to four laboratories designated for the isolation and identification of the relevant bacteria. Serotyping of *Salmonella* is carried out at the Department of Microbiology at the University Hospital of Iceland. The isolates obtained are tested for antimicrobial susceptibility at the NRL for AMR, which also carries out the specific monitoring of ESBL-producing *E. coli*.
7. The competent authorities have legal powers to take the necessary samples under the AMR monitoring programme. The legal basis for sampling is established in Regulation (IS) No 1048/2011 and Regulation (IS) No 714/2012. Article 22 of Act (IS) No 93/1995[5] states that LCAs, under MAST's supervision, are responsible for official

[4] http://www.eftasurv.int/media/food-safety/27.01.2017-10-13-00_FINAL-Country-Profile-Iceland-version-2017_-PART-1.pdf
[5] https://www.althingi.is/lagas/nuna/1995093.html

controls of distribution of foodstuffs and that MAST shall have access to LCAs' sampling results. There were sufficient staff at MAST, the LCAs and in the laboratories visited to ensure implementation of the AMR monitoring programme.

8. Coordination between MAST, LCAs and laboratories is ensured through email exchanges and distribution of instructions developed by MAST, which include relevant sampling plans. Evidence of this coordination was provided to the mission team. Regular informal communication also took place throughout the year for supervision purposes, to allow the sampling plan to be adapted to fulfil the requirements for sampling.
9. According to the pre-mission document, there is close collaboration between the Health Security and Communicable Disease Control sector at the Directorate of Health, the Icelandic Medicines Agency and MAST. For example, results and information are shared for preparation of the annual reports on AMR and the use of antimicrobial drugs and formal/informal communications and official opinions are shared on antimicrobial drugs without marketing authorisation.
10. MAST monitors the progress in the implementation of the AMR sampling plans by the different competent authorities involved. If issues are detected in relation to obtaining the minimum number of samples taken monthly or the number of samples received by the official laboratories, MAST informally communicates by phone or by email increases in the samples required for the following months under the sampling plan in order to compensate. Nevertheless, the mission team noted that the targeted number of samples of pig and bovine meat from retail outlets was not achieved in 2017. MAST explained that this was due to lack of communication with certain LCAs in the first year of sampling and that measures had been taken for 2018. Furthermore, the mission team noted that MAST was not able to detect weaknesses in the implementation of the sampling plan by LCAs at retail level, where the products' lot numbers were not monitored to avoid repetition of epidemiological units (see section 5.3.2.2).
11. The Veterinary Officer of zoonoses is a member of the EFSA Scientific Network for Zoonoses Monitoring Data and participates in workshops on reporting organised by EFSA and other relevant courses, including Better Training for Safer Food training sessions. However, the mission team noted that officers performing sampling did not receive any specific training on sampling for the purpose of AMR monitoring. This was reflected in weaknesses detected by the mission team in relation to sample sealing, temperature during transportation and randomisation of sampling.
12. MAST annually drafts instructions for collecting samples for *Campylobacter* isolation and for the specific monitoring of ESBL-producing *E. coli*. These contain a detailed explanation of most of the relevant requirements for sampling, the distribution of tasks, and the monitoring programme with the frequency and number of samples to be taken. These often include additional sampling to that required by Decision 2013/652/EU. The national control programmes (NCP) for *Salmonella* and *Campylobacter* in poultry and for *Salmonella* in pigs provide further detailed information, including a monitoring programme for official sampling.
13. MAST has developed templates for the forms accompanying samples taken by the competent authorities to the laboratories. These contain all the necessary information to identify and trace the samples, including the epidemiological unit of origin.

Conclusions

14. The competent authority responsible for the monitoring of AMR is clearly designated in line with Article 4(1) of Regulation (EC) No 882/2004 and Article 3(2) of Directive 2003/99/EC.
15. The competent authorities have the necessary legal powers to develop and implement the harmonised monitoring of AMR in line with Article 4(2)(e) of Regulation (EC) No 882/2004.
16. Coordination and cooperation between MAST, LCAs and laboratories is mostly ensured as required by Article 4(3) of Regulation (EC) No 882/2004 and Article 3(3) of Directive 2003/99/EC, although some weaknesses may negatively affect the implementation of the sampling plan for ESBL-producing bacteria at retail.
17. Official sampling was carried out by staff which had not always been trained for sampling under the monitoring programme, contrary to Article 6 of Regulation (EC) No 882/2004.

## 5.3.Organisation of the official monitoring system

### *5.3.1. National measures*

18. Regulation (IS) No 1048/2011 implementing Directive 2003/99/EC includes the general obligation for food business operators to (i) confirm presence of bacteria subject to monitoring; (ii) to retain analytical results and isolates and make them available to MAST if requested; and (iii) to immediately report positive results to MAST.
19. According to Article 24 of Act (IS) No 93/1995, food businesses operators, LCAs and laboratories are obliged to notify MAST when samples are positive for pathogens subject to notification. Article 5 of Regulation (IS) No 420/2008 on reporting of communicable diseases lists the notifiable diseases and their pathogens, which include *Salmonella* and *Campylobacter*.

### *5.3.2. Sampling design*

Legal Requirements

Article 4 of Directive 2003/99/EC provides general rules on monitoring of zoonoses and zoonotic agents. Article 6 of the same Directive requires that Member States ensure that, when food business operators carry out examinations for the presence of zoonoses and zoonotic agents subject to monitoring under Article 4(2), they keep the results and arrange for the preservation of any relevant isolate for a period to be specified by the competent authority and communicate the results or provide the isolates to the competent authority on request. Article 7 requires Member States to ensure, in accordance with the requirements set out in Annex II, that monitoring provides comparable data on the occurrence of antimicrobial resistance in zoonotic agents and, in so far as they present a threat to public health, other agents.

Article 8(1) of Regulation (EC) No 882/2004 requires that competent authorities carry out official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Article 1 of Decision 2013/652/EU indicates the bacteria obtained from samples from certain food-producing animal populations and certain food, which shall be covered by monitoring and reporting.

Article 2(1) of Decision 2013/652/EU states that Member States shall ensure sampling for the monitoring of AMR in accordance with the technical requirements set out in Part A of the Annex.

Article 2(2) of Decision 2013/652/EU states that Member States shall collect representative isolates of the following bacteria in accordance with the technical requirements set out in Part A of the Annex: *Salmonella* spp., *Campylobacter jejuni (C. jejuni)*, Indicator commensal *E. coli*, and ESBL- or AmpC- or carbapenemase-producing *Salmonella* spp. and *E. coli*.

Article 3 of Decision 2013/652/EU states that where, due to a low bacterial prevalence or a low number of epidemiological units in a Member State, the minimum number of *Salmonella* spp. isolates collected by the competent authority during official controls in accordance with point 1(a) of Part A of the Annex is not sufficient to achieve the minimal required number of isolates to be tested for antimicrobial susceptibility, the competent authority may use isolates obtained by food business operators provided that such isolates have been obtained by the food businesses operator in accordance with the following provisions: (a) the national control programme provided for in Article 5 of Regulation (EC) No 2160/2003; (b) the process hygiene criteria set out in points 2.1.3, 2.1.4 and 2.1.5 of Chapter 2 of Annex I to Regulation (EC) No 2073/2005.

Point 2.3. of Part A of the Annex to Decision 2013/652/EU states that not more than one isolate per bacterial species from the same epidemiological unit per year shall be included in the monitoring provided for this Decision. The epidemiological unit for laying hens, broilers, and fattening turkeys shall be the flock. For fattening pigs and bovines under one year of age, the epidemiological unit shall be the holding.

Findings

5.3.2.1.Sampling framework

20. For 2015 and 2016, the sampling programme did not cover all the bacterial species and food-producing animal populations and food combinations set out in Decision 2013/652/EU. However, the sampling programme of 2017 did cover all required combinations.
21. With regard to the minimum required number of isolates and samples to be tested and reported for the mandatory categories, the situation in recent years was as follows:

    - *Salmonella*: In 2015, 2016 and 2017, all available isolates at farm and in slaughterhouses for pig products and for poultry/ poultry products gathered under the *Salmonella* NCP and in the context of Regulation (EC) No 2073/2005 were tested. According to the pre-mission document, since all samples are included in the AMR monitoring, no stratification or randomisation procedures are implemented.
    - Indicator *E. coli*: In 2015, Iceland did not include such testing in the monitoring programme. In 2016, the minimum number of isolates from poultry was exceeded. In 2017, all available isolates required for pigs at the

end of the monitoring period were included in the Antimicrobial Susceptibility Testing (AST).

- *C. jejuni*: In 2016, all available isolates gathered, including those obtained from food business operators under the *Campylobacter* NCP, were tested for AST. According to the pre-mission document, all samples are included in the AMR monitoring, without stratification or randomisation procedures being implemented.
- ESBL-producing *E. coli*: In 2015, Iceland did not carry out any specific monitoring of these bacteria due to budget constraints. In 2016, the 150 required caecal samples at slaughterhouses was achieved for broilers, but broiler meat was not sampled at retail level. In 2017, the 150 required caecal samples at slaughterhouses was achieved for pigs on the basis that slaughter batches (rather than holdings, in accordance with the definition in Decision 2013/652/EU) were considered as epidemiological units as agreed between Iceland and EFSA. The targeted number of samples of pig and *bovine* meat from retail outlets was not achieved. According to MAST, this was due to lack of communication with certain LCAs in this first year of sampling

5.3.2.2. Representativeness of sampling

***Salmonella* isolates from samples collected at poultry primary production**

22. Under the *Salmonella* NCP, food business operators take samples derived from farms holding laying hens and broilers and for every flock. These samples are sent to *two laboratories*, *of which one is* the NRL for *Salmonella* *and the other is the NRL for AMR*.
23. MAST receives the analytical reports for *Salmonella* from the laboratories and maintains a list of the available isolates. The number of *Salmonella* isolates being below the required 85 for each population, MAST selects all available isolates from the mentioned list, avoiding repeated epidemiological units. It then requests the NRL for *Salmonella* to send the selected isolates to the NRL for AMR to be tested for AST. The mission team was provided with evidence from MAST and the laboratories, which confirmed that all available isolates were subject to AST.
24. For broilers, three *Salmonella* isolates were obtained in 2016 out of 713 samples taken at farm level. According to MAST, the low number of isolates can be explained by the low *Salmonella* prevalence of 0.4% in broiler flocks.

***Salmonella* isolates from carcass samples collected at slaughter**

25. All isolates in this category are obtained exclusively from the sampling activities carried out by food business operators at the broiler slaughterhouses, under the provisions of Regulation (EC) No 2073/2005 and in accordance with guidance provided by MAST. Every broiler flock is sampled and no randomisation is applied. The mission team noted that the competent authorities do not take any samples to verify food business operators' compliance with the process hygiene criteria under Regulation (EC) No 2073/2005.
26. MAST has a sampling plan in place for sampling pig carcasses at slaughterhouses under the NCP for pigs. *Salmonella* isolates derive solely from official samples taken by MAST from every slaughter batch, without taking into consideration repeated

epidemiological units. The mission team noted that in the slaughterhouse visited, the food business operator did not take any samples for *Salmonella*[6].

27. All samples are sent to the NRL for AMR for isolation and AST, and *Salmonella* is serotyped at the Department of Microbiology at the University Hospital of Iceland. The mission team was informed that a rapid test is first carried out by the laboratory in order to detect positive samples and to take any immediate action required in such a case. All samples are then tested following the Nordic Committee on Food Analysis (NMKL) method. The laboratory sends the analytical report for each sample to MAST the following day.
28. For broilers, one *Salmonella* isolate was obtained in 2016 out of 822 neck skin samples. For pigs, 17 *Salmonella* isolates were obtained in 2015 out of 2541 samples, and 9 *Salmonella* isolates were obtained in 2017 out of 1975 samples. According to MAST, the low numbers of isolates from pigs and broilers are explained by the low prevalence of *Salmonella* on poultry carcasses in 2016 (0.1%) and on pig carcasses in 2017 (0.5%).

**Isolates gathered from caecal samples collected at slaughter**

29. Caecal samples were taken at pig and poultry slaughterhouses processing at least 60% of the domestic animal population. The number of samples from domestically produced animals collected per slaughterhouse is allocated proportionally according to the different slaughterhouses' annual throughput.
30. The sampling plan for *Campylobacter* in poultry, which is part of the NCP for *Campylobacter* developed by MAST, is supported by specific guidelines/instructions. Caecal samples are taken from each broiler flock by the food business operator from April to October, from Monday to Friday, and by the competent authority in February, March, November and December. Samples are sent to the laboratory within 36 hours of sampling for isolation and identification of *C. jejuni,* for isolation of indicator *E. coli* and for the specific monitoring of ESBL-producing *E. coli*.
31. The mission team noted weaknesses related to the representativeness of caecal samples collected from broilers and pigs:

    - The collection of caecal samples from broilers was not evenly distributed over each month of the year. The sampling plan was usually sent by MAST to the slaughterhouse official veterinarians in February and caecal samples were generally collected from February to December. January was not included in the monitoring plan. According to the pre-mission document, the reason for this is that the funding for monitoring is generally not obtained until the beginning of the sampling year with the result that sampling at slaughterhouses did not start until February.
    - According to the *sampling plan for sampling at broiler slaughterhouses*, official samples have to be collected each month and on every day during each month starting from a specified date in the relevant month indicated in the plan. In one slaughterhouse visited, six samples per month had to be taken from Monday to Friday, with one sample per day from the date indicated in

[6] Comment provided by Iceland: *According to the NCP for* Salmonella *in pigs, all groups/batches of slaughtered pigs from each farm are sampled by the official authorities and therefore it is considered that the sampling is sufficient and additional sampling by the FBO is excessive.*

the plan. Restricting sampling to six consecutive days in the month may hinder the randomisation and representativeness of the sampling[7].

- The mission team noted that due to the low number of pig holdings, and following a request of clarification sent by MAST, EFSA agreed that Iceland may treat a slaughter batch as an epidemiological unit for pigs, instead of a holding. In 2017, 11 samples, collected from pigs from five different holdings, out of 151 caecal samples, were positive for ESBL-producing *E. coli*, and 21 out of 68 caecal samples were positive for indicator *E. coli*. The slaughter batch was considered as epidemiological unit.

32. The mission team was informed that for the purpose of isolation of indicator *E. coli* and for the specific monitoring of ESBL-producing *E. coli*, broiler caecal samples were, according to MAST's instructions, selected by the NRL for AMR from among the caecal samples collected under the NCP for *Campylobacter*. However, the mission team noted that the laboratory selected the caecal samples in order of arrival until the defined number was reached, rather than according to any random sampling strategy of the laboratory or MAST. This may hamper the representativeness of the selected samples.

**Isolates from meat samples collected at retail**

33. As recommended in EFSA technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria[8], retail premises serving more than 80% of the country's population were covered when sampling meat at retail level and numbers of samples were allocated proportionally according to the population of different LCAs. The biggest supermarkets supply at least 80% of the local market, and samples may be taken only from these stores according to the monitoring plan. According to documentation seen, the mission team noted that chilled fresh meat was collected from retail outlets including small retailers, between Monday and Thursday without pre-selecting samples based on the origin of the food and sent on the same day to the laboratory.

34. However, the mission team noted the following weaknesses:

- MAST and LCAs did not have information on the market share of these retail stores to ensure that sampling was carried out as required.
- Sampling started in March such that an even distribution of sampling over each month was not ensured.
- Samples assigned to an LCA for the month were generally taken in one retail store on a single occasion. LCAs present at the meeting were not implementing random sampling techniques and sampling days were not specifically defined, which could affect the representativeness of the samples.

[7] Comment provided by Iceland: *According to Point 2.3.1. of Part A of the Annex of Decision 2013/652 the collected samples at slaughter shall be evenly distributed over each month of the year to enable the different seasons to be covered. The Authority states that the restriction of sampling to six consecutive days in the month may hinder the randomization and representativeness of the sampling. This is debatable and difficult to see how that is disabling that the different seasons are covered. Again, in the technical specification, it is recommended that one sample per slaughterhouse per day is collected to ensure that there is no correlation between positive results that may derive from direct or indirect contact between sampled animals. That is obtained. The broiler production and slaughtering is scheduled months ahead by the FBO, they are not able to do any possible shifts on rearing flocks to be slaughtered to influence the randomized selection of slaughter lots. The fixed starting date is selected randomly and without knowledge of the slaughtering plan.*

[8] http://www.efsa.europa.eu/en/efsajournal/pub/3686.htm

- Although lot numbers were recorded, LCAs were not aware that according to EFSA technical specifications, no more than one sample per lot of chilled fresh meat per year should be collected.
- MAST received the results obtained from the meat sampled at retail from all LCAs. However, no checks were made by MAST on the lot numbers so as to avoid repetition in the lots sampled.

Conclusions

35. The competent authority has documented procedures in place to support the implementation of most of the provisions laid down in Decision 2013/652/EU. The sampling design generally ensured the collection of isolates from most bacteria species for monitoring of AMR in the food-producing animal populations and food categories as set out in Decision 2013/652/EU, with the exception of Indicator *E. coli* in 2015, and specific monitoring of ESBL-producing *E. coli* at retail in 2015 and 2016. In 2017, the first year sampling at retail was introduced for specific monitoring of ESBL-producing *E. coli* at retail, the targeted number of samples of pig and bovine meat from retail outlets was not achieved
36. All available isolates gathered under the *Salmonella* NCP for pigs and poultry, under the *Campylobacter* NCP in poultry and the isolates gathered in the context of Regulation (EC) No 2073/2005 were tested in line with Article 2(2) and Point 2.2. of Part A of the Annex of Decision 2013/652/EU.
37. However, certain shortcomings were noted that reduce the representativeness of data obtained, in particular: the lack of randomisation in selection of caecal samples at slaughterhouses, of retail samples, and of samples for specific monitoring of ESBL-producing *E. coli* and isolation of indicator *E. coli*; the lack of even distribution during all months of the year of retail and caecal samples from broilers collected at slaughter; and the sampling of repeated epidemiological units for pigs and retail samples, contrary to Point 2.3. of Part A of the Annex of Decision 2013/652/EU.

### *5.3.3. Official laboratories*

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 specified European Standards. Article 12(3) states that the accreditation and assessment of testing laboratories referred to in paragraph 2 may relate to individual tests or groups of tests.

Article 33(2) of Regulation (EC) No 882/2004 lays down the responsibilities of the national reference laboratories. Article 33(3) states that Article 12(2) and (3) shall apply to national reference laboratories.

Article 10 of Directive 2003/99/EC and Chapter VI of Regulation (EC) No 2160/2003 lay down provisions on the reference laboratories for zoonoses and zoonotic agents and antimicrobial resistance related thereto.

Article 4 of Decision 2013/652/EU states that the national reference laboratory for AMR shall perform the antimicrobial susceptibility testing of the isolates set out in points 2 and 3

of Part A of the Annex and the specific monitoring of ESBL- or AmpC- or carbapenemase-producing *Salmonella* spp. and *E. coli* set out in point 4 of Part A of the Annex.

Point 5 of Part A of the Annex to Decision 2013/652/EU states that the laboratories designated by the competent authority to perform the antimicrobial susceptibility testing of the isolates included in the harmonised monitoring programme shall be involved in a quality assurance system including proficiency test set up either at national or Union level, in identification, typing and susceptibility testing of the bacteria targeted by the harmonised monitoring of AMR. Isolates shall be stored by the national reference laboratories for AMR at a temperature of – 80 °C for a minimum period of five years. Other methods of storage may alternatively be used provided that they ensure viability and absence of changes in strain properties.

Findings

38. Four approved laboratories, including the NRL for *Salmonella* and the NRL for both *Campylobacter* and AMR, carry out the isolation and identification of *E. coli* and *Campylobacter* and the isolation of *Salmonella*. Serotyping for *Salmonella* of isolates from food, feed and animals is performed at the Department of Immunology of the University Hospital which is, however, not accredited for this analysis. Isolates from *Salmonella* and *Campylobacter* are sent to the NRL for AMR, which carries out AST, identification of indicator *E. coli*, and specific monitoring of ESBL-producing *E. coli*.

5.3.3.1.Coordination activities

39. Collaboration between the two NRLs and the EU Reference Laboratory (EURL) is ensured through participation in proficiency tests and regular exchanges of information. The mission team saw examples of reports from proficiency tests concerning isolation and serotyping of *Salmonella*, detection and identification of *Campylobacter*, identification of ESBL-producing bacteria and *E. coli*, and minimum inhibitory concentration (MIC) determination. Both laboratories designated as NRLs for the relevant microbiological analysis obtained satisfactory results, within the acceptance limit of 5% deviation. However, the mission team noted that the NRL for AMR and *Campylobacter* did not have a procedure for addressing deviations for the proficiency tests.
40. The other two laboratories involved in the isolation of *Salmonella* and *Campylobacter* in food and feed are accredited for their methods and take part in inter-laboratory trials, some of which are organised by the NRL for Sweden. Results for the quality analysis for *Salmonella* and *Campylobacter* since 2014 were made available and were found to be satisfactory.

5.3.3.2.Accreditation and quality system

41. The audit team checked the accreditation files of the NRLs for *Salmonella*, *Campylobacter* and AMR, which are accredited under International Organisation for Standardisation (ISO) Standard 17025, and were last audited by the Swedish accreditation body in September 2018.
42. The mission team noted that the MIC determination method, selective isolation of presumptive ESBL-producing *E. coli* and a new ISO method for isolating *Campylobacter* were not included in the scope of accreditation of the NRL for AMR. However, the laboratory participated successfully in the relevant proficiency tests organised by the EURL for MIC determination for Tables 1 and 2 of Decision

2013/652/EU and for identification of ESBL-producing bacteria. The laboratory informed the mission team that it aimed at including the method for MIC determination in the scope of accreditation in 2019.

43. In both approved laboratories, the mission team performed several traceability exercises. The laboratories could satisfactorily demonstrate the traceability of samples and isolates. However, the mission team noted that the isolation date was not interpreted consistently by all staff.

44. MAST informed the mission team that an internal audit had been carried out at the NRL for *Salmonella* focusing on control of *Salmonella* in poultry and poultry products. The scope of the audit was to verify if the reception, handling, analysis and documentation of results was in compliance with legislation and procedures, and that it was carried out effectively. The final report was not published yet at the time of the mission but preliminary results indicated that the laboratory was compliant with procedures.

45. In the two laboratories visited, the staff, the facilities and the equipment were considered satisfactory. The mission team noted the following:

- The staff interviewed were familiar with the procedures in place. However, staff experienced difficulties in relation to the adequate use of new equipment for MIC determination.
- Records for training of staff were considered insufficient in one laboratory where it was acknowledged that the system was not efficiently managed.
- The procedure in place in one laboratory for defining acceptability of the samples at reception did not include verification of temperature at arrival and failure to meet this temperature requirement was not a criterion for rejection[9].
- The temperature of the freezer in one laboratory for storing isolates at -20°C was neither monitored nor recorded[10].
- The NRL visited had the necessary equipment to freeze isolates at temperatures below -80°C and to store them for at least 5 years. However, the temperature was set at -75°C[11].

5.3.3.3.Analysis performed and methods used

46. The AST performed in the NRL included all the antimicrobials listed in Decision 2013/652/EU and results were interpreted using the relevant epidemiological cut-off values and the concentration ranges.

47. The laboratory method standards were available on the spot. In one laboratory, the method for isolation of *Campylobacter* followed the reference method, while the isolation of *Salmonella* followed the NMKL method, equivalent to the reference method. In another laboratory, *Salmonella* was isolated with a method based on the reference method and NMKL. *Campylobacter* was isolated using the in-house NMKL method, which had previously undergone successful internal verification with recovery checks for comparison with the reference method.

[9] Comment provided by Iceland: *For information: Thermometer has been purchased and procedure implemented at arrival of the samples*.
[10] Comment provided by Iceland: *For information: Thermometer has been installed and daily monitoring implemented.*
[11] Comment provided by Iceland: *For information: Was corrected immediately and is at -80°C.*

Conclusions

48. The laboratories participating in the isolation, identification and AST of bacterial isolates are designated and are involved in proficiency tests with satisfactory results generally in line with Articles 12 and 33 of Regulation (EC) No 882/2004, Article 10 of Directive 2003/99/EC, Chapter VI of Regulation (EC) No 2160/2003 and Article 4 and Point 5 of Part A of the Annex to Decision 2013/652/EU.
49. However, the NRL for AMR did not include the MIC determination and selective isolation of presumptive ESBL-producing *E. coli* in the scope of accreditation, and the laboratory performing serotyping of *Salmonella* was not accredited for that method, contrary to Articles 12 and 33(3) of Regulation (EC) No 882/2004.
50. Isolates were stored in the NRL for AMR at a temperature of -75°C, contrary to Point 5 of Part A of the Annex to Decision 2013/652/EU.

### 5.4. Assessment and reporting of AMR

Legal Requirements

Article 7(1) of Directive 2003/99/EC requires Member States to ensure, in accordance with the requirements set out in Annex II, that monitoring provides comparable data on the occurrence of antimicrobial resistance in zoonotic agents and, in so far as they present a threat to public health, other agents.

Article 9(1) of Directive 2003/99/EC requires Member States to assess trends and sources of zoonoses, zoonotic agents and antimicrobial resistance in their territory. Annex IV to the same 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.

Article 5 of Decision 2013/652/EU requires Member States to assess the results of the AMR monitoring provided for in Articles 2 and 3 and include that assessment in the report on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance provided for in Article 9(1) of Directive 2003/99/EC.

Part B of the Annex of Decision 2013/652/EU lays down general provisions for reporting of the data and the information to be included for each individual sample including the requirement for submission of harmonised AMR monitoring results under Point 2. of Part B.

Findings

51. MAST receives from the NRL for AMR a compiled overview of analytical results relevant for AMR reporting at the end of the year. If information is missing, cross-checks are made with the laboratory reports that are received by MAST for each analysis.
52. With the exception of the information to be conveyed in the narrative part of the reports, most of the results of the monitoring programme which were available were reported in line with the requirements of the data dictionary provided by EFSA. The mission team noted that, according to EFSA's comments on the AMR data reported annually by Iceland since 2015, not all data was initially submitted. MAST explained that this was simply due to errors in the submission. In all cases, EFSA's comments were addressed and missing information was provided as required.

53. The few discrepancies in 2015 and 2017 concerning the reported numbers of samples positive for *Salmonella* according to the NCP compared with the number reported to EFSA were explained. The competent authority stated that the differences were the result of *Salmonella* not being confirmed in official samples, but for which the AST was performed and reported to EFSA.
54. The mission team noted that reporting to EFSA on *Campylobacter* had been delayed in 2016 due to misunderstandings with the laboratory in relation to the isolates to be selected. In addition, EFSA excluded seven isolates because the competent authority had reported isolates from farm and from slaughterhouses together.
55. The mission team detected some weaknesses in the collection, analysis and reporting of AMR data related to repeated epidemiological units for retail samples and pig meat samples (see section 5.3.2.2), and in relation to the consistency of understanding of isolation date (see section 5.3.3.2), which may reduce the comparability of data and harmonised monitoring.

Conclusions

56. The annual reports include the mandatory information for each individual isolate reported under harmonised monitoring. However, improvements could be made in relation to reporting information in text form to EFSA and in reaching a common understanding of the isolation date, in order to ensure the accuracy of data reported to EFSA as detailed in Points 2 and 2.1. of Part B of the Annex to Decision 2013/652/EU,
57. The main AMR reporting requirements under Article 9(1) of Directive 2003/99/EC and under Article 5 and Part B of the Annex to Decision 2013/652/EU were met, although some weaknesses were detected. This hampered the ability of the competent authority to provide harmonised and comparable data on AMR, contrary to the requirements set out in Point 2 of Part B of the Annex to Decision 2013/652/EU and Article 7(1) of Directive 2003/99/EC.

## 6 Good practices and developing areas

Findings

58. According to the pre-mission document, the Minister of Health established a working group in October 2016, which delivered a report in April 2017 proposing measures aimed at reducing the spread of antimicrobial-resistant bacteria. Among the proposed recommendations were included implementation of Decision 652/2013/EU and the development of a policy on AMR.
59. According to the same document, MAST has agreed to contribute to the joint project with EFSA between 2018 and 2020 on 'Resistance dynamics in *E. coli* from food, animals, humans and the environment, using whole genome sequencing'. It aims at collecting ESBL/AmpC-producing *E. coli* from different reservoirs (environment, food-producing animals, fresh meat and humans) in order to study, among other objectives, the dynamics of ESBL/AmpC-producing *E. coli* and resistance plasmids between different reservoirs using standard phenotypic methods along with whole genome sequencing. Isolates will be collected and any changes in the resistance profiles of *E. coli* isolates before and after expected suspension of importation

restrictions of fresh meat will be monitored. The project has not yet been officially launched but Iceland is already collecting data on ESBL-producing *E. coli* from caeca and retail samples from both poultry and pigs every year, instead of every other year.

60. According to the pre-mission document, MRSA has been included in the monitoring programme for 2014/2015 and for 2018. Slaughter pigs from all farms that produce more than 200 fattening pigs per year were included in monitoring at slaughterhouse level in accordance with EFSA's technical specification where prevalence of MRSA in pigs is low or in countries that have little knowledge of MRSA situation. All samples to date have been negative.
61. MAST informed the mission team of a project which started in March 2018 for testing samples taken at retail for the specific monitoring of ESBL-producing *E. coli* and for isolating *Salmonella* and *Campylobacter*.
62. The Antibiotic Resistance Action Center, under George Washington University's Milken Institute School of Public Health, has launched a project in 2018 aimed at testing samples collected from different species, including pigs and poultry, to isolate indicator *E. coli*. This project is not under MAST's responsibility. However, MAST is currently deciding if data obtained should be reported to EFSA.
63. According to the pre-mission document, various awareness-raising initiatives concerning AMR have taken place, such as the conference organised with EFSA in Iceland in May 2017 on combating AMR and the biannual science day organised by the NRL for AMR which is open to the public and professionals

## 7 Final meeting

A final meeting was held on 13 September 2018 at MAST's office in Reykjavík with representatives from MAST, MoII, LCAs and the NRL for AMR present. At this meeting, the mission team presented its main findings and 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 findings and conclusions could be included in the report.

## 8 Recommendations

In order to facilitate the follow-up of the recommendations hereunder, Iceland should notify the Authority no later than **31 January 2019**, 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** | Iceland should ensure that Commission Implementing Decision 2013/652/EU is made part of the Icelandic legal order, in line with Articles 3 and 7 the EEA Agreement.<br><br>Recommendation based on conclusion No 3<br>Associated findings No 2 |
| **2** | Iceland should ensure that sampling at retail is performed according to the planned activities in order to obtain the minimum number of samples for specific monitoring of ESBL-producing *E. coli*, in line with Article 2(1) and Point 2.2. of Part A of the Annex of Decision 2013/652/EU.<br><br>Recommendation based on conclusion No 35<br>Associated findings No 21 |
| **3** | Iceland should ensure that sampling at slaughterhouses and at retail is representative, as required by Article 2(1) and Points 1, 2.3., 2.3.1. and 2.3.3. of Part A of the Annex of Decision 2013/652/EU, namely by evenly distributing samples over each month of the year, and by avoiding sampling of repeated epidemiological units for pigs and meat.<br><br>Recommendation based on conclusion No 37<br>Associated findings No 26, 31, 34 |
| **4** | Iceland should ensure that representative isolates of indicator *E. coli* and ESBL-producing *E. coli* are collected as required by Article 2(2) and Points 1 and 2.3.1. of Part A of the Annex of Decision 2013/652/EU, namely by randomly selecting the caecal samples available at the laboratory.<br><br>Recommendation based on conclusion No 37<br>Associated findings No 32 |
| **5** | Iceland should ensure that the information provided to the European Food Safety Authority is complete and accurate, and is timely reported, as detailed in Points 2 and 2.1. of Part B of the Annex to Decision 2013/652/EU, in order to comply with Article 5 of the said Decision.<br><br>Recommendation based on conclusion No 56<br>Associated findings No 43, 52, 55 |

## Annex 1 – List of abbreviations and terms used in the report

| | |
|---|---|
| AmpC | AmpC β-lactamases |
| AMR | Antimicrobial resistance |
| AST | Antimicrobial susceptibility testing |
| Authority | EFTA Surveillance Authority |
| *C. jejuni* | *Campylobacter jejuni* |
| EC | European Community |
| EEA | European Economic Area |
| EEA Agreement | Agreement on the European Economic Area |
| EFSA | European Food Safety Authority |
| ESBL | Extended-spectrum β-lactamases |
| *E. coli* | *Escherichia coli* |
| EU | European Union |
| EURL | EU Reference Laboratory |
| ISO | International Organisation for Standardisation |
| LCA | Municipal Environmental and Public Health Office |
| MANCP | Single integrated multi annual national control plan |
| MAST | Icelandic Food and Veterinary Authority |
| MIC | Minimum inhibitory concentration |
| MoII | Ministry of Industries and Innovation |
| MRSA | Methicillin-resistant Staphylococcus aureus |
| NCP | National Control Programme |
| NMKL | Nordic Committee on Food Analysis |
| NRL | National Reference Laboratory |
| SNCP | *Salmonella* National Control Programme |

## Annex 2 – Relevant legislation

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

a) The Act referred to at Point 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 1.1.12 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 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 amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

d) The Act referred to at Point 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 6.2.52 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs*, as corrected and amended;

g) 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;

h) 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;

i) The Act referred to at Point 7.1.8c of Chapter I of Annex I to the EEA Agreement, *Commission Implementing Decision 2013/652/EU of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria*;

j) The Act referred to at Point 7.1.13 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.

## Annex 3 – Guidance documents

| Guidance Documents |
| --- |
| EFSA. 2012 - Technical specifications on the harmonised monitoring and reporting of antimicrobial resistance in *Salmonella*, *Campylobacter* and indicator *Escherichia coli* and *Enterococcus* spp. bacteria transmitted through food.<br>In EFSA Journal. http://www.efsa.europa.eu/en/efsajournal/pub/2742.htm |
| EFSA. 2012 - Technical specifications for the analysis and reporting of data on antimicrobial resistance (AMR) in the European Union Summary Report.<br>In EFSA Journal. http://www.efsa.europa.eu/en/efsajournal/pub/2587.htm |
| EFSA. 2014 - Technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria.<br>In EFSA Journal. http://www.efsa.europa.eu/en/efsajournal/pub/3686.htm |
| EFSA. 2015 - Data dictionaries-guidelines for reporting data on zoonoses, antimicrobial resistance and food-borne outbreaks using the EFSA data models for the Data Collection Framework (DCF) to be used in 2015, for 2014 data.<br>In EFSA. http://www.efsa.europa.eu/en/supporting/doc/776e.pdf<br>EFSA. 2016 - Data dictionaries-guidelines for reporting data on zoonoses, antimicrobial resistance and food-borne outbreaks using the EFSA data models for the Data Collection Framework (DCF) to be used in 2016, for 2015 data<br>In EFSA. http://www.efsa.europa.eu/en/supporting/pub/992e |
| EFSA. 2015 - Manual for reporting on antimicrobial resistance within the framework of Directive 2003/99/EC and Decision 2013/652/EU for information deriving from the year 2014.<br>In EFSA. http://www.efsa.europa.eu/en/supporting/pub/771e.htm<br>EFSA. 2016 - Manual for reporting on antimicrobial resistance within the framework of Directive 2003/99/EC and Decision 2013/652/EU for information deriving from the year 2015.<br>In EFSA. http://www.efsa.europa.eu/en/supporting/pub/990e |

## Annex 4 – Iceland's response to the draft report

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

Selfoss, 16 November 2018
Ref: 1806964
Your ref: 82157/931896

Subject: Cover letter - Iceland's reply to the draft report of EFTA Surveillance Authority's mission to Iceland in September 2018 on monitoring and reporting of AMR in zoonotic and commensal bacteria.

Please find enclosed in two documents, Annex 1 – General comments and Annex 2 – TOC, which are Iceland's comments and table of corrective actions to the draft report mentioned above.

Respectfully
on behalf of MAST

Astfríður Sigurðardóttir
Senior officer
Office of legal affairs

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# Annex 5 – Iceland's comments to the draft report

## Annex 1

General remarks to the Draft report from the EFTA Surveillance Authority's Mission to Iceland from 10 to 13 September 2018 in order to evaluate the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria in certain food-producing animal populations and food

**Chapter 5.3.2.1. Sampling framework**

Finding No 21

In point/bullet 4:

*´ESBL-producing E. coli: In 2015, Iceland did not carry out any specific monitoring of these bacteria due to budget constraints. In 2016, the 150 required caecal samples at slaughterhouses was achieved for broilers, but broiler meat was not sampled at retail level. In 2017, the 150 required caecal samples at slaughterhouses was achieved for pigs on the basis that slaughter batches (rather than holdings, in accordance with the definition in Decision 2013/652/EU) were considered as epidemiological units as agreed between Iceland and EFSA. The targeted number of samples of pig and* **pork** *meat from retail outlets was not achieved. According to MAST, this was due to lack of communication with certain LCAs in this first year of sampling´*

COMMENT: It should say ´bovine´ instead of ´pork´.

**Chapter 5.3.2.2. Representativeness of sampling**

Findings No 22 and 23

*´22. Under the Salmonella NCP, food business operators take samples derived from farms holding laying hens and broilers and for every flock. These samples are sent to the official laboratory, which is also the NRL for Salmonella.´*

COMMENT: This finding may be based on some misunderstanding. The samples from the FBOs are sent to two different laboratories, not only the NRL for *Salmonella*. The other one is also the NRL for AMR.

*´23. MAST receives the analytical reports for Salmonella from the laboratories and maintains an overview of the available isolates. The number of Salmonella isolates being below the required 85 for each population, MAST selects all available isolates, avoiding repeated epidemiological units. It then requests the NRL for Salmonella to send the selected isolates to the NRL for AMR to be tested for AST. The mission team was provided with evidence from MAST and the laboratories, which confirmed that all available isolates were subject to AST´*

COMMENT: As the NRL for AMR also receives samples from the FBOs for isolating *Salmonella* (see finding no. 22) this should be corrected accordingly.

Finding No 31

In point/bullet 2:

*´According to the* ***NCP for Campylobacter****, official samples must be collected each month and on every day during each month starting from a specified date in the relevant month indicated in the plan. In one slaughterhouse visited, six samples per month had to be taken from Monday to Friday, with one sample per day from the date indicated in the plan. Restricting sampling to six consecutive days in the month may hinder the randomisation and representativeness of the sampling.´*

COMMENT: This is not according to the NCP for *Campylobacter* as stated, but the sampling plan for sampling at broiler slaughterhouses (see document: 2.5.r. Instruction for AMR monitoring in poultry - slaughterhouses 2018).

**Chapter 5.3.3.2. Accreditation and quality system**

Finding No 45

In point/bullet 3:

*'The procedure in place in one laboratory for defining acceptability of the samples at reception did not include verification of temperature at arrival and failure to meet this temperature requirement was not a criterion for rejection.'*

For information: Thermometer has been purchased and procedure implemented at arrival of the samples.

In point/bullet 4:

*'The temperature of the freezer in one laboratory for storing isolates at -20 C was neither monitored nor recorded.'*

For information: Thermometer has been installed and daily monitoring implemented.

In point/bullet 5:

*'The NRL visited had the necessary equipment to freeze isolates at temperatures below -80°C and to store them for at least 5 years. However, the temperature was set at -75°C.'*

For information: Was corrected immediately and is at -80°C

## Annex 6 – Iceland's action plan for corrective actions

| No | Recommendation | Reaction of Icelandic authorities | Date of Compliance | Comment/attachment |
|---|---|---|---|---|
| **1** | Iceland should ensure that Commission Implementing Decision 2013/652/EU is made part of the Icelandic legal order, in line with Articles 3 and 7 the EEA Agreement.<br><br>Recommendation based on conclusion No 3 Associated findings No 2 | A regulation on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria was published in the Icelandic official journal on the 15th of November 2018. Decision 2013/652/EU is published in an annex to that regulation. | 15 November 2018 | Link to the Icelandic regulation |
| **2** | Iceland should ensure that sampling at retail is performed according to the planned activities in order to obtain the minimum number of samples for specific monitoring of ESBL-producing *E. coli*, in line with Article 2(1) and Point 2.2. of Part A of the Annex of Decision 2013/652/EU.<br><br>Recommendation based on conclusion No 35 Associated findings No 21 | Meeting/s will be held to improve communication and to improve the common understanding of the roles of MAST and LCAs in the sampling at retail, moreover a short presentation/training of the sampling design and randomized sampling techniques at retail will be performed. | 1 May 2019 | |
| **3** | Iceland should ensure that sampling at slaughterhouses and at retail is representative, as required by Article 2(1) and Points 1, 2.3., 2.3.1. and 2.3.3. of Part A of the Annex of Decision 2013/652/EU, namely by evenly distributing samples over each month of the year, and by avoiding sampling of repeated epidemiological units for pigs and meat. | Funding has been secured for the next 3 years and therefore sampling plans will be sent out before the beginning of each year and sampling will start already in January each year.<br><br>MAST will actively check on the lot numbers to avoid repetition of the lots sampled and adjust the sampling plan | 1 January 2019 (New Decision and technical specifications) | Comment on finding No 26: According to the NCP for *Salmonella* in pigs, all groups/batches of slaughtered pigs from each farm are sampled by the official authorities and therefore it is considered that the sampling is sufficient and additional sampling by the FBO is excessive. |

| | | | | |
|---|---|---|---|---|
| | Recommendation based on conclusion No 37<br>Associated findings No 26, 31, 34 | accordingly, moreover MAST will change the sampling form in that way that the lot number will be included and that would also help the LCAs to check for the lot numbers when sampling.<br><br>Information on the market share has been requested from the Icelandic Competition Authority and will be considered for the design of the sampling plan at retail 2019.<br><br>See also point No 2<br><br>Regarding the excessive sampling at slaughter for pigs: This is a known issue at EFSA and is not only a problem for Iceland, but also for other countries with small production and few production units, especially in the pig production. It is impossible to comply with the requirements of minimum number of samples, randomizations and the definition of the epidemiological units. Icelandic representative at the Scientific Network for Zoonoses Monitoring Data and AMR took this issue up at a yearly meeting in November 2018 and this problem was recognized by EFSA and DG SANTE. These special circumstances will be addressed in the new Decision and technical specification (2020/2021) but until then EFSA and DG SANTE will have discussions and hopefully an agreement on how to address this issue until the publication of | | Comment on finding No 31: In Point 2.3.1. of Part A of the Annex of Decision 2013/652 it says: *´The collected samples at slaughter shall be evenly distributed over each month of the year to enable the different seasons to be covered.´* and in the second bullet in finding No 31 it is stated that the restriction of sampling to six consecutive days in the month may hinder the randomization and representativeness of the sampling.<br>This is debatable and difficult to see how that is disabling that the different seasons are covered.<br>Again, in the technical specification, it is recommended that one sample per slaughterhouse per day is collected to ensure that there is no correlation between positive results that may derive from direct or indirect contact between sampled animals.<br>That is obtained.<br>The broiler production and slaughtering is scheduled months ahead by the FBO, they are not able to do any possible shifts on rearing flocks to be slaughtered to influence the randomized selection of slaughter lots. The fixed starting date is selected randomly and without knowledge of the slaughtering plan. |

| | | | | |
|---|---|---|---|---|
| | | the new legislation. EFSA will hold a teleconference with these countries that are struggling with this issue and try to come up with an acceptable solution, scientifically and as harmonized as possible. | | |
| **4** | Iceland should ensure that representative isolates of indicator *E. coli* and ESBL-producing *E. coli* are collected as required by Article 2(2) and Points 1 and 2.3.1. of Part A of the Annex of Decision 2013/652/EU, namely by randomly selecting the caecal samples available at the laboratory.<br><br>Recommendation based on conclusion No 37<br>Associated findings No 32 | The NCP for *Campylobacter* in poultry will most likely change before the end of the year for sampling at the slaughterhouse, from caecal samples to neck skin samples. Therefore, all the caecal sampling for ESBL/AmpC producing *E. coli* and for indicator *E. coli* will be performed by the official authorities and the random selection will be performed at slaughterhouse level. | 1 January 2019 | See comment on finding No 31 in point 3 above. |
| **5** | Iceland should ensure that the information provided to the European Food Safety Authority is complete and accurate, and is timely reported, as detailed in Points 2 and 2.1. of Part B of the Annex to Decision 2013/652/EU, in order to comply with Article 5 of the said Decision.<br><br>Recommendation based on conclusion No 56<br>Associated findings No 43, 52, 55 | This will be improved for the next reporting period (April/May 2019). All text forms will be included, and the definition of the isolation date has been harmonized at national level. | 1 June 2019 | Comment on finding No 43: Isolation date is the day when the isolation of *E. coli* starts. |