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Final report

EFTA Surveillance Authority's mission to Norway

from 3 to 7 December 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

In response to information provided by Norway, any factual error noted in the draft report has been corrected and any clarification appears in the form of a footnote. Comments from Norway to the draft report are included in Annex 4, 5 and 6, and information on the corrective actions already taken and planned are included in Annex 7 to the report.

Executive Summary

This report describes the outcome of a mission carried out by the EFTA Surveillance Authority in Norway from 3 to 7 December 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 Norwegian competent authority has developed a framework for the official monitoring and reporting of AMR, supported by documented procedures, that generally follows the EEA requirements. However, the mission team found that further improvements are needed to ensure the effective implementation of the AMR monitoring programme, in particular in relation to representativeness of samples, the National Reference Laboratories' coordination role and official laboratories' work.

Some good practices were identified regarding voluntary monitoring that goes beyond EEA requirements, awareness-raising initiatives and activities related to prevention and control of AMR.

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

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1 Introduction

The mission took place in Norway from 3 to 7 December 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 Ministry of Agriculture and Food on 1 October 2018. A reply ('the pre-mission document') was provided on 16 November 2018.

The opening meeting was held on 3 December 2018 at the head office of the Norwegian Food Safety Authority (NFSA) in Oslo, with representatives of the NFSA, the Ministry of Health and Care Services, and the Norwegian Veterinary Institute (NVI). At the meeting, the mission team confirmed the objectives and the itinerary of the mission and the Norwegian representatives provided additional information to that set out in the pre-mission document.

Throughout the mission, representatives of the NFSA's head office accompanied the mission team. In addition, representatives of the relevant regional offices participated during meetings and visits to the different establishments.

A final meeting was held on 7 December 2018 at the NFSA's head office in Oslo, with representatives of the NFSA, the Ministry of Health and Care Services and NVI. During this meeting, 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 European Economic Area (EEA) requirements 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; and,

- gather information on good practices on AMR monitoring and reporting, including voluntary monitoring systems, as well as identify new initiatives for improving the awareness and understanding of AMR 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, 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 and a closing meeting in Oslo with representatives of the NFSA, NVI and Ministry of Health and Care Services.
Slaughterhouses	3	One poultry slaughterhouse and two multispecies slaughterhouses.
Laboratories	2	NVI, comprising the national reference laboratory (NRL) for *Campylobacter*, *Salmonella* and AMR, which also performs ESBL or AmpC or Carbapenemase selective isolation, and methicillin-resistant *Staphylococcus aureus* (MRSA) monitoring. One private official laboratory performing *Salmonella* analysis.

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- or 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.

Norway produces less than 100,000 tonnes of poultry meat slaughtered annually and more than 100,000 tonnes of pig meat slaughtered annually. On that basis, 85 isolates must be tested for each combination of bacteria in poultry and 170 isolates must be tested for each combination of bacteria in pigs, in accordance with point 2.2 of part A of the Annex to Decision 2013/652/EU.

Given that the production of meat of bovines under 1 year of age is less than 10,000 tonnes slaughtered annually, testing of *Salmonella* isolates from carcases and collection of caecal samples are not required at slaughterhouse from this population in accordance with point 1 of Part A of the Annex to Decision 2013/652/EU.

Production of fattening turkeys varies from one year to another, in some years being below 10,000 tonnes of turkey meat slaughtered annually and in other years above that threshold. Production was above 10,000 tonnes in 2015 and 2016, but below in 2017. Therefore, in 2018, no caecal samples are required at slaughterhouse from this population 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-, AmpC- or carbapenemase-producing *Escherichia coli* (*E. coli*), 150 and 300 caecal samples should be gathered from broilers and pigs respectively at slaughterhouses and 300 samples of pig and bovine fresh meat and 150 samples of broiler fresh meat at retail level 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 Norway from 11 to 20 June 2012. The final report from this mission can be found on the Authority's website (www.eftasurv.int).

The present mission will allow the Authority to follow-up on actions taken by the competent authority to address recommendations issued following this earlier mission.

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 Norwegian internal legal order.

Findings

1. The NFSA provided in the pre-mission document a list of adopted laws and regulations implementing the EEA legislation related to monitoring and reporting of AMR.
2. According to the pre-mission document, measures 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 are in place. Formal notification of these measures was submitted to the Authority in December 2005 and provisions implementing requirements of the Directive can be found in a number of different Norwegian legislative measures.
3. Commission Implementing Decision 2013/652/EU of 12 November 2013 on the monitoring and reporting of AMR in zoonotic and commensal bacteria was incorporated into Annex I to the EEA Agreement by EEA Joint Committee Decision No 166/2014 of 25 September 2014 which entered into force on 26 September 2014. Norway notified the Authority in September 2014 that Commission Implementing Decision 2013/652/EU had been implemented by the official Norwegian monitoring programme for antimicrobial resistance in bacteria from feed, food and animals NORM/NORM-Vet[1]. Norway later confirmed that the NORM-Vet monitoring programme is legally binding.

Conclusions

4. Relevant EEA legislation has been implemented in line with Articles 3 and 7 of the EEA Agreement.

[1] https://www.vetinst.no/en/surveillance-programmes/norm-norm-vet-report

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.

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 2(1) and (2) of Decision 2013/652/EU requires Member States to ensure sampling for the monitoring of AMR and collection of representative isolates in accordance with the technical requirements set out in Part A of the Annex.

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

5. Detailed information on the structure and organisation of the Norwegian competent authorities is provided in the Country Profile for Norway[2] published on the Authority's webpage, and in the Multi-Annual National Control Plan[3] (MANCP) available on the NFSA webpage.
6. The NFSA is the designated competent authority for food and feed safety, animal health and animal welfare. It has overall responsibility for the AMR monitoring programme, which is coordinated by the animal health section of the NFSA's head office. According to the pre-mission document, the NFSA is responsible for establishing annual sampling plans in compliance with EEA requirements and in accordance with national considerations, such as goals set in the government's national

[2] http://www.eftasurv.int/media/food-safety/Country-profile-NORWAY---July-2017---Part-1.pdf
[3] https://www.mattilsynet.no/om_mattilsynet/multiannual_national_control_plan__english_version.23956/binary/Multi-annual%20national%20control%20plan%20-%20English%20version

strategy against AMR[4] and in the Ministry of Food and Agriculture's action plan against AMR[5].

7. The NFSA's head office prepares surveillance instructions (OK-instruks) for each relevant combination of bacterial species in food-producing animal populations and in food. The NFSA regions take samples at slaughterhouses, farms and in retail outlets according to the OK-instruks.

8. NVI is responsible for drafting the AMR monitoring plans annually, in consultation with the animal health section of the NFSA's head office (in relation to sampling of live animals) and the hygiene and drinking water section (in relation to sampling of food), and for reporting data to the European Food Safety Authority (EFSA). According to the pre-mission document, NVI is responsible for analysing and summarising the monitoring results, which are published in a yearly report on the occurrence and distribution of AMR named NORM-VET, which was first established in 2000.

9. Samples are sent to NVI laboratories or to private official laboratories[6] for isolation of relevant bacteria, depending on the type of analysis to be carried out. Serotyping of *Salmonella*, antimicrobial susceptibility testing (AST) and the specific monitoring of ESBL-, AmpC- or carbapenemase-producing bacteria is carried out by NVI, which is the NRL for *Salmonella*, *Campylobacter* and AMR. Private laboratories are only involved in the collection of *Salmonella* isolates from sampling carried out in the *Salmonella* National Control Programme (SNCP).

10. The competent authority has legal powers to take the necessary samples under the AMR monitoring programme. The legal basis for sampling is established in Regulation (NO) No 124/2003[7] (Food Act). There were sufficient staff at the central and regional offices of the NFSA and in the laboratories visited to ensure implementation of the AMR monitoring programme.

11. Within the NFSA, each region is headed by a director responsible for coordinating the departments' activities, including planning and implementation of AMR monitoring plans. The regional directors report quarterly to the head office the main priorities and other important tasks carried out in the region. The report of the last period contains a summary for the whole year. A scoreboard with numerical indicators is used to follow-up priorities. However, reporting related to implementation of surveillance programmes is only general in nature, specific information on the implementation of the AMR monitoring plans being limited. Indeed, the NFSA's head office indicated that it rarely received specific feedback from the regions.

12. The regional monitoring plans are prepared based on the OK-instruks, with input from the NFSA departments. These plans are normally provided to the departments at the end of December or beginning of January each year and updated during the year if needed. An example was seen of redistribution of samples defined in the 2017 plan from one slaughterhouse to another at regional level and a consequent update of the monitoring plan by the head office.

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[4] https://www.regjeringen.no/contentassets/5eaf66ac392143b3b2054aed90b85210/antibiotic-resistance-engelsk-lavoppsloslig-versjon-for-nett-10-09-15.pdf

[5] https://www.regjeringen.no/contentassets/ce39ba2114884049a803a9441281985c/handlingsplan-mot-antibiotikaresistens---status-april-18.pdf

[6] Comment provided by Norway to the draft report: The great majority of samples are sent to NVI laboratories for both isolating and testing. Private laboratories are only involved in the collection of *Salmonella* isolates from sampling carried out in the national *Salmonella* control programmes and such isolates only – a handful each year.

[7] https://lovdata.no/dokument/NL/lov/2003-12-19-124

13. Coordination and cooperation between the NFSA and NVI is formalised in a written agreement which was signed in January 2013. The agreement establishes provisions concerning NVI's assistance to the NFSA in relation to design of monitoring and control programmes and reporting, including preparation of the zoonoses report and the NORM-VET report. It foresees an annual meeting between the NFSA and NVI and an obligation on NVI to notify the NFSA by phone/email of any suspicion of detection of A and B diseases including *Salmonella*. Finally, the agreement sets NVI's duties in relation to its function as NRL, including that of coordinating the activities of official laboratories carrying out relevant analysis and guiding laboratories with which the NFSA has an agreement. The mission team was informed that NVI sends a monthly overview to the NFSA's head office, including the number of samples for Norway obtained that month for all surveillance and monitoring programmes, the planned number of samples for the whole year and the overall number of samples reached that month. In addition, there are regular exchanges between the NFSA and NVI through e-mails, phone calls and skype meetings.

14. The NFSA's head office is generally responsible for overseeing progress in the implementation of the AMR monitoring programme. The mission team noted that a system is in place at central and regional level to follow implementation of the different AMR monitoring plans, in particular in relation to the number of samples to be taken. Based on the monthly overview provided by NVI for Norway, the NFSA's head office may request the regions to check or adjust their sampling. An example of an email sent by the NFSA's head office to all regions following detection of deviations in the implementation of the monitoring plan for MRSA in poultry was provided to the mission team. However, the e-mail did not target the underperforming regions since this information was not available in the overview provided, thus limiting its effect. In one region visited, the mission team noted that the sampling overview available at regional level combined the number of turkey and chicken meat samples collected in retail outlets, thus preventing monitoring of implementation of the plan for each of turkey and chicken samples alone.

15. The mission team noted that the system was not able to detect the following gaps and weaknesses in the specific monitoring of ESBL-, AmpC- or carbapenemase-producing bacteria at slaughterhouses visited and in retail outlets:

    - Repeated epidemiological units: information on epidemiological units was generally available in sampling forms, except for samples taken in retail outlets. The mission team saw examples of repeated sampling of the same epidemiological unit (see section 5.3.2.2). Epidemiological units were not monitored by the NFSA or by NVI, and whose responsibility it was for carrying out this check was not clear.
    - Number of samples taken not matching the plan: one region visited did not take any action when a discrepancy between the number of planned samples and the number of samples taken was detected.
    - Uneven distribution over the year: in a slaughterhouse visited, sampling for the specific monitoring of ESBL-, AmpC- or carbapenemase-producing bacteria had been grouped at the end of the year because the department had not realised that the slaughterhouse was included in the plan.

16. According to the pre-mission document, the NFSA offers several online courses, related to sampling through the NFSA's digital learning platform (Ransel), which also includes videos, collections and media library. Relevant training had recently been coordinated by the NFSA. Most of the samplers met by the mission team had undergone the training, although staff in one department were not aware of this training

initiative. The NFSA's head office arranges training programmes and seminars on a yearly basis aimed at the regional level, and the regional offices arrange the training courses for their departments. The objective is to train relevant staff from all regions and departments. General courses concerning relevant legislation and communication during inspections also take place.

Conclusions

17. 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.
18. The competent authority has the necessary legal powers to develop and implement harmonised monitoring of AMR in line with Article 4(2)(e) of Regulation (EC) No 882/2004.
19. Coordination and cooperation within the NFSA and between the NFSA and NVI is mostly ensured as required by Article 4(3) of Regulation (EC) No 882/2004 and Article 3(3) of Directive 2003/99/EC.
20. However, the inability to detect deviations from monitoring plans and requirements, in particular for the specific monitoring of ESBL-, AmpC- or carbapenemase-producing bacteria, undermines the effective implementation of the AMR monitoring programme. The competent authority was not always able to ensure that the monitoring is carried out in accordance with the relevant requirements of Part A of the Annex to Decision 652/2013/EU, contrary to Article 2(1) and (2) of that Decision.
21. Official sampling was generally carried out by staff which had been trained for sampling, in accordance with Article 6 of Regulation (EC) No 882/2004 and Article 3(4) of Directive 2003/99.

5.3 Organisation of official monitoring system

5.3.1. National measures

Legal Requirements

Article 6 of Directive 2003/99/EC requires Member States to 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.

Findings

22. The Food Act contains provisions related to the food business operator's obligations. According to Article 13, the food business operator is required to permit the competent authority unrestricted access to premises. The food business operator shall upon request provide to the competent authority, free of charge, the necessary samples or results of analysis carried out. Article 14 refers to the food business operator's information and reporting obligations to the competent authority.

23. The mission team was informed that national legislation did not include a general obligation for food business operators to retain isolates and to make them available to the competent authority if requested.
24. According to Article 20 of Regulation (NO) No 603/2007[8] on control of *Salmonella* in poultry, poultry feed, poultry meat and eggs, official laboratories are required to send isolates and related information about the sample to the NRL for confirmation, serotyping and AMR testing. An isolate with related information must also be sent to the Norwegian Institute of Public Health (NIPH). Analytical results must be sent to the NFSA together with information including the date and place of sampling, as well as identification of the flock and any other information intended to follow the sample. The analytical result must also be sent to the business operator from which the sample originates. The NRL shall store at least one isolate of each positive *Salmonella* per flock, per year, for at least two years.
25. Article 2(4)(a) of Regulation (NO) No 740/2003[9] requires laboratories to send isolates of infectious agents that can cause diseases to humans to the relevant reference laboratory in the area, according to the NFSA's specifications.
26. Article 6 of the Food Act requires the food business operator to immediately notify the competent authority if there is reason to suspect that food or goods are harmful to health or the environment. The food business operator must also notify any suspicion of a contagious animal disease that may have significant social consequences. The food business operator shall immediately take the necessary measures to prevent, reduce or eliminate any adverse effect, including stopping sales and initiating withdrawal from the market.
27. Regulation (NO) No 1841/2014[10] on notification of animal diseases establishes in Article 4 that veterinarians and laboratories shall immediately notify the NFSA if they detect or have reason to suspect category A or B diseases in animals. Its annexes include notifiable diseases and their pathogens listed under categories A, B and C, where *Salmonella* spp. is listed as Category B.
28. According to Article 17 of Regulation (NO) No 368/1995[11] on monitoring and control of the presence of *Salmonella* in fresh meat, the official veterinarian shall notify the NFSA when *Salmonella* is detected and when measures are taken. If there is a danger for public health, the official veterinarian shall also notify the local municipal doctor or county doctor.

5.3.2. Sampling design

Legal Requirements

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 4 of Directive 2003/99/EC provides general rules on monitoring of zoonoses and zoonotic agents. Article 7 requires Member States to ensure, in accordance with the requirements set out in Annex II, that monitoring provides comparable data on the

[8] https://lovdata.no/dokument/SF/forskrift/2007-06-08-603
[9] https://lovdata.no/dokument/SF/forskrift/2003-06-20-740?q=FOR-2003-06-20-740
[10] https://lovdata.no/dokument/SF/forskrift/2014-12-19-1841
[11] https://lovdata.no/dokument/SF/forskrift/1995-04-10-368

occurrence of antimicrobial resistance in zoonotic agents and, in so far as they present a threat to public health, other agents.

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 2.2. of Part A of the Annex requires Member States to include in the antimicrobial susceptibility testing all available isolates at the end of the monitoring period, where, due to a low bacterial prevalence or low number of epidemiological units, in any given year, the number of isolates required in accordance with the first paragraph for some of the combinations of bacterial species and type of sample of animal population or food category listed in point 1(a), (b), (c), (e) and (f), cannot be achieved.

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 in 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

29. Each year in autumn, the AMR monitoring programme is revised and updated by the NFSA and NVI. According to the pre-mission document, the NFSA sends a request for inputs to which the NVI replies with a list of suggestions. Existing data from previous monitoring, legal requirements, recommendations from international organisations like the World Health Organisation and World Organisation for Animal Health, the Norwegian Scientific Committee for Food and Environment, national demands or needs, neglected areas, and possible use of samples taken in other programmes for other purposes, are taken into consideration. Through further dialogue between the NFSA and NVI, and based on economic considerations, the NFSA decides what to include in the monitoring programme.

30. NVI annually drafts the monitoring plans for collecting samples for isolation of *Salmonella, C. jejuni*, indicator commensal *E. coli* and for the purpose of specific monitoring of ESBL- and AmpC-producing *E. coli* and carbapenemase-producing *Enterobacter*. The plans include additional sampling to that required by Decision 2013/652/EU such as: sampling of poultry, wild birds and horses for a combination of bacteria including MRSA, in 2017; sampling of chickens of more than 50 days, and sheep, for a combination of bacteria including MRSA, in 2018.
31. Sampling plans are sent to regions and departments, and to official inspectors carrying out sampling. These plans contain a description of most of the relevant requirements for sampling, including time and place of sampling and number of samples to be taken per year and month. The calculation of sample size and sample distribution in the regions or departments to ensure representativeness is generally carried out by NVI.
32. The national control programmes (NCP) for *Salmonella* and *Campylobacter* in poultry and for *Salmonella* in pigs and cattle provide further detailed information, including a monitoring programme for official sampling.
33. The NFSA has developed standard forms to accompany the samples taken by the competent authority to the laboratories. These contain most of the necessary information to identify and trace the samples, including the epidemiological unit of origin.
34. The mission team noted that procedures were not available for monitoring progress of implementation of the AMR monitoring programme and for cross-checking the monitoring data to be reported to EFSA, where weaknesses were detected by the mission team (see section 5.2 and 5.4).

5.3.2.1.Sampling framework

35. For 2015, 2016 and 2017, the AMR monitoring programme generally covered all the bacterial species and food-producing animal populations and food combinations set out in Decision 2013/652/EU, with the exception of *Salmonella* from broiler and turkey carcasses in 2016. The mission team noted that although production of turkey meat was just above 10,000 tonnes in 2015, caecal samples from fattening turkeys for *C. jejuni* isolation had not been included in the 2016 plan.
36. With regard to the fulfilment of requirements on the minimum number of isolates and samples to be tested and reported for the mandatory categories, the situation was as follows:

- *Salmonella*: In 2015, 2016 and 2017, isolates gathered under the SNCP and isolates gathered under Regulation (EC) No 2073/2005 were tested. However, the NFSA could not establish whether all available *Salmonella* isolates were subject to AST.
- Indicator commensal *E. coli*: In 2015, 2016 and 2017, the minimum number of isolates was achieved and exceeded for the relevant combination of bacterial species and sample types.
- *C. jejuni*: In 2016, the minimum 85 isolates was achieved for broilers.
- ESBL-, or AmpC- *E coli*: In 2016, the required 150 caecal samples at slaughterhouses for broilers and turkeys, and the targeted number of samples of broiler meat, were achieved and exceeded. In 2015 and 2017, the required 300 caecal samples at slaughterhouses was not achieved for pigs. The targeted 300 samples of pig and bovine meat from retail outlets was not reached in 2015.

5.3.2.2.Representativeness of sampling

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

37. Under the SNCP, farmers take samples derived from farms holding laying hens, and from every flock of broilers and turkeys between 7 and 19 days before slaughter. Poultry is required to be *Salmonella*-negative prior to slaughter. The NFSA takes official samples in broiler and turkey farms once a year and official sampling frequency for laying hens is once during the rearing and once during the production period. If the NFSA's official sampling coincides with the sampling of the farmer, the official sampling shall replace the farmer's sampling.
38. Samples are sent to NVI laboratories for isolation. However, the mission team noted, during a visit to a private laboratory, that two samples collected at poultry primary production had been received by the laboratory (rather than NVI) for *Salmonella* analysis[12]. *Salmonella* isolates are then sent to NVI in Oslo, which is also the *Salmonella* NRL, for confirmation and further typing.
39. The number of *Salmonella* isolates obtained by NVI being below the required 85 for each population due to the low national prevalence, NVI selects all isolates for AST. However, the mission team was informed by NVI that sometimes isolates could not be subject to AST as they lacked the basic epidemiological information required for reporting to EFSA, as already detected in the Authority's mission in 2012. In addition, it could not be sure that all *Salmonella* isolates obtained in private laboratories were sent to the NRL and subject to AST. As a result, and in combination with the fact that the private laboratory visited was not aware of its obligation to notify the NFSA in case it detected *Salmonella*, the competent authority was not able to establish whether all available *Salmonella* isolates were subject to AST, in particular those obtained by private laboratories.
40. For broilers, two *Salmonella* isolates were obtained in 2016 out of 4547 samples taken at farm level. According to the NFSA, the low number of isolates can be explained by the low *Salmonella* prevalence of 0.04% in broiler flocks. For layers, one *Salmonella* isolate was obtained in 2016 out of 845 samples taken at farm level. *Salmonella* isolates were not obtained from turkeys.

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

41. *Salmonella* isolates from poultry carcass samples collected at slaughter 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. According to a section of the SNCP on the sampling frequency for *Salmonella* in poultry carcasses, last updated in June 2017, the NFSA agreed to a monthly sampling frequency of neck skins by the food business operator. The NFSA does not take samples to verify the food business operators' compliance with the process hygiene criteria under Regulation (EC) 2073/2005. The mission team noted that neck skins are sampled; however, collection of carcass samples from poultry was not included in the 2016 monitoring plan.
42. The NFSA has a sampling plan in place for sampling pig and cattle carcasses at slaughterhouses under the SNCP. *Salmonella* isolates derive solely from official samples taken by the NFSA, which number is calculated by application of a formula

[12] Comment provided by Norway to the draft report: Such miss-sent samples are analyzed and reported at the private laboratory by a method which is not intended or validated for the sample matrix from primary production.

based on the previous year's slaughter volume and the food business operator's prevision for the following year. One carcass swab is taken from each of five different carcasses, each carcass coming from a different farm, and these are pooled in one sample, which however counts as five samples. All samples are sent to a private laboratory for *Salmonella* isolation. Analytical results are provided by the laboratory to the official veterinarian and recorded in NFSA´s electronic database MATS. The mission team was informed that no *Salmonella*-positive samples had been detected to date. The mission team noted that in the slaughterhouse visited, the food business operator did not take any samples from pig and cattle carcasses for *Salmonella* under Regulation (EC) No 2073/2005.

43. The mission team found that in one multispecies slaughterhouse visited, no specific strategy for planning sampling in pigs was in place to ensure randomisation, thus affecting the representativeness of the samples collected. In addition, no information on epidemiological units accompanied the sample sent to the laboratory.

44. For broilers and turkeys, no *Salmonella* isolates were obtained from carcass samples in 2016 as carcass samples were not included in the sampling plans. For pigs, no *Salmonella* isolates were found in 2015 out of 1792 samples, or in 2017 out of 1696 samples. According to the NFSA and NVI, the surveillance data indicate that the overall *Salmonella* prevalence is below 0.1%.

Isolates gathered from caecal samples collected at slaughter

45. Under the *Campylobacter* action plan, the sampling plan for broilers requires farmers to sample each flock at farm from May to October each year. Analysis is carried out by NVI using Polymerase Chain Reaction (PCR) method. From those flocks that are *Campylobacter*-positive and all those flocks with unknown status, caeca is sampled at the slaughterhouse by the NFSA from 1 May to 31 October, from Monday to Friday. Caecal samples are sent to NVI the same day and reach the laboratory the following day for isolation and identification of *C. jejuni*, except samples taken on Fridays which are placed in the refrigerator until Monday. Testing of caecal samples from fattening turkeys was included in the 2018 monitoring plan for isolation of *C. jejuni*, where the same samples are to be used for isolation of indicator commensal *E. coli*.

46. The mission team noted weaknesses related to the representativeness of caecal samples collected from broilers for *Campylobacter*:

- lack of randomisation in the collection of samples, given that only flocks found *Campylobacter*-positive at farm and those with unknown status are sampled at the slaughterhouse.
- official sampling is not distributed evenly during the year, rather being limited to the 6 months period between May and October[13].

47. In 2016, 141 *C. jejuni* isolates were obtained from 160 caecal samples taken from flocks identified as *Campylobacter*-positive by PCR screening of 2262 flocks at farms.

48. Caecal samples for isolation of indicator commensal *E. coli* and for the specific monitoring of ESBL- and AmpC-producing *E. coli*, carbapenemase-producing

[13] Comment provided by Norway to the draft report: sampling and testing for *Campylobacter* is performed on the whole population, thereby not limiting the representativeness of the sampling during the 6-month sampling period. The rest of the year, *Campylobacter* prevalence in broilers is almost not existing in Norway. Increasing the sampling period would not increase number of *Campylobacter* isolates to be AMR tested. If samples taken for the purpose of isolation of other bacteria should be used instead, very few isolates would be detected, thereby reducing the representativeness of the AMR results.

Enterobacter and *Enterococcus* were taken at slaughterhouses processing at least 60% of domestically produced meat each year and proportionate to the different slaughterhouses' annual throughput, starting with the slaughterhouses of largest throughput. The caecal samples collected from broilers for the purpose of this monitoring are different from the ones obtained under the *Campylobacter* NCP.

49. The number of samples to be collected per slaughterhouse each month is defined in the monitoring plans drafted by NVI and sent to the NFSA at the end of December/beginning of January each year. The mission team noted that samples are generally taken by the NFSA according to the plan, from Monday to Thursday, and sent to NVI on the same day.

50. The mission team noted weaknesses related to the representativeness of caecal samples collected from broilers and pigs:

- The collection of caecal samples from broilers and pigs was not evenly distributed over each month of the year, no sampling being foreseen in July. In one slaughterhouse visited, sampling in pigs had been carried out only in the last four months of 2017 and this had not been detected by the competent authority.
- There was no specific strategy in place to ensure randomisation in the collection of samples. Samples were generally collected from Monday to Wednesday or Thursday, and in one slaughterhouse visited, only on Mondays and Tuesdays. The batches to be sampled in the slaughterhouses were not always chosen randomly and different factors affected the choice of batch, such as the availability of personnel.
- According to the 2018 monitoring plan in turkeys, flocks must be randomly sampled from Monday to Thursday, whilst making sure that the same flock is sampled only once. The mission team was informed that all lots arriving at the slaughterhouse were sampled by the NFSA: from the same flock, males, which could arrive on two separate days and considered as two lots, and females, which are generally slaughtered earlier. This could lead to sampling of the same epidemiological unit up to three times.
- The 2017 monitoring plan for pigs specified that five caecal samples had to be taken from animals coming from different farms. However, the requirement was limited to the day caecal samples were collected. In two slaughterhouses visited, evidence of sampling of repeated epidemiological units over time was seen. Information available should allow for the exclusion of repeated epidemiological units.
- In one NFSA department, randomisation was not applied, with samplers generally understanding that they must target highest risk farms and animals for the purpose of monitoring AMR, thus affecting the representativeness of samples.

Isolates from meat samples collected at retail

51. As recommended in EFSA technical specifications[14], the country's population is taken into consideration for planning and calculation so as to ensure that the included municipalities cover at least 80% of the population when sampling meat at retail level. Samples were allocated proportionally to the population of each municipality on the basis of data collected from Statistics Norway.

52. NVI makes all the calculations according to a defined procedure. NVI decides the number of samples to be collected by each NFSA department from chicken/turkey/pork/beef meat in each municipality, and their distribution during the

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

year, by randomly selecting the sampling week on the basis of a seed number. This list is sent to the NFSA by NVI in December for the following year.

53. From the documentation seen, the mission team noted that chilled fresh meat was collected from the main retail outlets, generally between Monday and Thursday, and sent or brought to the laboratory on the same day.

54. The mission team noted the following weaknesses related to the representativeness of samples:

- Sampling is not carried out in July, and generally not in January, such that an even distribution of sampling over each month was not ensured.
- The common understanding of samplers at retail was that the meat to be sampled should be of Norwegian origin. Therefore, it was not ensured that samples were not pre-selected based on the origin of food.
- Random sampling techniques were not implemented in the different regions and departments visited and sampling days were not specifically defined. The mission team noted that in one department sampling was mainly carried out on Mondays, while in other cases, it depended on time availability.
- Although lot numbers were recorded when available, samplers were not aware that, according to EFSA technical specifications, not more than one sample per lot of chilled fresh meat per year should be collected[15]. No checks were carried out to avoid repetition of epidemiological units at department/regional or central level by the competent authority.
- Turkey meat was voluntarily included in the monitoring plan and reported to EFSA. Both chilled (preferably) and frozen meat could be sampled. However, the temperature of the product was not specified on the sampling forms seen and could therefore not be reported.

Conclusions

55. The competent authority has documented procedures in place to support 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 *Salmonella* from broiler and turkey carcasses in 2016.

56. The competent authority could not establish whether all available *Salmonella* isolates gathered under the SNCP were subject to AST and whether 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 to Decision 2013/652/EU.

57. The competent authority generally fulfilled the requirements on the minimum number of isolates and samples to be tested and reported for the mandatory

[15] Comment provided by Norway to the draft report: Point 2.3. of Part A of the Annex to Decision 2013/652/EU defines the epidemiological units relevant for this decision. It should be noted that an epidemiological unit is not defined for retail sampling. Considering the variety of food items that are eligible for sampling, wrapped as well as unwrapped fresh meat items, it is questionable that this requirement at all applies for the collection of samples at retail. Assuming that the purpose of the examination is to gather some proxy human exposure data, then the random selection without any pre-selection is much more important. Pre-selection is also excluding from sampling lots that are sampled earlier or elsewhere. In NORMVET only one item per category is sampled each sampling session.

categories, with the exception of caecal samples from pigs at slaughterhouses in 2015 and 2017, and samples of pig and bovine meat from retail outlets in 2015.

58. Certain shortcomings were noted that reduce the representativeness of data obtained. These included, in particular, the lack of randomisation in the collection of carcass samples from cattle and pigs for isolation of *Salmonella*, of caecal samples from broilers for isolating *Campylobacter*, of caecal samples for specific monitoring of ESBL- and AmpC-producing *E. coli*, in the isolation of indicator commensal *E. coli*, in the selection of retail samples, the lack of even distribution of sampling over the whole year and the sampling of repeated epidemiological units for samples from pigs, contrary to points 1., 2.3., 2.3.1. and 2.3.3. of Part A of the Annex to 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.

Findings

59. According to the pre-mission document, NVI is the main laboratory involved in analysing samples and testing isolates under the AMR monitoring programme. It includes one laboratory in Oslo, which is also the NRL for *Salmonella*, *Campylobacter* and AMR, and five regional laboratories. NVI is accredited according to International Organisation for Standardisation (ISO) Standard 17025 and performs isolation, identification, typing and AST of the relevant bacteria and specific monitoring of ESBL- or AmpC-producing *E. coli*.

60. The NFSA has two-year contracts, renewable once, with private laboratories designated according to a tendering and assessment procedure. A contract was signed in December 2017 with a private laboratory consisting of eight local laboratories in Norway, involved in the analysis of samples under the SNCP for poultry, cattle and pig[16]. *Salmonella* isolates obtained are then sent to NVI in Oslo for confirmation, serotyping and AST.

5.3.3.1.Coordination activities

61. Collaboration between the NRL and the EU Reference Laboratory (EURL) is ensured through participation in EURL workshops and proficiency tests.

62. The mission team noted that the exchanges between the private laboratory involved in isolating *Salmonella,* under contract with the NFSA, and the NRL for *Salmonella* were limited to sharing results of *Salmonella* inter-laboratory trials, for which date, source and matrix were not specified. In addition, the mission team noted that a meeting between the NFSA and the private laboratory had been organised when the contract was awarded but that exchanges generally remained limited[17]. The private laboratory visited was not even aware of its legal obligation to notify the NFSA of samples testing positive for *Salmonella* and this had not been detected by the NFSA. Weaknesses identified by the mission team during the visit of the private laboratory, some of which were of a serious nature relating to the laboratory's quality system, had not been previously detected by the NRL or the NFSA (see section 5.3.3.3). The NRL had not developed a system to fully ensure that those laboratories taking part in isolation and identification of bacterial isolates to be subject to AST maintained an adequate performance. Consequently, little progress has been made in relation to the NRL's coordination activities since the findings of the Authority's mission in 2012.

5.3.3.2.Accreditation

63. The audit team checked the accreditation files of NVI. NVI was last audited by the Norwegian accreditation body in March 2018, resulting in over 40 recommendations of which many were serious. An action plan and evidence of active follow-up was shown, leading to closure of some recommendations.

64. According to NVI's accreditation files, the methods for *Salmonella* and *Campylobacter* were described as an internal method based on the ISO reference

[16] Comment provided by Norway to the draft report: Private laboratories are not involved in the analysis of samples under the SNCP for poultry, only for cattle and pigs. Only poultry samples analysed by NVI are valid. Other samples, like those mentioned in finding no 38, do not count in official control programme statistics.

[17] Comment provided by Norway to the draft report: in addition to a meeting with NFSA and the private laboratory after signing the contract, there was a meeting on 9 February 2018 between the private lab, NRL and NFSA, where information was exchanged and roles, expectations and tasks were discussed. The aim of the meeting was also to get to know each other, and make it easier for the private laboratory to contact experts whenever needed. A comprehensive report was written after the meeting. Among other things there was a brief presentation of the institutions, information about roles and duties of all parts, presentation of the existing Norwegian and EU/EEA-regulations, and information on the general obligation for any laboratory to report *Salmonella* to the NFSA. The private laboratory was informed that metadata (matrix, species, premises and name of owner) should follow *Salmonella* isolates from official samples when they are submitted to the NRL. The NRL also informed about the ISO standard methods for the different microorganisms, and the differences between the different *Salmonella* methods intended for different matrices were underlined. In November 2016, NVI established a NRL coordinator position assisting the NRL-contacts in keeping in contact with NFSA and the private laboratories. The private laboratory also participates in the Norwegian National Committee of NMKL, discussing microbiological methods (including ISO-methods). The secretariat of this committee is hosted by NVI. The committee has meetings four times a year, and in addition to ad-hoc meetings, there is a regular contact between the NRL coordinator and private laboratory.

method; however, the mission team was informed that the ISO reference method was being used.

65. The mission team noted that the minimum inhibitory concentration (MIC) determination method, the selective isolation of presumptive ESBL- or AmpC-producing *E. coli* and the method for indicator commensal *E. coli* were not included in the scope of accreditation. The mission team was informed that in NVI, internal audits are carried out only on accredited methods. Since the methods used in AMR monitoring are not accredited, they are not subject to internal audit or to audits carried out by the accreditation body.

66. NVI participated in proficiency tests organised by the EURLs and relevant for the scope of this mission. These tests involved susceptibility testing, species identification and genotypic characterisation of *E. coli*, *Enterococcus* spp., *Staphylococcus aureus*, *Campylobacter* spp, and *Salmonella* spp., and a proficiency test on matrix samples to recover ESBL-, AmpC- or carbapenemase-producing *E. coli*. The mission team saw examples of reports since 2015 and the results were generally satisfactory, with the exception of deviations found for ESBL-producing *E. coli* in 3 out of 8 tests in 2015 and 2017, and unsatisfactory results regarding *Campylobacter* in 2015. No action had been taken by NVI to follow-up on unsatisfactory results for ESBL-producing *E. coli* in 2017[18].

67. NVI participated in the Scandinavian inter-laboratory trials on detection of *Salmonella*, organised by the NRL in Sweden. The files since 2016 were made available to the mission team who noted important deviations in 2017 and 2018 in the analysis of pig and chicken faeces[19].

68. The audit team checked the accreditation files of the private laboratory visited, which is accredited under ISO Standard 17025. The private laboratory informed the mission team that no external audit had taken place recently, and an internal audit was planned for 2019.

69. In the private laboratory visited, the samples were tested for *Salmonella* with PCR. Those resulting *Salmonella*-positive were analysed using an internal method based on the Nordic Committee on Food Analysis (NMKL) 71 of 1999. Whilst NMKL 71 is considered equivalent to the reference method EN/ISO 6579, the laboratory could not establish at the time of the mission that the method used reflected the last updated version of the ISO method of 2017[20].

70. The private laboratory had participated successfully in inter-laboratory trials for *Salmonella* PCR testing organised by the same group to which the laboratory belonged, under an internal proficiency testing scheme. The methods used for isolation of *Salmonella* had not been recently audited and the laboratory did not participate in inter-laboratory trials for these methods.

[18] Comment provided by Norway to the draft report: This was followed up by the EURL-AR themselves.

[19] Comment provided by Norway to the draft report: The cause of the non-conformance by the NVI in 2017 and 2018 was detected and corrected in February 2018. The NVI has scored correct in all the ring-trials from the EURL *Salmonella* for the last ten years.

[20] Comment provided by Norway to the draft report: According to EURL *Salmonella* and certification/validation organizations Afnor NF-validation, MicroVal and NordVal International consider that in the main changes in the document 2017, compared to ISO 6579:2002 are considered as minor. There are little to no effect on the performance characteristics and re-validation and verification for most labs are not needed, only for specific cases, e.g.: in case a lab wants to use MSRV instead of RVS but has no experiences with MSRV; in case up to now only ISO 6785 was followed for dairy products. As NMKL 71 is considered equivalent to the reference method EN/ISO 6579, NMKL 71 is also considered to be equivalent to the ISO method of 2017.

71. In both laboratories visited, all requested documents were provided and explained as needed. Staff interviewed were generally familiar with the procedures in place and the analysis carried out. However, training records for AMR were not available for all NVI staff involved in MIC determination at the time of the mission. In addition, technical difficulties were experienced by staff in relation to adequate use of new equipment for MIC determination.

5.3.3.3.Analysis performed, methods used and quality system

72. The AST performed in NVI included all the antimicrobials listed in Decision 2013/652/EU and the results were interpreted using the relevant epidemiological cut-off values and the concentration ranges. Laboratory procedures were available on the spot and generally followed relevant international standards.

73. The mission team performed several traceability exercises in NVI. The laboratory could satisfactorily demonstrate the traceability of samples and isolates (as applicable). MIC values were as reported to EFSA. However, the mission team noted the following weaknesses:

- The sampling date and AST date reported to EFSA and the actual documented dates were different in all cases examined by the mission team. The mission team was informed that the sampling date had been incorrectly deemed to be the day the sample arrived at the laboratory. NVI indicated that this would be corrected to reflect the actual sampling date.
- The isolation date was not documented in the laboratory data management system, but the sampling and isolation dates were systematically reported as four days apart from each other in EFSA files.
- The time lapse between sampling and analysis was more restrictive than required in the updated EURL's ESBL protocol.

74. The mission team noted the following weaknesses in NVI's quality control system:

- For isolation, quality control of new batches of selective plates was not performed, and the batch number of the plates in use was not recorded. In addition, some expired plates were found in the fridge.
- There was no incubator kept at 44°C and incubation for ESBL-producing *E. coli* was done at 41.5°C for caecal samples, contrary to the EURL protocol.
- Manual records of the working temperature for incubators and fridges were taken. However, the mission team noted that the temperature check was not always reliable, with temperatures noted as out of range but indicated as 'OK' and no action taken when a deviation was detected.
- Concentration of the inoculum was not checked.
- The average volume (in µl) per well of the auto-inoculator was not determined.
- No procedure was in place for rejection of samples, reference strains or re-testing.
- Quality control was performed at NVI using a suitable quality control strain. However, it was advised by the EURL to include a second strain for testing EUVSEC. Although this strain was provided by the EURL in 2016, is was not tested by NVI.

75. The mission team noted weaknesses in the private laboratory visited, which had not been previously detected by NVI or the NFSA. In particular, the laboratory generally showed lack of quality assurance system and bio-safety measures:

- The cold store used for samples received also stored inoculated media, unidentified products, sterile materials and expired media.
- The *Salmonella* incubator, labelled as such, contained *Listeria*-positive plates and *Legionella* was also stored in that incubator.
- Inoculated plates with *Vibrio* colonies were randomly placed on top of a refrigerator.
- Expired plates (CTX and others) were stored with new valid plates in a refrigerator. *Salmonella* cultures were stored on expired brilliance plates, which had not been recorded. There was also a lack of quality control on commercial plates.

Conclusions

76. 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 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, with the exception of *Salmonella* isolation in the private laboratory for which method no inter-laboratory trials had been carried out.
77. The NRL did not fulfil its obligations in relation to the coordination of activities of official laboratories in the framework of the AMR monitoring programme, contrary to Article 33(2)(b) of Regulation (EC) No 882/2004.
78. Weaknesses identified by the mission team in the NRL and private laboratory in relation to the quality control system and the limited extent to which methods relevant for AMR monitoring are included in the scope of accreditation, contrary to Articles 12 and 33(3) of Regulation (EC) No 882/2004, could undermine the reliability of the results of the AMR monitoring programme required by Article 2 of 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 s 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 to Decision 2013/652/EU lays down general provisions for reporting 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

79. NVI is responsible for recording in its data management system all information related to samples, isolates and analysis performed in the framework of the AMR monitoring programme, and for reporting the results to EFSA. The mission team was informed that data is assessed and undergoes careful quality checks according to a recently introduced system involving a background excel sheet with specific codes to identify inconsistent results (such as conflicting MIC values and typos) and missing information. When information is missing, cross-checks are made with the laboratory reports. Although no specific procedure or instruction was available at the time of the mission for checking data reported to EFSA, records of actions taken to correct data were shown to the mission team.
80. 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. In all cases, EFSA's comments were addressed and missing information was provided as required.
81. The mission team detected some weaknesses in the collection, analysis and reporting of AMR data related to repeated epidemiological units (see section 5.3.2.2) and in the recording of sampling and isolation dates (see section 5.3.3.3), which may reduce the comparability of data and harmonised monitoring.

Conclusions

82. The annual reports include the mandatory information for each individual isolate reported under harmonised monitoring rules. However, improvements could be made in relation to reporting information in text form to EFSA and in reporting the sampling and isolation date, in order to ensure the accuracy of data reported to EFSA in accordance with points 2 and 2.1. of Part B of the Annex to Decision 2013/652/EU.
83. 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 generally met in 2015, 2016 and 2017, in line with 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

84. According to the pre-mission document, Norway carries out monitoring of livestock-associated-MRSA in the pig population. Surveys carried out in 2008, 2011 and 2012 indicated a very low prevalence of MRSA-positive herds. Measures for eradication were imposed on MRSA-positive herds to avoid the swine population from becoming a reservoir of MRSA with the potential of zoonotic transmission. From 2014, a yearly surveillance programme of MRSA in the swine population has been put in place, to identify MRSA and initiate control measures, such as movement restrictions,

depopulation of positive holdings, cleaning and disinfection and restocking with pigs from MRSA-negative holdings. Suspected and positive MRSA samples are reported by NVI to the NFSA through a web-based reporting system. A yearly report[21] summarising the results is published on the NVI website. Furthermore, Regulation (NO) No 247/2018[22] on preventive measures against certain antimicrobial resistant bacteria in pigs was developed to protect swine from being infected with livestock-associated-MRSA, for example, by requiring people to wear protective equipment when coming into contact with a pig herd.

85. According to the same document, the NFSA and NVI are members of the national committee for prevention and control of AMR 'Antibiotikakomitéen' which meets twice a year. The committee evaluates existing measures and suggests new initiatives if deemed desirable and appropriate. NIPH chairs the committee. Institutions, agencies and authorities with tasks and responsibilities in the AMR field participate. The NFSA and NVI also participate, together with the NIPH, in a One Health AMR expert group established by the Nordic council and the Nordic council of Ministers in 2013. Its aim is to foster Nordic cooperation and sharing of information concerning AMR, including undertaking work towards Nordic solutions outlined in the Nordic council's White paper on combating AMR. Appointed members meet once a year and report to the Nordic council of Ministers.

86. Consultations with other interest parties, such as the Strategic Forum Resistance and Animal Health, may also take place. The NFSA organises meetings twice a year and invites NIPH, the national veterinary and breeding associations and other stakeholders. The NFSA presents the surveillance programmes for the coming year and invites participants for comments.

87. The animal industry has issued its own action plan against AMR aimed at preventing problems related to AMR in Norwegian livestock through preventative veterinary medicine, organised disease eradication campaigns and best practices for treatment of animals. It comprises actions to maintain a high level of biosecurity nationally, reduce disease prevalence and encourage the prudent use of antimicrobials. Additional activities aim at organising surveillance against selected resistant bacteria, researching AMR mechanisms and disease-prevention measures, and fostering communication and interaction with other stakeholders at national and international level. Among others, the poultry industry has established a monitoring programme for ESBL-producing bacteria in imported breeding stock and production animals (broiler and fattening turkeys).

88. According to the pre-mission document, various awareness-raising and research initiatives concerning AMR have taken place, such as (i) NFSA's communications strategy for fighting AMR, identifying objectives, targeting the audience and deciding on the corresponding message to convey; (ii) workshops organised by the Norwegian Medicines Agency during which therapy recommendations and guidance on prudent use of antimicrobials were shared for cats and dogs (March 2014) and for food-producing animals (February 2012); (iii) free e-learning course on AMR developed by the NFSA for veterinarians, veterinary students and other stakeholders, giving an overview of Norway's status, legislation and therapeutic guidelines; (iv) multiple research initiatives such as a study mapping research on AMR in Norway in 2017 on behalf of the Research Council of Norway, and other projects funded by NordForsk (organisation under the Nordic Council of Ministers), by the Norwegian Environment Agency, by the Norwegian University of Life Science and by NVI; and (v) a socio-

[21] https://www.vetinst.no/en/surveillance-programmes/mrsa-in-pigs
[22] https://lovdata.no/dokument/SF/forskrift/2018-02-14-247

economic analysis of measures to prevent the spread of MRSA in Norwegian pig holdings.

7 Final meeting

A final meeting was held on 7 December 2018 at the NFSA's head office in Oslo, with representatives of the NFSA, the Ministry of Health and Care Services and NVI. During this meeting, the mission team presented its main findings and preliminary conclusions from 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, Norway should notify the Authority no later than 31 May 2019 of additional corrective actions planned or already taken other than those already indicated in the reply to the draft report of the Authority. In case no additional corrective actions have been planned, the Authority should be informed of this. The Authority should be kept continuously informed of such changes made to the already notified corrective actions and measures, including changes to the deadlines indicated for completion and also the completion of the measures included in the timetable.

No	Recommendation
1	Norway should ensure that the sampling framework for AMR monitoring is effectively implemented in order to meet the requirements set out by Article 2(1) and (2) of Decision 2013/652/EU. Recommendation based on conclusion No 20, 57 Associated findings No 15, 36
2	Norway should ensure that all available *Salmonella* isolates at the end of the monitoring period are included in the antimicrobial susceptibility testing when the minimum required number of *Salmonella* isolates is not achieved, in line with Article 2(1) and (2) and point 2.2. of Part A of the Annex to Decision 2013/652/EU. Recommendation based on conclusion No 56 Associated findings No 36, 39, 41
3	The competent authority should ensure that sampling at slaughterhouses and at retail outlets is representative, as required by Article 2(2) and Points 1, 2.3., 2.3.1. and 2.3.3. of Part A of the Annex to Decision 2013/652/EU, notably as regards the randomisation of the sampling scheme, the even distribution of samples over each month of the year, the random selection of sampling days and the avoidance of repeating epidemiological units for caecal content of pigs and meat at retail outlets. Recommendation based on conclusion No 58 Associated findings No 43, 45, 46, 50, 54
4	The competent authority should ensure that national reference laboratories act in accordance with Article 33(2)(b) of Regulation (EC) No 882/2004. In particular, the

	national reference laboratories shall coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples. Recommendation based on conclusion No 77 Associated findings No 62
5	The competent authority should ensure that official laboratories put in place quality controls so that analysis are performed in line with Articles 12 and 33(3) of Regulation (EC) No 882/2004 and comply with Article 2 of Decision 2013/652/EU. Recommendation based on conclusion No 78 Associated findings No 65, 66, 67, 68, 69, 70, 71, 73, 74, 75
6	Norway should ensure that the information provided to the European Food Safety Authority is complete and accurate, and is timely reported, as required in Points 2, 2.1. and 2.3. of Part B of the Annex to Decision 2013/652/EU, and Article 5 of that Decision. Recommendation based on conclusion No 81 Associated findings No 43, 54, 70, 79, 80

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
EQAS	External Quality Assurance System
ESBL	Extended-spectrum β-lactamases
E. coli	*Escherichia coli*
EU	European Union
EURL	EU Reference Laboratory
ISO	International Organisation for Standardisation
MANCP	Single integrated multi annual national control plan
MIC	Minimum inhibitory concentration
MRSA	Methicillin-resistant Staphylococcus aureus
NCP	National Control Programme
NIPH	Norwegian Institute of Public Health
NMKL	Nordic Committee on Food Analysis
NORM-VET	Norwegian monitoring programme for antimicrobial resistance in bacteria from feed, food and animals.
NRL	National Reference Laboratory
OK-instruks	Surveillance instructions
PCR	Polymerase Chain Reaction
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. 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. 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. 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. In EFSA. http://www.efsa.europa.eu/en/supporting/doc/776e.pdf 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 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. In EFSA. http://www.efsa.europa.eu/en/supporting/pub/771e.htm 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. In EFSA. http://www.efsa.europa.eu/en/supporting/pub/990e

Annex 4 - Norway's response to the draft report

ROYAL NORWEGIAN
MINISTRY OF AGRICULTURE AND FOOD

EFTA Surveillance Authority
35 Rue Belliard
BE 1040 Brussels
BELGIUM

Your ref	Our ref	Date
	17/1209-	14 March 2019

EFTA Surveillance Authority's Mission to Norway from 3-7 December 2018 in order to evaluate the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria in certain food-producing animal population and food.

Please find enclosed the Norwegian Food Safety Authority's comments regarding the draft report.

Yours sincerely

Cathrine Steinland
Director

Henrik Høyer Holgersen
Adviser

This document is signed electronically and has therefore no handwritten signature

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Annex 5 - Norway's comments to the draft report

EFTA Surveillance Authority's Mission to Norway from 3-7 December 2018 in order to evaluate the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria in certain food-producing animal population and food.

Thank you very much for a thorough and instructive report. The report with its findings supports our continuous work on improving AMR monitoring and reporting activities.

We appreciate this opportunity to comment on your draft report.

The report reproduce an overall picture we can agree upon. However, we do have a few comments concerning the factual content of the report and some of your interpretations of the observations done during your visits to establishments and authorities involved.

1) Concerning 5.1 regarding Legislative and implementing measures and conclusion 4.

Commission Implementing Decision 2013/652 of 12 November 2013 on the monitoring and reporting of AMR in zoonotic and commensal bacteria has not been made part of the Norwegian legal order, contrary to Articles 3 and 7 of the EEA Agreement.

It is not correct that the NORMVET monitoring programme is not legally binding. The program is issued by the Norwegian Food Safety Authority's Head Office and sent to the Authority's regional offices and specifies which samples **must** be taken as part of NORMVET (*"det skal tas ut prøver"/"skal det tas ut prøver"*). In Norwegian law, an instruction given by a higher administrative level in the state administration is legally binding for lower levels directly under it (*"instruksjonsmyndighet"*) and does not need to be issued in legislation.

Decision 2013/652/EU Article 4 nevertheless requires that the NRL (The Norwegian Veterinary Institute) performs specified analysis. The Norwegian Food Safety Authority has ensured that this requirement is fulfilled through a legally binding agreement with the Norwegian Veterinary Institute [*KONTRAKT mellom Mattilsynet og Veterinærinstituttet om kjøp av laboratorietjenester i forbindelse med overvåknings- og kartleggingsprogrammer*] which also include the NORMVET program. The agreement is revised and renewed annually. NORMVET in more detail and its legal and scientific basis is described in the Surveillance instruction [OK-instruks].

Decision 2013/652/EU entails that Member States must ensure sampling for the monitoring of AMR, collect isolates and assess the results which are to be included in a report. These obligations do not create any rights for individuals and do not in general have to be implemented in national

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legislation. The attached administrative instructions ensures that the required sampling is carried out by the competent authority in Norway. The implementation is therefore sufficient and in line with the EEA Agreement Article 3. It should be noted that Article 7 of the EEA Agreement specifies the method for implementation of Regulations and Directives, but not for Decisions.

2) Concerning 5.2 Competent authorities and finding 9
Samples are sent to private official laboratories or to NVI laboratories for isolation of relevant bacteria, depending on the type of analysis to be carried out.

The great majority of samples are sent to NVI laboratories for both isolating and testing. Private laboratories are only involved in the collection of *Salmonella* isolates from sampling carried out in the national *Salmonella* control programmes and such isolates only – a handful each year. The current phrasing of point 9 in the report may leave the impression that private laboratories play a much greater role in the AMR monitoring and reporting tin Norway than they actually do.

3) Representativeness of sampling

3.1) *Salmonella* isolates from samples collected at poultry primary production finding no 37
The NFSA takes official samples in broiler and turkey farms once a year and samples laying hens once during rearing and once (< 1,000 birds) or twice (> 1,000 birds) during the egg production period.

Official sampling frequency laying hens is once during the rearing and once during the production period.

3.2) *Salmonella* isolates from samples collected at poultry primary production finding no 41
Salmonella isolates from poultry carcass samples collected at slaughter 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 the SNCP.

The above mentioned sampling by food business operators is not part of the SNCP.

3.3) Isolates from meat samples collected at retail finding no 54
The mission team noted the following weaknesses related to the representativeness of samples:

- *Although lot numbers were recorded when available, samplers were not aware that, according to EFSA technical specifications, not more than one sample per lot of chilled fresh meat per year should be collected. No checks were carried out to avoid repetition of epidemiological units at department/regional or central level by the competent authority.*

Point 2.3. of Part A of the Annex to Decision 2013/652/EU defines the epidemiological units relevant for this decision. It should be noted that an epidemiological unit is not define for retail sampling. Considering the variety of food items that are eligible for sampling, wrapped as well as unwrapped fresh meat items, it is questionable that this requirement at all applies for the collection of samples at retail. Assuming that the purpose of the examination is to gather some proxy human exposure data, then the random selection without any pre-selection is much more important. Pre-selection is also excluding from sampling lots that are sampled earlier or elsewhere. In NORMVET only one item per category is sampled each sampling session.

4) Official laboratories: Legal Requirements finding no 60
The NFSA has two-year contracts, renewable once, with private laboratories designated according to a tendering and assessment procedure. A contract was signed in December 2017 with a private laboratory consisting of eight local laboratories in Norway, involved in the analysis of samples under the SNCP for poultry, cattle and pig.

Private laboratories are not involved in the analysis of samples under the SNCP for poultry, only for cattle and pigs. Only poultry samples analysed by NVI are valid. Other samples, like those mentioned in finding no 38, do not count in official control program statistics.

5) Additional documents

Please, find attached a plan for the corrective measures and actions. Also enclosed is the feedback from the Norwegian Veterinary Institute on the draft report from EFTA Surveillance Authority's mission to Norway 2018 to evaluate the AMR surveillance.

Yours sincerely,

Anne Marie Jahr

Head of section Animal Health
NFSA Head Office

Annex 6 - Norwegian Veterinary Institute's comments to the draft report

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Norwegian Veterinary Institute

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Deres ref.:	Vår ref.	Dato:
	18/19892-3	07.03.2019

Feedback from the Norwegian veterinary Institute on "the Draft report from EFTA Surveillance Authority's mission to Norway 2018 to evaluate the AMR surveillance"

As asked for in e-mail 14th of February and in telephone meeting on 25th of February the Norwegian veterinary Institute with this letter gives feedback on the "Draft report EFTA Surveillance Authority's mission to Norway from 3 to 7 December 2018 min order to evaluate the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria in certain food-producing animal populations and food".

In general the NVI thinks the report reflects the issues and focused areas that were discussed under the evaluation (i.e. the parts NVI participated in). Though, we have some comments and further information to some of the conclusions and numbered points in the report as shown below.

Conclusion 20 (based on point 15.). …"detect deviations from monitoring plans and requirements….

- Repeated epidemiological units - from *now* on, i.e. from the 2018 data and on, the NVI will include a test for repeated epidemiological units, and exclude repeated units, before reporting data to the EFSA. This will be performed on the epidemiological units cattle and swine herds, and broilers and turkey flocks. For retail samples this is more difficult as lot numbers are not available for all samples received at the NVI, but will be performed on those where data is available.
- Number of samples taken not matching the plan -the NVI will introduce a more detailed feedback to the NFSA showing deviations from the monitoring plans. This detailed feedback will be set up during spring 2019.
- Uneven distribution over the year -The NVI can analyze samples all year through as requested if the NFSA can do the sampling accordingly. This could be introduced from 2020. For Campylobacter, see comments for conclusion 58.

Point 38. "… that two samples collected at poultry primary production had been received by the private laboratory (rather than NVI) for *Salmonella* analysis…."
To be added: Such miss-sent samples are analyzed and reported at the private laboratory by a method which is not intended or validated for the sample matrix from primary production.

Conclusion 58 (based on 46, 50, 54). «..shortcomings that reduce the representativeness of data obtained…. …..the lack of even distribution of sampling over the whole year……and repeated units…"
See also comments for conclusion 20 with regard to uneven distribution over the year and repeated units.

- Ceacal samples from broilers for *Campylobacter* - The sampling and testing for *Campylobacter* is performed on the whole population, thereby not limiting the representativeness of the sampling during the 6-month sampling period. The rest of the years, the *Campylobacter*

prevalence in broilers are almost not existing in Norway. This is the reason behind the *Campylobacter* Action plan sampling and is well documented. Thereby, increasing the sampling period would not increase number of *Campylobacter* findings, i.e. *Campylobacter* isolates to be AMR tested. If the use of information from *Campylobacter* Action plan should be avoided, and samples taken for the purpose of isolation of other bacteria should be used instead, very few isolates would be detected, thereby reducing the representativeness of the AMR results.

Conclusion 76 (based on 62, 69, 70). ….."with the exception of *Salmonella* isolation in the private laboratory for which method no inter-laboratory trials had been carried out."
The NRL Salmonella fully agree that an isolation step should be included in the ring-trials at the private laboratories, and that the results should be included in the reports to NRL. NVI has taken the initiative to a meeting with the private laboratory in the end of March/beginning of April where this will be taken up. The NRL will inform the private laboratories that isolation of Salmonella from positive samples are a mandatory part of the Salmonella ring trials.

Conclusion 77 (based on 62, 69, 70, 75). "The NRL did not fulfil its obligations in relation to the coordination of activities of official laboratories in the framework of the AMR monitoring programme, contrary to Article 33(2)(b) of Regulation (EC) No 882/2004."
Please, see added information to point 62 under on NRL's coordination activities.

To be added for 62. In addition to a meeting with NFSA and the private laboratory after signing the contract, there was a meeting 9 February 2018 between the private lab, NRL and NFSA, where information were exchanged and roles, expectations and tasks were discussed. The aim of the meeting was also to get to know each other, and thus make it easier for the private laboratory to contact experts whenever needed. A comprehensive report was written after the meeting. Among other things there was a brief presentation of the institutions, information about roles and the duties of all parts, presentation of the existing Norwegian and EU/EEA-regulations, and information on the general obligation for any laboratory to report Salmonella to the NFSA. The private laboratory was informed that metadata (matrix, species, premises and name of owner) should follow salmonella isolates from official samples when they are submitted to the NRL. The NRL also informed about the present ISO standard methods for the different microorganisms, and the differences between the different salmonella methods intended for different matrices were underlined. In November 2016, NVI established a NRL coordinator position assisting the NRL-contacts in keeping in contact with NFSA and the private laboratories. The private laboratory also participates in the Norwegian National Committee of NMKL, discussing microbiological methods (including ISO-methods). The secretariat of this committee is hosted by NVI. The committee has meetings four times a year, and in addition to ad-hoc meetings, there is a regular contact between the NRL coordinator and private laboratory.

Conclusion 78 (based on 63 - 75). "Weaknesses identified by the mission team in the NRL and private laboratory in relation to the quality control system and the limited extent to which methods relevant for AMR monitoring are included in the scope of accreditation, contrary to Articles 12 and 33(3) of Regulation (EC) No 882/2004, could undermine the reliability of the results of the AMR monitoring programme required by Article 2 of Decision 2013/652/EU."
Comments to conclusion 78, see comments to specific points underneath.

Point 64. «According to NVI's accreditation files, the methods… were described as internal methods based on ISO….., however….. ISO ref. method was being used."
The NVI's accreditation files will be corrected before the end of March 2019 in the next report to the accreditation organ.

Point 66. Regarding proficiency tests: "The mission team saw examples of reports since 2015 and the results were generally satisfactory, with the exception of deviations found for ESBL-producing E. coli in 3 out of 8 tests in 2015 and 2017, and unsatisfactory results regarding Campylobacter in 2015. No action had been taken by NVI to follow-up on unsatisfactory results for ESBL-producing E. coli in 2017."

- Regarding the unsatisfactory results for ESBL-producing *E. coli* (Matrix) in 2015 - no MICs were scored, only the findings of ESBL conclusion. Not followed up.
- Regarding the unsatisfactory results for Campylobacter in 2015 - this was followed up with emails between the NRL and EURL-AR. The issue this year was that we went from using the VetMIC panels to the Sensititre EUCAMP2 panels. The panels were read manually and growth/no growth marked on the reading scheme. The reading scheme used previous years was not updated from the VetMIC panel layout to EUCAMP2 layout. This was unfortunately

not detected until after the EQAS was delivered. When transferring the readings to the correct template, there were no discrepancies to the results. Fortunately this was discovered and corrected before we started testing our own isolates for 2015.

- Regarding the unsatisfactory results for ESBL-producing E. coli (Matrix) in 2017. This was followed up by the EURL-AR themselves. We got an email dated April 5th 2018 about the delay in the matrix EQAS report for 2017. They conclude that there was challenges regarding the data treatment, as some of the test strains, had changed phenotype after passage in the meat matrix. Because of this, the one strain was omitted completely from the evaluation (M-3.4), and for M-3.5 they had omitted results for specific antibiotics. Sample M-3.2 was reported to be CARBA negative but expected positive. No growth on the plates. Sample M-3.4 was omitted. Sample M-3.6 was reported to be OXA positive but expected negative. This was a typo when reporting the EQAS. The isolate contained a blaCTX-M gene successfully reported. There was presumptive colony on the OXA-48 plates but after phenotypic testing it showed to be susceptible to carbapenems and "low" in temocillin.

Point 67. The ring-trials on Salmonella in animal faeces organized by the NRL in Sweden does not include serotyping. The cause of the non-conformance by the NVI in 2017 and 2018 was detected and corrected in February 2018. The NVI has scored correct in all the ring-trials from the EURL Salmonella for the last ten years.

Point 69. According to EURL Salmonella (Kirsten Mooiman) and certification/validation organizations Afnor NF-validation, MicroVal and NordVal International consider that in the main changes in the document 2017, compared to ISO 6579:2002 are considered as minor. There are little to no effect on the performance characteristics and re-validation and verification for most labs are not needed, only for specific cases, e.g.: in case a lab wants to use MSRV instead of RVS but has no experiences with MSRV; in case up to now only ISO 6785 was followed for dairy products. As NMKL 71 is considered equivalent to the reference method EN/ISO 6579, NMKL 71 is also considered to be equivalent to the ISO method of 2017.

Point 73.

- Regarding documentation of the isolation, sampling and AST dates: The NVI has emphasized the importance of documenting the correct dates in the Sampling journal system. These dates will be reported to EFSA from now on.
- Regarding ..."the restrictive time lapse between sampling and analysis was more restrictive than required in the updated EURL's ESBL protocol." For the 2019 sampling, these aspects have been taken under consideration by changing the sampling procedure to five days a week, thereby following the recommendations from EURL-AR. However, this needs to be evaluated if as a consequence many samples use too long time to reach the laboratory due to long distances and delayed mail.

Point 74. "The mission team noted the following weaknesses in NVI's quality control system:

- For isolation, quality control of new batches of selective plates was not performed, and the batch number of the plates in use was not recorded. In addition, some expired plates were found in the fridge."
  The NVI have already updated their protocols and routines regarding these matters.
- "There was no incubator kept at 44°C and incubation for ESBL-producing E. coli was done at 41.5°C for caecal samples, contrary to the EURL protocol."
  From January 2019 NVI has an incubator fixed at 44°C.
- "Manual records of the working temperature for incubators and fridges. However, the mission team noted that the temperature check was not always reliable, with temperatures noted as out of range but indicated as 'OK' and no action taken when a deviation was detected."
  This issue has been reported in NVI's QC system, as well as communicated to the people doing the temperature recordings.
- "Concentration of the inoculum was not checked.
- The average volume per well of the auto-inoculator was not determined.
- No procedure was in place for rejection of samples, reference strains or re-testing."
  These three aspects are now to be implemented in the lab routines.
- "Quality control was performed at NVI using a suitable quality control strain. However, it was advised by the EURL to include a second strain for testing EUVSEC. Although this strain was provided by the EURL in 2016, is was not tested by NVI."
  Unfortunately, inclusion of this second strain had been forgotten. It has now been added to the updated protocol for sensitivity testing using Sensititre TREK plates, and has been included in the testing.

Conclusion 82 (based on 81 and more.). Improvements in relation to reporting information in text form, and the sampling and isolation date will be performed from 2019 on the 2018 data. Also, an internal check to avoid repeated epidemiological units to be reported will be performed for the samples where data is available. See also comments for conclusion 20.

Point 85. "Antibiotikakomiteen which meets three or four times a year..... This is not correct. The Antibiotikakomiteen meets twice a year.

For the recommendations on page 25-26, see comments for the Conclusions and specific points over.

Med vennlig hilsen,

Merete Hofshagen
Avdelingsdirektør
Avdeling for dyrehelse og trygg mat

Anne Margrete Urdahl
Fagansvarlig antibiotikaresistens
Seksjon for Mattrygghet og antibiotikaresistens

Annex 7 – Norway's action plan for corrective actions

Tablel: Follow up on ESA-inspection AMR 3. - 7. December 2018 - Monitoring and reporting of antimicrobial resistnance in zoonotic and commensal bacteria in sertain food-producing animal population and food - Action Plan						
No	**Recommendations/subject**	**Not in compliance**	**Responsible section**	**Action**	**Time aspect**	**Enclosures**
1	Norway should ensure that Commission Implementing Decision 2013/652/EU is made part of the Norwegian legal order, in line with Articles 3 and 7 the EEA Agreement. Recommendation based on conclusion No 4 Associated findings No 3	Commission Implementing Decision 2013/652/EU was incorporated into Annex I to the EEA Agreement by EEA Joint Committee Decision No 166/2014 of 25 September 2014 and entered into force on 26 September 2014. Norway notified the Authority in September 2014 that Commission Implementing Decision 2013/652/EU had been implemented by the official Norwegian monitoring programme for antimicrobial resistance in bacteria from feed, food and animals NORMVET. However, at the closing meeting Norway confirmed that the NORMVET monitoring programme is not legally binding (3).	Seksjon dyrehelse	Done.		
2	Norway should ensure that the sampling framework for AMR monitoring is effectively implemented in order to meet the requirements set out by Article 2(1) and (2) of Decision 2013/652/EU.Recommendation based on conclusion No 20, 57 Associated findings No 15, 36	Repeated epidemiological units, number of samples taken not matching the plan, uneven distribution over the year (15). NFSA could not establish whether all available Salmonella isolates were subject to AST, required number of samples/sampling targets not alway met (36).	Seksjon dyrehelse	Adjust the Surveillance instruction (OK-instruks) and the Norm Vet program in it. Some adjustments have already been done, see "Feedback from the NVI on ESA's draft report". Those remaining will be corrected when preparing OK-instruks 2020. Meetings with food business operators, private official laboratories and NRL to improve the collection of available Salmonella isolates for AMR testing.	End of 2019	Feedback from the NVI on ESA's draft report
3	Norway should ensure that all available *Salmonella* isolates at the end of the monitoring period are included in the antimicrobial susceptibility testing when the minimum required number of *Salmonella* isolates is not achieved, in line with Article 2(1) and (2) and point 2.2. of Part A of the Annex to Decision 2013/652/EU.Recommendation based on conclusion No 56 Associated findings No 36, 39, 41	NFSA could not establish whether all available Salmonella isolates were subject to AST (36). NVI selects all isolates for AST. However, the mission team was informed by NVI that sometimes isolates could not be subject to AST as they lacked the basic epidemiological information required for reporting to EFSA. In addition, it could not be sure that all Salmonella isolates obtained in private laboratories were sent to the NRL and subject to AST (39). The mission team noted that neck skins are sampled; however, collection of carcass samples from poultry was not included in the 2016 monitoring plan (41).	Seksjon dyrehelse & Seksjon hygiene og drikkevann	Instruction to the private laboratories on MSIS and their responsability to send positive zoonose samples to the NRL. Information to privat laboratories about their obligation to send isolates to NRL enclosed required information.	During 2019	

4	The competent authority should ensure that sampling at slaughterhouses and at retail outlets is representative, as required by Article 2(2) and Points 1, 2.3., 2.3.1. and 2.3.3. of Part A of the Annex to Decision 2013/652/EU, notably as regards the randomisation of the sampling scheme, the even distribution of samples over each month of the year, the random selection of sampling days and the avoidance of repeating epidemiological units for caecal content of pigs and meat at retail outlets.Recommendation based on conclusion No 58 Associated findings No 43, 45, 46, 50, 54	No specific strategy for planning sampling pigs was in place to ensure randomisation. In addition, no information on epidemiological units accompanied the sample sent to the laboratory (43). The mission team noted weaknesses related to the representativeness of caecal samples collected from broilers for Campylobacter (46). The mission team noted weaknesses related to the representativeness of caecal samples collected from broilers and pigs and there was no specific strategy in place to ensure randomisation in the collection of samples. The mission team was informed that all lots arriving at the slaughterhouse from the same turkey flock were sampled, which could lead to sampling of the same epidemiological unit up to three times. In two pig slaughterhouses visited, evidence of sampling of repeated epidemiological units over time was seen. In one NFSA department, randomisation was not applied, with samplers generally understanding that they must target highest risk farms and animals for the purpose of monitoring AMR (50). The mission team noted that sampling is not carried out in July, and generally not in January. The common understanding of samplers at retail was that the meat to be sampled should be of Norwegian origin. Random sampling techniques were not implemented in the different regions and departments visited and sampling days were not specifically defined. No checks were carried out to avoid repetition of epidemiological units at department/regional or central level by the competent authority (54).	Seksjon hygiene og drikkevann	The Head office has sent a letter to all the regions the 05.03.2019 containing a reminder of the legislation on the sampling of salmonella "Instruks om overvåkning av og tiltak mot salmonella i ferskt kjøtt" https://www.mattilsynet.no/om_mattilsynet/gjeldende_regelverk/instrukser/. The legislation states that samples should be taken from different holdings, distributed during the time of slaughtering and taken on different days of slaughtering. The letter also contained a reminder that all NORM-VET samples should be taken randomly and that samples should not be taken from the same epidemiological units. We have also discussed and explained this recommendation on a meeting in the "IRF næringsmiddelproduksjon og slakteritilsyn" the 07.03.2019. We will also post a reminder about this on our blog. The head office will also change our "OK - instruks 2020" on NORM – VET and Salmonella to clarify these requirements.	March 2019	
5	The competent authority should ensure that national reference laboratories act in accordance with Article 33(2)(b) of Regulation (EC) No 882/2004. In particular, the national reference laboratories shall coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples.Recommendation based on conclusion No 77 Associated findings No 62	The mission team noted that the exchanges between the private laboratory involved in isolating Salmonella, under contract with the NFSA, and the NRL for Salmonella were limited to sharing results of Salmonella inter-laboratory trials, for which date, source and matrix were not specified. In addition, the mission team noted that a meeting between the NFSA and the private laboratory had been organised when the contract was awarded but that exchanges generally remained limited. The private laboratory visited was not even aware of its legal obligation to notify the NFSA of samples testing positive for Salmonella and this had not been detected by the NFSA. Weaknesses identified by the mission team during the visit of the private laboratory, some of which were of a serious nature relating to the laboratory's quality system, had not been previously detected by the NRL or the NFSA. The NRL had not developed a system to fully ensure that those laboratories taking part in isolation and identification of bacterial isolates to be subject to AST maintained an adequate performance. Consequently, little progress has been made in relation to the NRL's coordination activities since the findings of the Authority's mission in 2012 (62).	Seksjon dyrehelse	Meeting with the NRL to clarify our expectations concerning the the NRS's role and tasks according to Art 33 in Regulation 882/2004 (subsequently 2017/625). See also "Feedback from the NVI on ESA's draft report".	1st half 2020	

6	The competent authority should ensure that official laboratories put in place quality controls so that analysis are performed in line with Articles 12 and 33(3) of Regulation (EC) No 882/2004 and comply with Article 2 of Decision 2013/652/EU.Recommendation based on conclusion No 78 Associated findings No 65, 66, 67, 68, 69, 70, 71, 73, 74, 75	NVI participated in proficiency tests organised by the EURLs. The results were generally satisfactory, with exceptions. No action had been taken by NVI to follow-up on unsatisfactory results (66). NVI participated in the Scandinavian inter-laboratory trials on detection and serotyping of Salmonella, organised by the NRL in Sweden. The mission team noted important deviations (67). In the private laboratory visited, the samples were tested for Salmonella with PCR. Those resulting Salmonella-positive were analysed using an internal method based on the Nordic Committee on Food Analysis (NMKL) 71 of 1999. The laboratory could not establish that the method used reflected the last updated version of the ISO method of 2017 (69). The methods used for isolation of Salmonella had not been recently audited and the laboratory did not participate in interlaboratory trials for these methods (70). However, training records for AMR were not available for all NVI staff involved in MIC determination (71).The mission team noted weaknesses in the reporting to EFSA (73). The mission team noted the following weaknesses in NVI's quality control system (74). The mission team noted weaknesses in the private laboratory visited, which had not been previously detected by NVI or the NFSA. In particular, the laboratory generally showed lack of quality assurance system and bio-safety measures (75).	Seksjon dyrehelse	Carry out NRL assisted audits in official private laboratories. See also "Feedback from the NVI on ESA's draft report".	During 2020	
7	Norway should ensure that the information provided to the European Food Safety Authority is complete and accurate, and is timely reported, as required in Points 2, 2.1. and 2.3. of Part B of the Annex to Decision 2013/652/EU, and Article 5 of that Decision.Recommendation based on conclusion No 81 Associated findings No 43, 54, 70, 79, 80	No specific strategy for planning sampling pigs was in place to ensure randomisation, thus affecting the representativeness of the samples collected. In addition, no information on epidemiological units accompanied the sample sent to the laboratory (43). An even distribution of sampling over each month was not ensured. It was not ensured that samples were not pre-selected based on the origin of food. Random sampling techniques were not implemented in the different regions and departments visited and sampling days were not specifically defined. No checks were carried out to avoid repetition of epidemiological units at department/regional or central level by the competent authority.Turkey meat was voluntarily included in the monitoring plan and reported to EFSA. Both chilled (preferably) and frozen meat could be sampled. However, the temperature of the product was not specified on the sampling forms seen and could therefore not be reported (54). The methods used by the private laboratory for isolation of Salmonella had not been recently audited and the laboratory did not participate in interlaboratory trials for these methods (70). NVI is responsible for recording in its data management system all information related to samples, isolates and analysis performed in the framework of the AMR monitoring programme, and for reporting the results to EFSA (79). 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 (80).	Seksjon dyrehelse	Meeting with NVI to discuss possible improvements.	End of 2019	