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Final report

EFTA Surveillance Authority mission to Norway

from 11 to 20 June 2012

regarding application of EEA legislation

related to

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

Please note that comments from the Norwegian competent authorities to factual errors in the draft report have been included in *underlined italic print* in the body of the report. Comments and information on the corrective actions already taken and planned by the Norwegian competent authorities are included in Annex 6 and referred to in footnotes in *underlined italic print*.

Executive Summary

This report describes the outcome of a mission carried out by the EFTA Surveillance Authority in Norway from 11 to 20 June 2012. The objective of the mission was to verify that official controls related to the monitoring and control of zoonotic agents in live animals and products of animal origin, with emphasis on Salmonella, were carried out in compliance with the European Economic Area legislation.

The mission team found that the epidemiological situation in Norway in relation to zoonotic agents with special emphasis on Salmonella was satisfactory and that official controls carried out by the Norwegian Food Safety Authority were in principle in line with the legislative requirements and, in particular for Salmonella in swine and cattle and Campylobacter in poultry, even more strict.

Some shortcomings with a different degree of significance were identified by the mission team in the system, and concerned in particular:

- the role of the national reference laboratory;*
- the collection of epidemiological data by the competent authorities in relation to all the zoonotic agents;*
- the competence of the staff involved in official controls at food and feed business operators level and the lack of relevant enforcement measures;*
- the fulfilments of the requirements by the food business operators (e.g. general hygiene and hazard analysis and critical control points).*

Of particular concern to the mission team was the serious deficiencies identified in an establishment catering meals to a substantial number of hospitalised people. The immediate actions taken by the Norwegian Food Safety Authority included the suspension of preparation of meals, the implementation of hygienic corrective measures and the destruction of the relevant quantity of expired, unlabelled and “not to be frozen” products found in a freezer of the establishment.

Finally – although not included in the scope of this mission – the mission team noted that feedingstuffs with fishmeal for non-ruminants was produced in the same facilities as feedingstuffs for ruminants in a feed mill visited.

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

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1 Introduction

The mission took place in Norway from 11 to 20 June 2012. The mission team comprised two inspectors from the EFTA Surveillance Authority (the Authority) and a national expert.

The opening meeting was held with representatives of the Norwegian Food Safety Authority (NFSA), the Ministry of Health and Care Service and the Norwegian Veterinary Institute (NVI) on Monday 11 June 2012 at the head office of the NFSA in Oslo. The meeting was arranged as a video conference, allowing the head office of the NFSA located in Sandnes to participate.

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

Throughout the mission, the mission team was accompanied by representatives of the NFSA head office together with representatives of the relevant regional and district offices.

A final meeting was held with representatives of the NFSA, the Ministry of Health and Care Service, the NVI and the Norwegian Institute of Public Health (NIPH) in Oslo on 20 June 2012. This meeting was also arranged as a video conference, allowing the participation of the head office of the NFSA located in Sandnes.

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

2 Scope and objective of the mission

The following main European Economic Area (EEA) Acts and related EEA legislation fall within the scope of the mission:

- a) *Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents* (as amended) and
- b) *Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 (as amended) on the control of Salmonella and other specified food-borne zoonotic agents* (as amended).

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

A particular focus was put on the Norwegian control and monitoring of *Salmonella* in live animals and animal products.

The assessment was based on the following main issues:

- the national legislation, policy and operating procedures regarding the objective of this mission;
- the compliance action and procedures, reporting and competence of personnel;
- the uniformity in national implementation;

- the status of implementation of corrective measures with respect to the previous mission carried out by the Authority from 23 to 27 April 2007.

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

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

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

	Number	Comments
Competent authorities	2	An initial meeting and a final meeting between the mission team and the Norwegian competent authorities.
	3	In the three districts visited, located in two different regions, representatives of the correspondent regional offices also joined the meetings.
Municipal medical officers	2	Two municipalities.
Public health institutions	1	The Norwegian Institute of Public Health (<i>Folkehelseinstituttet</i> .)
Laboratories	3	The Norwegian Veterinary Institute in Oslo (National Reference Laboratory for the zoonotic agents falling within the scope of this mission including <i>Salmonella</i>) and the regional NVI laboratory in Trondheim; a private laboratory designated to analyse official samples.
Establishments	3	A catering facility providing meals to hospitalised people, a feed mill and a slaughterhouse.
Farms	3	A breeding pigs farm, a parent turkey farm and a broilers farm.

3 Legal basis for the mission

The legal basis for the mission was:

- a) Point 4 of the Introductory Part of Chapter I of Annex I to the EEA Agreement;
- b) Article 1(e) of Protocol 1 to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice (Surveillance and Court Agreement);

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

4 Background

The last mission to Norway regarding the application of EEA legislation related to the objective of this mission was carried out from 23 to 27 April 2007. The final report from this mission can be found on the Authority's website (www.eftasurv.int). After evaluation of the corrective measures taken by the NFSA, the Authority considered that in particular two of them (passive surveillance for *Listeria* spp. and official laboratories designated by the NFSA) should be followed-up during the next mission on the same topic (see chapters 5.3 and 5.4).

Information on production, intra-EEA and third country trade of products subject to controls on zoonotic agents for the years 2009, 2010 and 2011 is given in Annex 3.

5 Main findings and conclusions

5.1 Legislation and implementing measures

Legal requirements

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

Findings

According to information provided by the NFSA in its reply to the pre-mission document of the Authority, the Norwegian Regulation of 23 December No. 1703 implements several of the legal acts listed in Annex 2 to this report, including Regulation (EC) No 2160/2003, with the following adaptation: "Norway" shall be added after the word "Finland" in Article 9(3). This was adopted by the EEA Joint Committee Decision No 49/2005 of 29 April 2005 and entered into force on 30 April 2005.

Directive 2003/99/EC entered into force in Norway on 30 April 2005. At that time measures ensuring full implementation of the mentioned directive were, according to the information provided by the NFSA in its reply to the pre-mission document of the Authority, already in place. Formal notification of these measures was submitted to the Authority in January 2006.

The Norwegian legislation includes stricter national measures regarding monitoring and control of *Salmonella* and *Campylobacter* than those laid down in EEA legislation such as Regulation of 31 January No. 107 regarding monitoring and control of *Salmonella* in live cattle and swine and Order of 23 June 2004 No 1033 to veterinary officers at the NFSA district offices for monitoring and control of *Campylobacter* in poultry and fresh poultry meat in poultry abattoirs. Additional information regarding the stricter rules implemented in Norway are provided in chapter 5.7 of this report.

Conclusions

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

5.2 Competent authorities¹

Designation of competent authorities and competence of their staff, coordination and cooperation between and within competent authorities, enforcement measures

Legal Requirements

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

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

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

Article 54 of Regulation (EC) No 882/2004 lays down the action in case of non-compliance and in particular states that (1) when the competent authority identifies non-compliance, it shall take action to ensure that the operator remedies the situation. When deciding what action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance.

Article 55 Regulation (EC) No 882/2004 states that the sanctions provided for must be effective, proportionate and dissuasive.

Findings

According to information provided by the NFSA in its reply to the pre-mission document of the Authority, the NFSA is the competent authority for the purpose of the legislative acts falling within the scope of this mission. Public health institutions, such as the Norwegian Institute of Public Health (NIPH) described below, have a general responsibility for public health, whereas the NFSA has a sector-specified responsibility when hazards to the public have its source in animals and/or food of animal origin.

The NFSA had organised several training courses for its staff covering zoonotic agents including *Salmonella*. The staffs of the NFSA met by the mission team was well prepared and familiar with the framework and roles defined in the control of zoonotic agents with emphasis on *Salmonella* and the national control plans. However, limited knowledge of the hazards analysis critical control points (HACCP) principles by the NFSA inspectors

¹ Further information on the organisation of the competent authorities and how official controls are carried out in Norway is given in the country profile available on the Authority's website: <http://www.efasurv.int/internal-market-affairs/fields-of-work/food-safety/country-profiles/>

dealing with food and feed business operators was also observed by the mission team, as well as shortcomings related to enforcement and use of sanctions (see chapter 5.9 for a more detailed description of these findings).

The mission team met with representatives of the NIPH who explained that the NIPH is the main coordinator when outbreaks of human diseases occur, also with regard to food poisoning and zoonotic outbreaks². In accordance with the Communicable Disease Control Act (Act no 55 of 5 August 1994) the NIPH is the national governmental centre for communicable disease prevention and control. The institute performs research and surveillance of communicable diseases in humans and advises governmental and municipal authorities and the public on the prevention of communicable diseases, investigation of outbreaks and control of antimicrobial resistance. The NIPH accommodates:

- the National Surveillance System for Communicable Diseases (MSIS);
- the National Outbreak Notification System,
- the National Outbreak Preparedness and Response Group,
- several national reference and surveillance laboratories appointed by the Ministry of Health and Care Services, including the National Reference Laboratory for Enteropathogenic Bacteria (*from humans*) where *Salmonella* isolates are further analysed.

In the reply to the pre-mission document of the Authority, the NFSA stated that “An outbreak guidance document” owned by both NFSA and NIPH was first published in 2006 and later revised in 2009 and renamed “Outbreak manual, Contagion protection 17 (*Utbruddshåndboka, Smittevern 17*)”. The guide is targeted at municipal medical offices and the NFSA at all three levels (head office, regional and district offices). It describes the investigation of foodborne outbreaks and zoonoses and covers responsibilities, cooperation and stages of investigation at local, regional and national level. The outbreak manual can be found online at both the NPHI and the NFSA website.

In order to formalise the cooperation between the NFSA and the municipal medical offices, the NFSA has drafted an agreement that provides detailed instructions to each one of the authorities involved. Appendix B to the outbreak manual contains guidelines on how to finalise the agreement which can be downloaded as a word document. The agreement is adapted to the local situation and signed by the district officers of the NFSA and the municipal medical officers.

Information on the agreement was provided to the Authority following the previous mission carried out in 2007. During this mission (2012), the NFSA representative explained to the mission team that an annual evaluation of the status of the implementation of the agreement at national level is carried out. The district offices report the number of municipalities which have signed (or not) the agreement as well as whether the level of cooperation is considered to be “good” or “bad”. The mission team received contradicting information from the NFSA related to how many municipalities had signed the agreement. After the initial meeting (three to four had not signed), the numbers varied from 77 to 100 to a final number of 94 that had not signed. The cooperation with 22 out of these 94 municipalities was reported to be “bad”. The NFSA stated that it was mainly with small municipalities the cooperation was reported to be “bad”. The three biggest cities in Norway were among the municipalities which had not signed the agreement.

² See Annex 6 for comments from the NFSA.

During the meeting in a NFSA district office the mission team was informed that five out of nine municipalities in the district had signed the agreement. The largest municipality in the district, with around 250.000 inhabitants, had not signed it. The mission team went through a practical example in which the municipal medical officer of this municipality and a representative of the district office of the NFSA demonstrated good cooperation in the management of a foodborne outbreak. The municipal medical officer present at the meeting explained that there had been delays in signing the agreement and assuring that this will be solved as soon as possible. Additional information on the cooperation between the NFSA and the municipal medical officers is given in chapter 5.6.

Conclusions

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

Compliance with Article 4(2)(c) of Regulation (EC) No 882/2004 could not be ensured, in particular related to knowledge of the HACCP principles, general hygienic requirements, use of enforcement and sanctions (see also chapter 5.9).

Enforcement measures have not been found to be in compliance with Articles 54 and 55 of Regulation (EC) No 882/2004 considering the operator's past record with regard to non-compliance and the absence of measures which should have been effective, proportionate and dissuasive.

Efficient and effective coordination and cooperation between the NFSA, the NIPH and certain municipalities was demonstrated in accordance with Article 4(3) of Regulation (EC) No 882/2004. However, the cooperation with a number of municipalities was characterised as “bad” by district offices of the NFSA. Furthermore, the inconsistencies pointed out in relation to the number of municipalities which have signed the agreement of cooperation with the NFSA undermine the reason why this agreement has been conceived.

5.3 Laboratory services

Legal Requirements

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

Chapters VI of Directive 2003/99/EC and Regulation (EC) No 2160/2003 lay down provisions on the reference laboratories. Annex II to Commission Decision 2004/564/EC lays down the responsibilities and tasks of the national reference laboratories for *Salmonella*, pursuant to Directive 2003/99/EC and Regulation (EC) No 2160/2003.

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

Findings

According to the Country Profile of Norway³, The NFSA has designated private local laboratories that carry out the analysis of samples taken during official controls. All the laboratories are assessed and accredited in accordance with the Standard ISO 17025. The Norwegian Accreditation Body (*Norsk Akkreditering*) monitors all these laboratories annually. Should a laboratory fail to meet the standard the designation is cancelled.

According to information provided by the NFSA during the mission, 17 private local laboratories are designated as official laboratories in the context of official controls. The NFSA has a written agreement with each of the private local laboratories which are designated according to a tendering and assessment procedure. The laboratories have a two year contract with the NFSA which is renewable once, where after there is a call for a new tender. The NFSA was, at the time of this mission prolonging the agreements with designated private laboratories. The agreements were valid from 2008 to 2010 and are being prolonged to 2012. The private local laboratories are used by the NFSA district offices and they also analyse samples from own-check controls by the food and feed business operators.

According to information provided by the NFSA in its reply to the pre-mission document of the Authority, the NVI has been appointed as National Reference Laboratory (NRL) for the zoonoses falling within the scope of this mission (apart from zoonotic agents in seafood), including *Salmonella*. The mission team visited the NVI/NRL in Oslo and one of its regional laboratories in Trondheim. The mission team also visited a private local laboratory.

The Norwegian Veterinary Institute in Oslo- NRL

Concerning the role of the NVI/NRL within the *Salmonella* control plans in poultry the following major activities have been confirmed during the visit:

- coordination of the regional laboratories of the NVI that receive and analyse samples taken by both the food business operators and the NFSA;
- serotyping and storing of *Salmonella* strains received by the regional laboratories;
- antimicrobial susceptibility testing of *Salmonella* isolates;
- distribution of practical instructions and sample materials (boot swabs, fabric swabs 900 cm², sterilized water, forms for collecting data etc.) to the food business operators and the NFSA;
- management of a database where analytical results are reported and available for both the food business operators and the NFSA;
- management of the information regarding the implementation of the control plans and in particular collection of the following data: number of flocks submitted to sampling, number of samples rejected because of non compliance with the requirements and number of flocks tested positive identifying the *Salmonella* serovar.

Forms used to collect data on sampling were available at the NVI and detailed information on sampling frequency and number and type of samples were presented to the mission team; sampling scheme for breeders flocks of *Gallus gallus* and breeding turkeys were confirmed to be identical (see chapter 5.7).

³ Further information on the organisation of the laboratory services in Norway is given in the country profile available on the Authority's website; <http://www.efsa.europa.eu/en/internal-market-affairs/fields-of-work/food-safety/country-profiles/>

Four regional laboratories of NVI are involved in analyzing samples taken within the *Salmonella* control plans; three of them (Trondheim, Sandnes, Harstad) are analysing samples from the poultry sector while the fourth one (Bergen) is in charge for analyzing faecal materials of breeding pigs. The NVI/NRL confirmed that all these laboratories including the NVI/NRL use the analytical procedure ISO 6579-2002/Amd1:2007 accredited for *Salmonella*. The NVI/NRL is also accredited for serotyping of *Salmonella*.

The NVI/NRL confirmed that in each of the four regional laboratories involved in the control plans a key person has been identified to be in charge for rejecting samples not in compliance with the requirements.

The mission team confirmed that the NVI/NRL keeps contacts with the Community Reference Laboratory (CRL) by participating in the meetings and in the proficiency testing (both for isolation and serotyping) organised by the CRL with good results. However, the NVI/NRL does not organize ring trials to evaluate isolation performances of its regional laboratories. All the regional NVI laboratories and the NVI/NRL are required to participate in ring trials organized by the Swedish NRL for *Salmonella* (Nordic ring trials) once a year. Moreover these laboratories participate also three times a year to ring trials organized by the Veterinary Laboratory Agency based in the United Kingdom. The mission team observed that the NVI/NRL did not play a primary role in the coordination and results evaluation of the Nordic ring trials. Unsatisfactory results are discussed in specific meetings but no follow up is organized by the NRL. Training of staff and maintenance of competences, as well as environmental controls, are done in accordance with the requirements of the accreditation body⁴.

Salmonella strains isolated by the regional laboratories within the control plans for poultry are sent to the NVI/NRL for confirmation (re-isolation, biochemical testing by a standardised identification system and serotyping); samples are received mostly by mail. The mission team verified that the document accompanying samples contained all relevant information.

Serotyping is performed by means of slide agglutination, using commercially available antisera. No control strains are used for serotyping. Out of around 400 strains that are serotyped per year by the NVI/NRL, a very low percentage originated from samples taken within the *Salmonella* control plans.

All *Salmonella* strains isolated by the NVI/NRL are sent to NIPH for the Multilocus Variable Number Tandem Repeat Analysis (MLVA) that is performed at least for *S. Typhimurium* isolates. Representatives of the NVI/NRL confirmed that there is good collaboration between the NVI/NRL and the Foodborne Infection Reference Laboratory of the NIPH. Meetings are organised twice a year to discuss common issues. The representatives of the NVI/NRL also stated that even if the National Reference Laboratory for Enteropathogenic Bacteria (from humans) at the NIPH is in charge of performing analysis of strains isolated from humans, it receives as well *Salmonella* strains isolated by private local laboratories from veterinary matrices. There is an agreement between the NIPH and the NVI/NRL that *Salmonella* strains from veterinary matrices received only by the NIPH should be sent to the NVI/NRL.

⁴ See Annex 6 for comments from the NFSA.

The representatives of the NVI/NRL informed the mission team that they thought that the agreements signed between the NFSA and the private local laboratories stated that all *Salmonella* isolates should be sent to the NVI/NRL. In addition, in November 2008 the NVI/NRL sent a letter to all private local laboratories (including the designated private laboratories with the agreement signed with the NFSA) analysing samples from feed, food and animals. The letter stated that if the laboratories needed verification on those parameters for which the NVI is appointed NRL, the isolates should be sent to the NVI/NRL. The letter specifically stated that all *Salmonella* isolates should be sent to the NVI/NRL. However, some of the private local laboratories were still sending isolates to the NPHI only. This procedure was confirmed to the mission team in the only designated private laboratory visited (see below). According to a representative of this laboratory, it was for the NFSA to decide whether to send isolates to the NVI/NRL and the laboratory procedure indicated the NIPH as the receiving laboratory for isolates of *Salmonella*. NVI/NRL receives very seldom information concerning the origin of strains from positive samples originating from own checks, even if the strains themselves might be sent from the private local laboratories to the NVI/NRL.

The mission team noted that the NFSA did not involve the NVI/NRL at any stage of the work of drafting agreements with designated private laboratories. In particular, the NVI/NRL was not consulted on which analytical methods could be used for different parameters. The NVI/NRL is not familiar with the contents of the agreements between the NFSA and designated private laboratories. The mission team noted that the NVI/NRL was not aware of the use of a rapid test for *Salmonella* in the designated private laboratory visited and The use of rapid tests for *Salmonella* for lymph nodes and carcass swabs was not discussed with the NVI/NRL for *Salmonella*. The NFSA had informed the NVI/NRL that a new list of designated private laboratories will be provided to the NVI/NRL after the new agreements has been signed.

At present, the NVI is not doing any follow up or organizing ring tests for the designated private laboratories for any of the parameters for which it has been appointed by the NFSA as NRL. The designated private laboratories should provide evidence of participation to ring trials in the context of the accreditation system leaving them free to decide to what provider apply for the organisation of ring tests. No feedback in this context is given to the NVI/NRL and no follow-up of the results is provided by the NVI/NRL.

With regards to other zoonotic agents than *Salmonella* and the role of the NVI as NRL, the mission team noted that the NVI was not aware of the analysis carried out by the designated private laboratories in the context of official controls. In particular for e.g. *Listeria spp.*, *Campylobacter spp.* and *E coli O157* which could be verotoxin-producing or not, the NVI/NRL is not receiving relevant information from the designated private laboratories concerning the positive samples, and such data are not reported from the NFSA to the NVI to be included in the zoonosis report (see chapter 5.4). Samples in the context of the National *Campylobacter* Action Plan for broilers and all slaughtered poultry are analysed by the NVI/NRL and its regional laboratory in Trondheim.

Designated private laboratory

The mission team visited one of the 17 private laboratories designated by the NFSA to perform analysis in the context of official controls.

The mission team noted that the analytical method NMKL No 71, 1995, 5th edition was replaced in February 2011 by a rapid culture method. This method was validated and approved by AFNOR (which is the French national organization for standardization)

according to ISO 16140 standards against the reference method ISO 6579:2002 standard for the detection of *Salmonella* in food, animal feed and environmental samples. Despite the laboratory being accredited according to ISO 17025 (*Norsk Akkreditering* Test 089), the analytical method used was not clearly indicated in the analytical reports provided to the mission team, despite a dedicated column on the reporting sheet. The reference to the method was missing or stating only “AFNOR”.

In this laboratory, as mentioned before, confusion was noted with regards to whom the *Salmonella* strain following identification from food of animal origin was to be sent. Nevertheless the designated private laboratory shall send monthly reports to the NVI/NRL with detailed information on official samples collected by the NFSA within the *Salmonella* control plans. The mission team observed that the following relevant information was missing in the monthly report: date of the end of the analysis and analytical method used.

The mission team saw examples of *Salmonella* analytical reports from other designated private laboratories and noted that one of the laboratories used a polymerase-chain-reaction method. One laboratory indicated three different methods of analysis in analytical reports for *Salmonella* in a period of six months. Culture method 1 was indicated in an analytical report dated 13/01/2012, culture method 2 in a report dated 16/01/2012 and finally AFNOR BIO 12/10-09/02 was indicated in a report dated 15/06/2012. The NFSA was not informed of the changes in the methods used by the designated laboratory neither was the NVI/NRL for *Salmonella*.

The regional NVI laboratory in Trondheim

The mission team visited the regional laboratory of NVI in Trondheim; it is accredited according to ISO 17025.

In the analytical reports, reference was made to method ME02_108 for isolation of *Salmonella* from faecal and dust sample from poultry. Also in reports from another regional laboratory of NVI (Bergen), the method was indicated as ME02_108. According to the information received from the NVI/NRL all the NVI laboratories used the accredited method ISO 6579-2002/Amd1:2007 for isolation of *Salmonella*. It was not clear from the analytical reports seen whether ME02_108 corresponds to the ISO 6579-2002/Amd1:2007. Furthermore, the accreditation document issued by *Norsk Akkreditering* (Test 110) ME02_108 was stated to correspond to the method based on ISO 6579:2002 (/Amd1:2007 was not mentioned) leading to confusion on the method used by NVI regional laboratories for *Salmonella* testing

According to this method Modified Semi-solid Rappaport Vassiliadis (MSRV) plates may be stored in a refrigerator for maximum 72 hours. The mission team received an information note dated 1998 demonstrating that refrigeration up to 72 hours does not affect the result of the analysis, however no reference to the MSRV medium was indicated in this note. Scientific bibliography is however supporting the assumption that MSRV plates can be stored in a refrigerator after primary incubation without affecting analytical results.

The mission team noted shortcomings in the laboratory’s bio-safety measures. The working sheet contained no information on the refrigeration of samples and implementation of measures to protect the operators and avoid cross-contamination between the samples were more based on confidence that no *Salmonella* was entering the

laboratory together with the samples rather than a proper implementation of bio-safety measures.

Results of proficiency tests organized by the Swedish NRL for *Salmonella* were available and satisfactory.

Conclusions

The Norwegian competent authorities have designate laboratories that may carry out the analysis of samples taken during official controls in accordance with Article 12(1)(2) and (3) of Regulation (EC) No 882/2004.

However the lack of full implementation of the provisions laid down in Chapters VI of Directive 2003/99/EC and Regulation (EC) No 2160/2003 and Annex II to Commission Decision 2004/564/EC on the role of the reference laboratories was pointed out; furthermore, inconsistencies in the role of the national reference laboratories according to Article 33(2) of Regulation (EC) No 882/2004 have been noted and in particular with reference to: (b) coordination of the activities of official laboratories responsible for the analysis of samples, (c) organization of comparative tests between the official laboratories and ensuring an appropriate follow-up of such comparative testing, (d) ensuring the dissemination to the competent authorities and official laboratories of information that the Community reference laboratory supplies, (e) providing scientific and technical assistance to the competent authorities for the implementation of coordinated control plans adopted in accordance with Article 53.

5.4 Monitoring of zoonosis and zoonotic agents

Legal Requirements

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

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

Findings

The results of the monitoring/control programs of zoonotic agents referred to in Annex I of Directive 2003/99/EC and the number of outbreaks/identifications of zoonotic agents in production animals in Norway (2009, 2010 and 2011) are included in Annex 4 and 5 to this document.

The NVI is responsible to edit the annual report provided by Norway on trends and sources of zoonoses and zoonotic agents in humans, foodstuffs, animals and

feedingstuffs⁵. The report for 2011 was provided to the mission team on the spot. The institutions and laboratories involved in the reporting are the NFSA, the NVI, the National Institute of Nutrition and Seafood Research and the NIPH. The information available in the reports is in conformity with the legal requirements, however the mission team noted that the flow of information regarding passive surveillance of agents such as *Listeria* spp., *Campylobacter* and *E coli* O157 which could be verotoxin producing or not, is not clearly and consistently reported through the system. Relevant information regarding isolation of these agents by designated private laboratories does not reach the NRL/NVI (see chapter 5.3).

After the previous mission carried out in 2007, the NFSA explained to the Authority that, for *Listeria* spp., the notification system in Norway is based on passive surveillance. During this mission, however, it appeared that epidemiological information concerning the isolation of zoonotic agents (*Listeria* spp., *Campylobacter* and *E coli* O157 which could be verotoxin producing or not) following official controls and/or own checks, was not gathered by the NFSA and reported in a structured way to the NVI. Consequently, and even though the Norwegian Food Act makes compulsory the notification from the food business operators to the NFSA of isolation of relevant agents as *Listeria* spp. and *E. Coli* O157, this information is not aggregated at central level and analysed in order to provide an exhaustive overview of the prevalence of these zoonotic agents in food products.

Conclusions

Norway ensures that data on the occurrence of zoonoses and zoonotic agents and antimicrobial resistance related thereto are collected, analysed and published without delay in accordance with the requirements laid down in Article 3(1), Article 9 and Annex IV of Directive 2003/99/EC.

However shortcomings have been identified in the effective and continuous cooperation based on free exchange of general information and, where necessary, of specific data between the NFSA and the NVI/NRL as required in Article 3(3) of the same Directive. Thus the reporting system within the frame of Article 9 of Directive 2003/99/EC could miss some relevant and comparable data as mentioned in Article 6 of the same Directive concerning results for zoonotic agents not included in the active surveillance (monitoring plans).

5.5 Antimicrobial resistance

Legal Requirements

Annex II to Directive 2003/99/EC lays down the requirements for monitoring of antimicrobial resistance pursuant to Article 7 of the same Directive.

Findings

According to information available in the Norwegian report on “Trend and source of zoonoses and zoonotic agents in humans, foodstuffs, animals and feedingstuffs” (editions 2010 and 2011) antimicrobial resistance in zoonotic agents and some pathogenic microbiological agents is monitored in the following way:

- all *Salmonella* found in production animals, irrespective if they are found in the Norwegian *Salmonella* control plan or in connection with clinical problems,

⁵ See Annex 6 for comments from the NFSA.

surveys or other investigations, are included in the resistance monitoring (one isolate per herd);

- as part of the Norwegian action plan against *Campylobacter* in broilers, caecal samples are collected at slaughterhouses; one isolate per positive flock has to be included for susceptibility testing;
- *E. coli* and *Enterococcus spp.*, non pathogenic; data from a monitoring programme called NORM-VET indicate a low to moderate prevalence of resistance in indicator *E. coli* and *Enterococcus spp* from Norwegian food producing animals and food. Resistance most commonly encountered are due to antimicrobials that have been or still are typically used therapeutically.

Antibiotic resistance in human isolates is monitored in a similar way and the use of antibiotics and the results from the monitoring are published in an annual report, the NORM/NORM-VET report, published jointly by the NVI and the NIPH. The reports are available on the internet (<http://www.vetinst.no/eng/Publications/Norm-Norm-Vet-Report>).

Conclusions

The monitoring of antimicrobial resistance in Norway is carried out in accordance with the legislative requirements.

5.6 Food-borne zoonoses in humans

Legal Requirements

Article 8 of Directive 2003/99/EC outlines different rules for the competent authorities' epidemiological investigation of food-borne outbreaks.

Findings

According to information provided by the NFSA in its reply to the pre-mission document of the Authority, all health personnel, and personnel from the NFSA, shall report suspected foodborne outbreaks to the municipal medical officer, who is required to report to the county administrator and to the NIPH. If a food or animal source is suspected, the municipal medical officer shall immediately notify the relevant district office of the NFSA. Thus, there is a mutual obligation to notify suspected outbreaks between the NFSA district offices and the municipal medical officers. All reporting on suspected outbreaks should be done immediately. Outbreaks on the national level are also notified through two early warning e-mail addresses at both NIPH and NFSA. The two e-mail boxes are checked frequently throughout every working day⁶. The obligation to report human outbreaks as described above is regulated by the Communicable Disease Control Act and by the National Surveillance System for Communicable Diseases (MSIS) regulation (see chapter 5.2).

At local level, the municipal medical officer has the responsibility to initiate an outbreak investigation. If a national outbreak is detected, the responsibility lies with the NIPH.

According to information provided by the NFSA in the reply to the pre-mission document, foodborne outbreaks are defined as a number of human cases of the same disease which exceeds the endemic level, or infection where the cases are linked or probably linked to the same food source. A database available on the internet (www.utbrudd.no) is used by

⁶ See Annex 6 for comments from the NFSA.

all municipal medical offices and the NFSAs district offices to report foodborne outbreaks. The database is called VESUV and has been in use since July 2005. It is owned by both NIPH and NFSAs. Monthly reports are published on the NFSAs internal website and are also discussed at the national level in monthly meetings between the NFSAs and the NIPH. The database comprises information on time, place and person, the causative microbial agent, the source of infection, and the hygienic non compliance that caused the outbreak. In addition all human cases, including sporadic cases as well as cases involved in outbreaks are notifiable to the MSIS. This comprises laboratory-confirmed cases of salmonellosis, campylobacteriosis and other foodborne and zoonotic infections. Selected information on present and historical cases is made available for health personnel, the NFSAs and the general public on the Internet (www.msis.no), and is updated on a daily basis. Each month, an overview of notified outbreaks is published.

The mission team went through a practical example (see chapter 5.2) in which the NFSAs district officers and a local municipality cooperated well in the management of a foodborne outbreak.

Conclusions

The Norwegian competent authorities demonstrated that epidemiological investigation of food-borne outbreaks is performed in compliance with the legislative requirements.

5.7 *Salmonella* national control plans

Legal Requirements

For breeding flocks

Regulation (EC) No 2160/2003 outlines how targets shall be established for the reduction of the prevalence of zoonoses, including *Salmonella*. The target for breeding hens has been fixed by Regulation (EC) No 200/2010. To achieve the targets, Member States have to implement a *Salmonella* national control plan in breeding flocks, including detailed sampling rules both for the food business operator and for the official services. However, for those Member States whose *Salmonella* national control plan in breeding flocks were approved in line with Regulation (EC) No 1003/2005, the provisions contained in the Annex of this Regulation are still applicable.

For laying hens

Regulation (EC) No 2160/2003 and Regulation (EC) No 517/2011 lay down rules for the *Salmonella* national control plan in the laying hens' population of the Member States.

For broilers

Regulation (EC) No 2160/2003 and Regulation (EC) No 646/2007 set rules for the *Salmonella* national control plan in the broiler population of the Member States.

For turkeys

Regulation (EC) No 2160/2003 and Regulation (EC) No 584/2008 set rules for the *Salmonella* national control plan in the turkey population of the Member States.

The EFTA Surveillance Authority Decision of 6 September 2007 (Dec. No: 364/07/COL) approved the provisions related to breeding flocks and laying hens of *Gallus gallus* which were included in the national control plans for the control of *Salmonella* in certain live animals and products of animal origin presented by Norway.

Findings

In Norway, *Salmonella* control plans are compulsory for breeding flocks of *Gallus gallus*, laying hens, broilers, turkeys, swine and cattle. Since swine and cattle are not covered by Regulation (EC) No 2160/2003 the mission team focused particularly on the control plans in breeding flocks of *Gallus gallus*, broilers, laying hens, fattening turkeys and breeding turkeys but gathered also information on the breeding pigs control plan's implementation.

In general both the food business operators and the NFSA demonstrated full awareness of the proper implementation of the *Salmonella* control plans: relevant documentation and sampling materials were available on the spot and the mission team observed that sampling schemes applied on the spot were in compliance with the Norwegian control plans. The Norwegian control plans were confirmed to be more stringent compared to the minimum requirements laid down in EEA legislation e.g.:

- in breeding turkeys holdings the food business operator collects samples every two weeks instead of every three weeks;
- all broilers holdings are submitted to official controls each year (not only at least one flock of broilers on 10% of the holdings with more than 5000 birds);
- the application of sanitary restrictive measures are considered mandatory for all *Salmonella* serovars (not only for *Salmonella* Enteritidis and *Salmonella* Typhimurium) and these measures are applied immediately after the suspicion of a positive result;
- use of vaccines is forbidden at all levels.

The definition of flocks reported in the Norwegian control plans is in compliance with the definition under the EEA legislation, moreover each flock is identified clearly by a unique code. The use of antimicrobials is forbidden as a specific method to control *Salmonella* and the mission team verified that the use of antibiotics occurs very seldom in Norway.

As far as the control plan in turkeys is concerned, the NFSA collects official samples in holdings of breeding turkeys twice a year irrespectively of the age of the birds. According to the plan the two official visits have to be done with a reasonable time in between.

The mission team verified that transport of samples from the farm to the laboratory was properly carried out. Samples are rejected on arrival in the laboratory in case of any problem with the samples as part of the formal procedure in the laboratories visited.

Negative analytical results (no *Salmonella* in the samples) the report is not sent to the food business operator or to the NFSA. The NFSA may download from a database the reports from the NVI laboratories.

In all the district offices visited by the mission team, it was confirmed by the NFSA representatives that no specific training was organised by the competent authorities addressed to the food business operators concerning e.g. the collection of samples. In one district it was explained that the farmer accompanies the NFSA officer when official samples are taken thus providing a practical example of the correct sampling procedure. The NFSA representatives acknowledged the fact that other people working for a farm could be in charge of sampling without having been trained before.

The mission team visited three farms rearing: breeding turkeys in the production phase, broilers and breeding pigs. In all the three farms relevant bio-safety measures were implemented, documentation and sampling materials were available and records were properly kept. Concerning the breeding pigs herd, it was the food business operator's

responsibility to collect samples for *Salmonella* testing in the herd once a year. The sampling protocol consisted in collecting 20 pooled faecal samples in 20 different pens. The herd visited had never experienced a positive finding. Nevertheless both the farm's owners and the NFSA were aware of the sanitary measures in case of *Salmonella* isolation.

Conclusions

The Norwegian *Salmonella* national control plans cover a wider range of species than those considered in the EEA legislation and some specific measures applied in Norway are even stricter than the EEA requirements.

However, concerning breeding turkeys, sampling by the competent authority did not include, at least once a year, all flocks on 10 % of holdings with at least 250 adult breeding turkeys between 30 and 45 weeks of age in accordance with Point 1 (iii) of the Annex to Commission Regulation (EC) No 584/2008.

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

Legal Requirements

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

Findings

The mission team noted that when a designated private laboratory isolates any *Salmonella* serovar, before the result has been confirmed by the NVI/NRL, the food business operator is immediately informed by phone and sanitary restrictive measures are taken. Analytical reports from the laboratory that performed isolation and typing are provided to food business operators as soon as they are available.

Sanitary restrictive measures include destruction of birds and eggs (shell eggs and hatching eggs both incubated and not yet incubated). Shell eggs already on the market are withdrawn. Housing facilities and equipment are cleaned and disinfected and official bacteriological testing of the in-house environment is performed before animal restocking.

The mission team confirmed that the information flow and application of sanitary measures following a *Salmonella* positive sample in 2011 in the broilers farm visited had been rapid, in compliance with the legislation and properly implemented. The NFSA at district level stated that epidemiological investigations following the outbreak were carried out. However, no documentary evidence of this investigation was available. Furthermore, the mission team verified that no guidelines were available at national level on how to perform such an epidemiological investigation.

Conclusions

The Norwegian national control plans specify and implement the control measures to be taken following the detection of zoonoses and zoonotic agents, in particular to protect public health in accordance with the requirements laid down in Article 5 of Regulation (EC) No 2160/2003. However a guide related to the epidemiological enquiry which should follow the detection of positivity for *Salmonella* at farm level was not available, thus leading to subjective and non harmonized interpretations.

5.9 Food and feed safety issues

Legal Requirements

Article 3 of Regulation (EC) No 853/2004 requires Member States to carry out regularly, on a risk basis and with appropriate frequency controls on feed or food businesses.

Article 5 of Regulation (EC) No 853/2004 lays down the general principles concerning the HACCP and Annex II to the same Regulation lays down the general hygiene provisions for all food business operators.

Article 4 of Regulation (EC) No 853/2004 specifies that the competent authority shall carry out official controls in respect of products of animal origin to verify food business operators' compliance with these requirements.

Regulation (EC) No 1831/2003 lays down requirements for feed hygiene. In particular Article 6 states that feed business operators shall put in place, implement and maintain a permanent written procedure or procedures based on the HACCP principles.

Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. In particular Article 7(1) states that the feeding to ruminants of protein derived from animals shall be prohibited.

Findings

The mission team visited a kitchen preparing and catering meals to around 600 hospitalised patients. During the previous mission carried out by the Authority in 2007, the mission team noted that the official controls of the establishment had not included inspections of the whole establishment or an evaluation of the own-checks systems since the start of operation several years before. Furthermore, the findings of the mission team included bad maintenance and non-hygienically procedures, e.g. in relation to storage of unprotected ready to eat products. Corrective actions in relation to the Authority's conclusions were notified by Norway, including follow up in this establishment. In the fall of 2007, a food borne outbreak involved several patients in the hospital and included fatal cases. In January 2008, the management of the kitchen established a list of products barred from being served to patients; the list includes smoked salmon, raw milk products, cured ham etc.

The establishment is registered by the NFSA. According to the risk assessment carried out by the NFSA, the establishment is categorised as level 1 (the highest risk) and should therefore be inspected at least twice a year and the HACCP plan should be audited every second year. The mission team requested information whether any non-compliance had been identified in the previous inspections by the NFSA and whether any of these were still outstanding. The NFSA confirmed that the last inspection was carried out in September 2011 and that the only remark during that inspection was related to storage temperature of refrigerated fish (HACCP plan stated 10°C not 4°C). The last audit of HACCP was carried out by the NFSA in March 2012 with no remarks and the case was closed in May 2012.

Following this, the mission team inspected the facilities accompanied by the NFSA. Several shortcomings, with a degree of gravity from minor (e.g. HACCP plan) to very

serious (general hygienic requirements), which had not been reported by the NFSA, were identified:

HACCP Manual:

- no clear understanding of the meaning of hazard;
- *Salmonella* was included in the list of hazards to be tested for, however no samples were analysed for *Salmonella*;
- *Campylobacter* not included in the list of parameters of the own-checks.

General requirements for food premises:

- poor housekeeping in general and in particular where heavy infestation of flies was identified;
- an operator was washing containers for meals adjacent to clean equipment and tools and nearby an area where meals were prepared at the same time without physical separation.

Specific requirements in rooms where foodstuffs are prepared:

- layout and maintenance not permitting good food hygiene practice, including protection against contamination (e.g. building construction on going using wooden wall which was absorbent, not permitting adequate cleaning and/or disinfection and allowing the shedding of particles into food, overhead ceiling open);
- equipment in contact with food not in sound conditions and not corrosion-resistant;
- absence of adequate facilities for the cleaning, disinfecting and storage of working utensils and equipment;
- wooden table, chair with worn out seat, rusted equipment;

A special remark should be made concerning the discovery, by the mission team, of a freezer room with a considerable quantity of expired frozen products, with unreadable labels or frozen despite the labelling indicated that they should have been kept at the temperature between 0° and 4°C.

Immediate actions were taken on the spot by the NFSA representative. Actions included the suspension of preparation of meals and the destruction of the expired products, of products with unreadable labels and “not to be frozen” products found by the mission team in the freezer room.

The mission team visited a feed mill establishment. The facility had only one production line and produced feedingstuffs for ruminant, pigs, poultry and horses. Fishmeal was incorporated in feedingstuffs for non-ruminants. There was no cleaning procedure in place between production of feedingstuffs for different species. The competent authorities informed the mission team that instructions had been sent from the head office of the NFSA to the district offices that maximum 0.15% of carryover of fishmeal was allowed in feedingstuffs for ruminants.

The mission team identified several inconsistencies in the implementation of the HACCP. The NFSA had not audited the HACCP plan and was consequently not aware of these inconsistencies, namely:

- absence of a blue-print and a flow-chart describing the process;
- no identification of the proper hazards during the process flow;
- no critical control points (e.g. heating temperature for feedingstuffs) had been identified;

- no description of critical limits or corrective measures;
- no description of sampling procedures/frequency/parameters.

During the visit to the facilities the mission team had however the possibility to verify a good housekeeping and a computerised system utilised to survey the process.

Finally, the mission team visited a slaughterhouse processing fattening pigs, sows and boars. The NFSA officer in charge explained the procedures in place concerning the collection of samples in the context of the national control plan for *Salmonella* in swine (collection of lymph nodes and carcasses' swabs). The following was noted:

- the written sampling procedure contained no information on how to perform sampling from a hygienically point of view. The official NFSA veterinarian who performed the simulation of swabs sampling from the carcasses of pigs took samples touching first the external side of the carcasses (skin) followed by the internal part, thus allowing contamination of the exposed meat;
- the entrance (and exit) to the slaughterhouse facilities allowed cross flow and possible cross contamination of persons wearing protective clothes (clean or dirty);
- in the HACCP of the company, the step related to the collection of samples for *Salmonella* carried out by the NFSA was not mentioned.

Conclusions

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

The provisions laid down in Article 6 of Regulation (EC) No 1831/2003 were not fulfilled in the feed mill visited.

The competent authority carrying out official controls in respect of products of animal origin according to Article 4 of Regulation (EC) No 853/2004 had not identified all non-compliance in the slaughterhouse visited.

The use of fishmeal in ruminant feedingstuffs is prohibited according to Article 7(1) of Regulation (EC) No 1831/2003.

6 Final meeting

A final meeting was held with representatives of the NFSA, the Ministry of Health and Care Service, the NVI and the NIPH in Oslo on Wednesday 20 June 2012. At this meeting, the mission team presented its main findings and some preliminary conclusions of the mission. At the meeting the mission team also explained that, based on a more detailed assessment of the information received during the mission, additional conclusions and recommendations could be included in the report.

The NFSA did not have any objections to the observations made and the preliminary conclusions presented. In particular, the NFSA handed to the mission team copy of the relevant documentation related to the actions immediately implemented in the kitchen producing and catering meals to vulnerable hospitalised people as described in chapter 5.9.

7 Recommendations

Norway should notify the Authority, within two months of receiving the final report, by way of written evidence, of the corrective actions taken and a plan for corrective measures and actions, including a timetable for completion of measures still outstanding, relevant to all the recommendations hereunder. The Authority should also be kept informed of the completion of the measures included in the timetable.

No	Recommendation
<i>Designation of competent authorities and competence of their staff, coordination and cooperation between and within competent authorities, enforcement measures</i>	
1	Norway should ensure compliance with Article 4(2)(c) of Regulation (EC) No 882/2004 concerning access to suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively.
2	Norway should ensure that enforcement measures and sanctions are used in compliance with Articles 54 and 55 of Regulation (EC) No 882/2004, in particular considering the operator's past record with regard to non-compliance.
3	Norway should ensure that efficient and effective coordination and cooperation between the NFSA and municipal authorities is assured in accordance with Article 4(3) of Regulation (EC) No 882/2004.
<i>Laboratory services</i>	
4	The competent authorities should ensure that national reference laboratories act in accordance with Article 33(2) 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, where appropriate, organize comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing, ensure the dissemination to the competent authorities and official national laboratories of information that the Community reference laboratory supplies, provide scientific and technical assistance to the competent authorities.
<i>Monitoring of zoonosis and zoonotic agents</i>	
5	Norway should ensure that data on the occurrence of zoonoses and zoonotic agents are collected, analysed and published within the effective and continuous cooperation based on free exchange of general information and, where necessary, of specific data between the NFSA and the NVI as required in Article 3(3) of Directive 2003/99/EC.
6	Norway should ensure that the reporting system within the frame of Article 9 of Directive 2003/99/EC collect relevant and comparable data, in particular for zoonotic agents not included in the active surveillance, as required in Article 6 of the same Directive.
<i>Salmonella national control plans</i>	
7	Norway should ensure that sampling carried out by the competent authorities in the context of the <i>Salmonella</i> national control plans are in conformity with the requirements laid down at Point 1(iii) of the Annex to Commission Regulation (EC) No 584/2008 for breeding turkeys.
<i>Food and feed safety issues</i>	

8	The Norwegian competent authorities should ensure that food business operators comply with the general hygiene provisions as laid down in Annex II to Regulation (EC) No 852/2004.
9	The competent authority should ensure that the official controls in respect of products of animal origin are carried out in line with the provisions laid down in Article 4 of Regulation (EC) No 854/2004.
10	The Norwegian competent authority should ensure that the provisions laid down in Article 6 of Regulation (EC) No 1831/2003 concerning procedures based on the HACCP principles are fulfilled in feed business operators' establishments.
11	Norway should ensure that the use of fishmeal in ruminant feedingstuffs is prohibited in line with the provisions laid down in Article 7(1) of Regulation (EC) No 999/2001.

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

AFNOR	<i>Association Française de Normalisation</i> The standards organization of France
Authority	EFTA Surveillance Authority
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
HACCP	Hazards Analysis Critical Control Points
ISO	International Organization for Standardization
MSIS	Norwegian Surveillance System for Communicable Diseases
MSRV	Modified Semi-solid Rappaport Vassiliadis
NFSA	Norwegian Food Safety Authority
NMKL	<i>Nordisk Metodik Komité for Levnedsmidler</i> Nordic Committee on Food Analyses
NVI	Norwegian Veterinary Institute
NIPH	Norwegian Institute of Public Health (<i>Folkehelseinstituttet</i>)

Annex 2 - Other relevant legislation

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

- a) The Act referred to at Point 1.1.11 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, as corrected, amended and adapted to the EEA 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;
- c) the Act referred to at Point 1.2.74 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 98/139/EC laying down certain detailed rules concerning on-the-spot checks in the veterinary field*;
- d) The Act referred to at Point 6.1.16 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs*, as amended;
- e) The Act referred to at Point 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;
- f) 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;
- g) The Act referred to at Point 7.2.23 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2004/564/EC of 20 July 2004 concerning Community reference laboratories for the epidemiology of zoonoses and for salmonella and national reference laboratories for salmonella*;
- h) The Act referred to at Point 7.2.47 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 646/2007 of 12 June 2007 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Community target for the reduction of the prevalence of *Salmonella enteritidis* and *Salmonella typhimurium* in broilers* and repealing Regulation (EC) No 1091/2005, as amended;
- i) The Act referred to at Point 7.2.51 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 584/2008 of 20 June 2008 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Community target for the reduction of the prevalence of *Salmonella enteritidis* and *Salmonella typhimurium* in turkeys*;

- j) The Act referred to at Point 7.2.53 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EU) No 200/2010 of 10 March 2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of Salmonella serotypes in adult breeding flocks of Gallus gallus*, as amended;
- k) The Act referred to at Point 7.2.55 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EU) No 517/2011 of 25 May 2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of certain Salmonella serotypes in laying hens of Gallus gallus* and amending Regulation (EC) No 2160/2003 and Commission Regulation (EU) No 200/2010;

Other:

Decision of the EFTA Surveillance Authority No 364/07/COL of 6 September 2007 to approve the provisions related to breeding flocks and laying hens of Gallus gallus which are included in the national programme for the control of salmonella in certain live animals and products of animal origin presented by Norway.

Annex 3 – Information on production and trade

Information as provided by the NFSA in its reply to the pre-mission document of the Authority. The production numbers below are covered by the annual surveillance- and control plans implemented by the NFSA. In addition there are mandatory controls on Trichinella.

Production ¹		2009 (tons)	2010 (tons)	2011 (tons)
Poultry meat	Domestic	81 737	84 785	84 701
	Intra-EEA trade	533	937	1 019
	Third country trade	415	864	494
Egg	Domestic	58 916	59 900	-
	Intra-EEA trade	854	397	1 490
	Third country trade	0	1	41
Beef	Domestic	84 787	83 508	81 638
	Intra-EEA trade	3 213	718	5 754
	Third country trade	5 261	5 599	5 387
Pork	Domestic	123 623	128 753	130 787
	Intra-EEA trade	2 914	4 033	3 885
	Third country trade	2392	3 598	3 178
Mutton	Domestic	23 927	24 438	23 382
	Intra-EEA trade	59	41	676
	Third country trade	1 243	1 240	907
Game meat ²	Domestic	326	339	272
	Intra-EEA trade	142	171	242
	Third country trade	74	84	60
Feed for food producing land animals	Domestic	1 776 707	1 811 198	1 825 484
	Intra-EEA trade	0	0	0
	Third country trade	0	0	0
Feed for poultry	Domestic	379 353	384 802	388 971
	Intra-EEA trade	0	0	0
	Third country trade	0	0	0

¹ Information on domestic production from Statistics Norway (*Statistisk Sentralbyrå*). Some of their statistics end with the year 2010. Information on trade from Norwegian Agricultural Authority (*Statens Landbruksforvaltning*).

² Statistics Norway have no distinction between farmed game and wild game, and in the statistic where these numbers are drawn from goat meat is also included with game meat in a group called “other meat”.

Annex 4 – Results of the monitoring/control programmes of zoonotic agents referred to in Annex I of Directive 2003/99/EC⁷

		No of samples			No of herds/flocks/establishments tested			No of positive herds/flocks/establishments			Estimated current prevalence
		2009	2010	2011	2009	2010	2011	2009	2010	2011	
Brucellosis	Cattle	45	56	61	35	40	28	0	0	0	0%
	Sheep	26681	8160	13629	816	269	467	0	0	0	0%
	Goat	3124	779	2698	104	25	93	0	0	0	0%
Campylobacteriosis	Poultry (Gallus gallus)	1924	2170	2282	1924	2170	2282	117	110	139	5%
Salmonellosis	Cattle	2441	1854	2246	-	-	-	0	0	10 (7 herds)	0.4%
	Pig										
	- breeder herds	1954	2148	1762	116	117	99	0	0	0	
	- slaughter pigs	2479	2226	2305	-	-	-	0	1	1	< 0.1 %
	Poultry - Gallus gallus										
	- breeders	3618	3575	3556	313	264	266	0	0	0	
	- egg producing	2282	2224	2056	1187	1127	968	0	0	1	
	- meat producing	4243	4549	4664	640	600	590	1	2	2	
	Poultry - turkeys										
	- breeders (flocks)	-	-	-	19	15	17	0	0	0	
- meat producing (flocks)	-	-	-	455	385	208	0	0	1		
Poultry - ducks, geese, quails											
- breeding flocks	-	-	-	8	7	5	0	0	1		
- meat producing (flocks)	-	-	-	455	385	70	0	0	0		
Fresh meat establishments											

⁷ Source: The Norwegian Food Safety Authority, June 2012

	- cattle carcasses	2097	1619	1799	25	24	20	0	0	0	< 0.1 %
	- pig carcasses	2029	1780	2212	21	16	18	0	0	0	< 0.1 %
	- crushed meat/meat	1184	1661	2582	60	53	45	1	0	1	< 0.1 %
	Feedstuffs										
	- feed materials	4424	4716	4802	-	-	-	121	67	68	
	- compound feed terrestrial animals	555	917	472	-	-	-	0	0	0	
	- compound feed fish	2806	1798	865	-	-	-	7	191	30	
	- environmental samples	13193	13385	13344	-	-	-	108	146	129	
Tuberculosis	Deer										
	- farmed	0	1	0	-	-	-	0	0	0	0%
	- wild	0	0	0	-	-	-	0	0	0	0%
Echinococcosis	Fox	396	0	533	-	-	-	0	0	0	0%

Campylobacter poultry: All flocks slaughtered in the period 1 May - 31 October (peak season) are tested four days before slaughter. The estimated current prevalence is the estimated yearly prevalence.

Salmonella poultry: Data for positive are on flock level.

Salmonella turkey - meat producing flocks: For 2009 and 2010, the figures correspond to the number of tested slaughter batches.

Tuberculosis deer: only deer for slaughter with suspect findings are investigated.

Annex 5 – Number of outbreaks / identifications of zoonotic agents in production animals - Norway - years 2009, 2010 and 2011⁸

2009	Cattle	pigs	small ruminants	poultry
<i>Campylobacter jejuni</i>	clin cases ⁹	clin cases	clin cases	117 (6,1 %)
<i>Listeria monocytogenes</i>	4	2	25	
<i>Yersinia pseudotbc.</i>			3	
<i>Toxoplasma gondii</i>			9 (29 %)	
2010	Cattle	pigs	small ruminants	poultry
<i>Campylobacter jejuni</i>				110 (5,1 %)
<i>Listeria moncytogenes</i>	4		60	
<i>Yersinia pseudotbc.</i>			3	
<i>Toxoplasma gondii</i>			23 (46,9 %)	
2011	Cattle	pigs	small ruminants	poultry
<i>Campylobacter jejuni</i>				137 (6,0 %)
<i>Listeria monocytogenes</i>	1		44	
<i>Yersinia pseudotbc.</i>			4	
<i>Toxoplasma gondii</i>			3	
<i>Cysticercus bovis</i>	2			

⁸ Source: The Norwegian Food Safety Authority, May 2012

⁹ clin cases= clinical cases

Annex 6 - Reply from the NFSA to the draft report



**ROYAL NORWEGIAN
MINISTRY OF AGRICULTURE AND FOOD**

EFTA Surveillance Authority
Rue Belliard 35
B-1040 BRUSSELS
Belgium

Your ref
C No 71384 Ev N 641415

Our ref
201101337/ADO-44

Date
31.08.2012

Subject: EFTA Surveillance Authority mission to Norway from 11 to 20 June 2012 regarding application of EEA legislation related to the monitoring and control of zoonotic agents in live animals and products of animal origin with emphasis on Salmonella - draft report

Please find enclosed the Norwegian Food Safety Authority's response to the draft report concerning the above-mentioned mission.

Yours sincerely,


Cathrine Steinland
Acting Deputy Director General


Anne Felde Doser
Adviser

Enclosures: 3

Copy: The Norwegian Ministry of Health and Care Services

Postal address PO Box 8007 Dep 0030 Oslo	Office address Teatergata 9	Telephone +47 22 24 90 90 Org. no.: 972 417 874	Department of Food Policy Telefax +47 22 24 95 59	Our officer Anne Felde Doser +47 22 24 91 39
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EFTA Surveillance Authority
Rue de Belliard 35
B-1040 Brussels

Deres ref:
Vår ref: 2012/82610
Dato: 28.06.2012
Org.nr: 985 399 077

Att: Luca Farina

Statens tilsyn for planter, fisk, dyr og næringsmidler



Mattilsynet

COMMENTS ON THE FACTUAL CONTENT OF THE REPORT

Subject:

EFTA Surveillance Authority mission to Norway from 11 to 20 June 2012 regarding application of EEA legislation related to the monitoring and control of zoonotic agents in live animals and products of animal origin with emphasis on *Salmonella* – draft report.

The Norwegian Food Safety Authority has some comments on the factual content of the report, please see below.

A preliminary plan for corrective measures and actions, including an annexed letter, is attached. Please see two annexes. The process with the action plan is not fulfilled and the time table is not yet settled.

COMMENTS ON THE FACTUAL CONTENT OF THE REPORT

Page 8

At the top of the page.

«The mission team met with representatives of the NIPH who explained that the NIPH is the main coordinator when outbreaks of human diseases occur, also with regard to food poisoning and zoonotic outbreaks.»

This is not quite accurate, please cf. The Outbreak Manual and The Norwegian Veterinary Journal 4/2012 (special number, topic contingency on foodborne diseases): At national outbreaks NIPH is responsible for investigation in the **population**, whereas NFSA is responsible for the investigation in the **food chain**. At local outbreaks the municipal medical officer is responsible for investigation in the population, and NFSA in the food chain.

However, please cf. the formulation at page 16: «At local level, the municipal medical officer has the responsibility to initiate an outbreak investigation. If a national outbreak is detected, the responsibility lies with the NIPH».

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Page 8

At the end of the same paragraph, the last indent.

“... including the **National Reference Laboratory** for Enteropathogenic Bacteria ...”.

This laboratory is not an NRL according to the zoonoses regulation.

Page 10-12

NFSA designated 17 not 27 private local laboratories.

Page 11

The third paragraph, at the start of the paragraph.

Suggestion for amended text is highlighted:

“The mission team confirmed that the NVI/NRL keeps contacts with the CRL by participating in the meetings and in the proficiency testing (both for isolation and serotyping) organised by the CRL with good results. The NVI/NRL does not produce ring trials themselves to evaluate isolation performances of its regional laboratories, but they require that the regional laboratories (and the NRL themselves) take part in the ring trials produced by the Swedish NRL for Salmonella (Nordic ring trials) once a year, and the results from the ring trials are discussed in meetings with the regional laboratories.”

Page 11

The third paragraph, the end of the paragraph.

Suggestion for amended text is highlighted:

“Unsatisfactory results in ring trials in general are discussed in specific regular meetings between NVI/NRL and their regional laboratories. In Salmonella ring trials, only one unsatisfactory result has occurred since the ring trial started a few years back – by the NRL themselves in 2012. This was discussed in a meeting with their regional laboratories, the follow up of this trial is on-going. If unsatisfactory results should occur in regional laboratories, this would be discussed in a specific meeting and followed up according to the Quality Assurance system.”

Page 11

The last paragraph but one, the end of the paragraph.

Suggestion for amended text is highlighted:

“ The representatives of the NVI/NRL also stated that even if the **National Reference Laboratory for Enteropathogenic Bacteria (from humans)** at the NIPH is in charge of performing analysis of strains isolated from humans, it receives as well Salmonella strains isolated by private local laboratories from veterinary matrixes. **There is an agreement between the NIPH and NVI/NRL that Salmonella strains from veterinary matrixes received only by the NIPH should be sent to NVI/NRL from NIPH.**”

Page 12

First paragraph, end of the paragraph (replacing the last sentence).

Suggestion for amended text is highlighted:

“NVI/NRL receives very seldom information concerning the origin of strains from positive samples originating from own checks, even if the strains themselves might be sent from the private local laboratories to the NVI/NRL.”

Page 14

Second paragraph.

Suggestion to amending of description of laboratories. In points (c) and (d). Preferably the term used should be “official laboratories”, not “official national laboratories” (to harmonise with the term “official laboratories” used in (b) in the same paragraph).

Page 14

The last paragraph.

“The NVI is responsible to edit the annual report provided by Norway on trends and sources of zoonoses and zoonotic agents in humans, foodstuffs, animals and feedingstuffs.”

Correct as far as the report in Norwegian language. As regard the **European report** from ECDC and EFSA, NIPH is reporting data directly to ECDC via Tessy, not via NVI.

Page 16

In the middle of the page, the eight line in the paragraph.

«Outbreaks on the national level are also notified through two early warning e-mail addresses at both NIPH and NFSA. The two e-mail boxes are checked frequently throughout every working day.”

Mention of the two 24 hour-open contingency telephons at NIPH and NFSA would have been relevant here. The contingency telephons and e-mail boxes are not only in use by national outbreaks, cf. annex of warning to the agreement of cooperation between NIPH og NFSA – this annex, which regulates warning between national authorities, could also have been mentioned.

Page 16

The paragraph at the top of the page.

Reports are not published jointly by the NFSA and the NIPH. Correct is by NVI and NIPH.

Regards,


Randi Edvardsen
Head of Section

2012 Monitoring and control of zoonotic agents in live animals and products of animal origin with emphasis on Salmonella

**Table 2: Following-up ESA Missions:
- plan for corrective measures and actions**

No	Recommendations/s subject (cf. Final report pp. 29-30)	Findings	Resp. Unit	Corrective measures/ actions	Time aspect	Enclosures
1	Ensure compliance with Article 4(2)(c) of Regulation (EC) No 882/2004 concerning access to suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively.	Compliance with Article 4(2)(c) of Regulation (EC) No 882/2004 could not be ensured, in particular related to knowledge of the HACCP principles, general hygienic requirements, use of enforcement and sanctions. (cf. Draft report p. 9)	SAM	A. training course on HACCP-principles for officials at DO(?) Issue at the regularity training program for officials in meat inspection(?) Professional forum for fresh meat(?) ROs' supervision of their DOs(?) Internal audits(?)	2013(?)	
2	Ensure that enforcement measures and sanctions are used in compliance with Articles 54 and 55 of Regulation (EC) No 882/2004, in particular considering the operator's past record with regard to non-compliance.	Enforcement measures have not been found to be in compliance with Articles 54 and 55 of Regulation (EC) No 882/2004 considering the operator's past record with regard to non-compliance and the absence of measures which should have been effective, proportionate and dissuasive. (cf. Draft report p. 9)	SAM	Guideline on enforcement measures(?) Issue at the regularity training program for officials in meat inspection(?) Professional forum for fresh meat(?) ROs' supervision of their DOs(?) Internal audits(?)	2013(?)	
3	Norway should ensure that efficient and effective coordination and cooperation between the NFSA and municipal authorities is assured in accordance with Article 4(3) of Regulation (EC) No 882/2004.	Efficient and effective coordination and cooperation between the NFSA, the NIPH and certain municipalities was demonstrated in accordance with Article 4(3) of Regulation (EC) No 882/2004. However, the cooperation with a number of municipalities was characterised as "bad" by district offices of the NFSA. Furthermore, the inconsistencies pointed out in relation to the number of municipalities which have signed the agreement of cooperation with the NFSA undermine the reason why this agreement has been conceived. (cf. Draft report p. 9)	SAM/ stab	NFSA will conduct another survey monitoring the cooperation between the District Offices and the Municipal Medical Officers. The results will be discussed with the Norwegian Board of Health Supervision to clarify if the cooperation could be a topic for the County Medical Officers' supervision of the Municipalities.	31.12.2012	

<p>4 The competent authorities should ensure that national reference laboratories act in accordance with Article 33(2) of Regulation (EC) No 853/2004. In particular the national reference laboratories shall coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples, where appropriate, organize comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing, ensure the dissemination to the competent authorities and official national laboratories of information that the Community reference laboratory supplies, (e) providing scientific and technical assistance to the competent authorities for the implementation of coordinated control plans adopted in accordance with Article 53. (cf. Draft report p. 14)</p>	<p>However the lack of full implementation of the provisions laid down in Chapters VI of Directive 2003/99/EC and Regulation (EC) No 2160/2003 and Annex II to Commission Decision 2004/564/EC on the role of the reference laboratories was pointed out; furthermore, inconsistencies in the role of the national reference laboratories according to Article 33(2) of Regulation (EC) No 853/2004 have been noted and in particular with reference to: (b) coordination of the activities of official laboratories responsible for the analysis of samples, (c) organization of comparative tests between the official national laboratories and ensuring an appropriate follow-up of such comparative testing, (d) ensuring the dissemination to the competent authorities and official national laboratories of information that the Community reference laboratory supplies, (e) providing scientific and technical assistance to the competent authorities for the implementation of coordinated control plans adopted in accordance with Article 53. (cf. Draft report p. 14)</p>	<p>STUJ/ stab</p>	<p>(b) NFSA is in a tendering process, and private laboratories will be designated as official laboratories in September 2012. NFSA will invite the laboratories that are analysing official samples to a meeting with NRL. The coordination of activities of the official laboratories and NRL will be on the agenda for this meeting. (c) NFSA will together with NRL give information to the official laboratories concerning comparative tests (d) NFSA will set up a plan on how to ensure the dissemination of information from EU-NRL to NRL and further on to NFSA and the official laboratories. (e) NFSA will inform the official laboratories that are designated to inform NRL about positive results from official samples so that these results may be included in the control plans.</p>	<p>Oct. - Dec. 2012</p>	
<p>5 Norway should ensure that data on the occurrence of zoonoses and zoonotic agents are collected, analysed and published within the effective and continuous cooperation based on free exchange of general information and, where necessary, of specific data between the NFSA and the NVI as required in Article 3(3) of Directive 2003/99/EC.</p>	<p>However shortcomings have been identified in the effective and continuous cooperation based on free exchange of general information and, where necessary, of specific data between the NFSA and the NVI/NRL as required in Article 3(3) of the same Directive. (cf. Draft report p. 15)</p>	<p>STUJ/ stab</p>	<p>To aggregate information of relevant zoonotic agents the DO may ask the FBO in their district to provide an overview (own check laboratory results) of which zoonotic agents that are isolated from their food products. The DO may send this information further to the central level of NFSA and to the relevant NRL.</p>	<p>2013</p>	

<p>6 Norway should ensure that the reporting system within the frame of Article 9 of Directive 2003/99/EC collect relevant and comparable data, in particular for zoonotic agents not included in the active surveillance, as required in Article 6 of the same Directive.</p>	<p>Thus the reporting system within the frame of Article 9 of Directive 2003/99/EC could miss some relevant and comparable data as mentioned in Article 6 of the same Directive concerning results for zoonotic agents not included in the active surveillance (monitoring plans). (cf. Draft report p. 15)</p>	<p>SLD/ SAM</p>	<p>Improvement of the collection of data concerning positive laboratory results of <i>Listeria</i>, <i>Campylobacter</i>, <i>E. coli</i> (others?)</p>		
<p>7 Norway should ensure that sampling carried out by the competent authorities in the context of the <i>Salmonella</i> national control plans are in conformity with the requirements laid down at Point 1(iii) of the Annex to Commission Regulation (EC) No 584/2008 for breeding turkeys.</p>	<p>However, concerning breeding turkeys, sampling by the competent authority did not include, at least once a year, all flocks on 10 % of holdings with at least 250 adult breeding turkeys between 30 and 45 weeks of age in accordance with Point 1(iii) of the Annex to Commission Regulation (EC) No 584/2008. (cf. Draft report p. 18-19)</p>	<p>SLD</p>	<p>The Norwegian surveillance and control program (NOK) sets out the monitoring and control procedures for turkey breeders that NFSA must follow to control the flock prevalence of all <i>salmonella</i> species. According to NOK 2012 the NFSA should carry out sampling twice a year with a reasonable time in between. It was pointed out ESA's draft report a discrepancy between the above mentioned procedure and procedure set out in Point (iii) of the Annex to Commission Regulation (EC) 854/2008. Sampling of turkey breeders should take place between 30 and 45 weeks of age. However our official instruction on sampling frequency (twice a year) and a reasonable time in between occurs most probably during the week 30 and 45. We are aware of the fact that sampling is not quite in accordance with provisions of the regulation. Therefore amendment of the NOK in line with Regulation 854/2008 is considered and will not be implemented in NOK later than 2013.</p>		
<p>8 The Norwegian competent authorities should ensure that food business operators comply with the general hygiene provisions as laid down in Annex II to Regulation (EC) No 852/2004.</p>	<p>The Norwegian competent authorities carried out official controls on a risk basis, in accordance with Article 3 of Regulation (EC) No 882/2004. However, serious infringements of the general hygiene provisions laid down in Annex II to Regulation (EC) No 852/2004 have been identified by the mission team during the visit. (cf. Draft report p. 22)</p>	<p>SOF</p>	<p>First of all we refer to the overall description of our risk based control in chapter 4 of the Multi-Annual National Control Plan (2012-2014). The requirement to have a risk based control is further taken care of by our long term plan for control (2012-2016). Each section in the Head Office in the Department of Control is meant to have risk as the base for determining the frequency of the area in focus. How far each section at the head office has come in detailing this, varies. In addition, we have a risk assessment of our efficacy goals as the base of our priorities as well as our analysis of certain areas which also will include risk assessments. Our data system, MATS, will also be used to support a systematic use of the risk assessments down to the level of the food business operator. This is not yet put into place.</p>	<p>2012 -2013</p>	

9	The competent authority should ensure that the official controls in respect of products of animal origin are carried out in line with the provisions laid down in Article 4 of Regulation (EC) No 854/2004.	The competent authority carrying out official controls in respect of products of animal origin according to Article 4 of Regulation (EC) No 854/2004 had not identified all non-compliance in the slaughterhouse visited. (cf. Draft report p. 22)	SAM	Lay-out and design in the slaughterhouses (i.e. decontamination sites for the staff) possible issue at the regularly training program for officials in meat inspection(?) Professional forum for fresh meat(?) ROs' supervision of their DOs(?) Internal audits(?)	2013(?)
10	The Norwegian competent authority should ensure that the provisions laid down in Article 6 of Regulation (EC) No 1831/2005 concerning procedures based on the HACCP principles are fulfilled in feed business operators' establishments.	The provisions laid down in Article 6 of Regulation (EC) No 1831/2005 were not fulfilled in the feed mill visited. (cf. Draft report p. 22)	SLD	NFSA will give priority to control of feed mill establishments. Improvements of the HACCP in the feed industry and compliance with article 6 of Regulation (EC) 1831/2005 is therefore foreseen.	
11	Norway should ensure that the use of fishmeal in ruminant feedingstuffs is prohibited in line with the provisions laid down in Article 7(1) of Regulation (EC) No 999/2001.	The use of fishmeal in ruminant feedingstuffs is prohibited according to Article 7(1) of Regulation (EC) No 999/2001. (cf. Draft report p. 22)	SLD	Please find enclosed letter	
12					
13					
14					
15					