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Final report

EFTA Surveillance Authority mission to Norway

from 15 to 19 April 2013

regarding the application of EEA legislation related to

Bovine Spongiform Encephalopathy (BSE) epidemio-surveillance

Please note that comments from the Norwegian competent authorities to the draft report and information on the corrective actions already taken and planned by the Norwegian competent authorities are included in Annex 4 in the report and referred to in footnotes in *underlined italic print* in the body of the report.

Executive Summary

This report describes the outcome of a mission carried out by the EFTA Surveillance Authority (the Authority) in Norway from 15 to 19 April 2013.

The objective of the mission was to verify that official controls related to Bovine Spongiform Encephalopathy (BSE) epidemio-surveillance were carried out in compliance with the European Economic Area (EEA) legislation.

Previous related mission on Transmissible Spongiform Encephalopathy's (TSEs) and the feed ban was carried out 31 August to 4 September 2009. Follow up on some of the recommendations from that mission was observed during missions to Norway on animal by-products in September 2010 and mission on feed safety in October 2010. The main outstanding issue is that in Norway the production of ruminant feed may take place in facilities not physically separate from facilities that also produce feed for non-ruminant species containing fishmeal, as long as the two different productions are separated in time. Furthermore, a contamination of the ruminant feed of up to 0,15% of fishmeal is tolerated in Norway. At present, Norway therefore does not fully respect the prohibition of feeding animal protein to ruminants as required by Article 7 of Regulation (EC) No 999/2001.

The current Norwegian monitoring programme for BSE is based on a specific adaptation to Regulation (EC) No 999/2001, allowing Norway to test a random sample of 10,000 healthy slaughtered cattle over 30 months of age per year. Norway has applied for a revision of its annual monitoring programme for BSE.

The shortcomings identified on this mission by the Authority should be fully addressed by Norway and the Norwegian competent authorities. The main needs for improvement were identified in the following areas:

- *The use of the domestic animal database as a tool to implement BSE control measures can be improved and registration of events in the database was seen not always done within the required time limit.*
- *Active BSE surveillance is not fully satisfactory as not all required animals in the relevant sub-populations of bovines are sampled and tested for BSE.*
- *It is not fully ensured that relevant NFSA staff and other stakeholders such as veterinary practitioners, slaughterhouse personnel and animal breeders, keepers and handlers have been given training in the clinical signs relating to BSE.*
- *Organization and procedures to verify the effectiveness of official controls related to BSE monitoring and the feed ban are not fully in place.*
- *The competent authority does not regularly verify the competence of the laboratory carrying out official controls related to the feed ban.*

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

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1 Introduction

The mission took place in Norway from 15 to 19 April 2013. The mission team comprised three inspectors from the EFTA Surveillance Authority (the Authority), a national expert and an observer from the Food and Veterinary Office of the European Commission.

The opening meeting was held in Oslo 15 April 2013 with representatives of the Norwegian Food Safety Authority (NFSA), The Norwegian Veterinary Institute (NVI) and the Ministry of Health and Care services. The mission team confirmed the objectives and the itinerary of the mission and the Norwegian representatives provided additional information to that set out in the reply to the Authority's pre-mission document.

Throughout the mission, the mission team was accompanied by a representative of central NFSA together with representatives of the relevant regional and/or district offices in charge of official controls in the places visited.

The final meeting was held in Oslo on 19 April 2013 with representatives of NFSA, the NVI and the Ministry of Health and Care services.

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.

Meetings with the competent authorities and the mission visits 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 NFSA, NVI and the Ministry of Health and Care services.
	6	Meetings with NFSA officers from six district offices and two regional offices.
Laboratories	2	The NRL for constituents of animal origin in feed and the NRL for TSEs.
Slaughterhouses	3	One of the establishments was receiving emergency slaughtered animals only.
ABP processing plant	1	A private company processing and collecting animal by-products and where sampling was performed by the company employees.
ABP collection centre	1	A private company collecting fallen stock and where sampling for BSE was performed by NFSA staff.
Farm	1	Bovine holding with on farm mixing.

The abbreviations used in the report are listed in Annex 2.

2 Scope and objectives of the mission

The main scope of the mission was the following European Economic Area (EEA) Act and related EEA legislation:

a) The Act referred to at Point 7.1.12 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement.

The main objective of the mission was to assess the Norwegian competent authorities application of the above mentioned legislation with a particular focus on Bovine Spongiform Encephalopathy (BSE) epidemio-surveillance, the identification and traceability of bovine animals insofar as relevant to BSE protective measures, removal and disposal of bovine specified risk material (SRM) and the feed ban, including the control and supervisory measures in place.

This assessment was carried out based on, and related to, the above mentioned legal act and other relevant EEA legislation referred to in Annex 3 to this report. The assessment was also based on Norway's reply to the pre-mission document of the Authority.

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;

c) *Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States,* as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I thereto;

d) Article 45 of *Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I thereto;

e) Article 21(1) of *Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement.

4 Background - Previous missions

The current Norwegian monitoring programme for BSE is based on a specific adaptation of the EEA Agreement to Regulation (EC) No 999/2001, allowing Norway to test a random sample of 10,000 healthy slaughtered cattle over 30 months of age per year[1].

In November 2011 Norway applied to the Authority for a revision of its annual monitoring programme for BSE[2]. With reference to Article 31 of Regulation (EC) No 178/2002 the Authority requested the European Food Safety Authority (EFSA) to provide its scientific and technical assistance concerning Norway's application in April 2012. EFSA has published a report concerning the initial mandate in February 2013[3]. Norway amended its application in December 2012 and applied to stop testing of healthy slaughtered cattle for human consumption. In assessing Norway's amendment to its original application, the Authority has requested EFSA's further scientific and technical assistance with a given deadline for EFSA to reply set to 30 September 2013.

The Authority carried out a mission on Transmissible Spongiform Encephalopathy's (TSE) and the feed ban in Norway 31 August to 4 September 2009. Follow up on some of the recommendations from that mission was done on missions to Norway on animal by-products (ABPs) in September 2010 and on feed safety in October 2010. The main outstanding issue after these missions is that Norway does not fully comply with the feed ban. According to the Feed ban guideline[4], issued by NFSA and provided to the Authority, the production of ruminant feed may take place in facilities not physically separate from facilities that also produce feed for non-ruminant species containing fishmeal, as long as the different productions are separated in time. Furthermore, it is stated in the Feed ban guideline that a contamination of the ruminant feed of up to 0,15% of fishmeal is tolerated. At present, Norway therefore does not respect the prohibition of feeding animal protein to ruminants as required by Article 7 of Regulation (EC) No 999/2001.

The final reports from the above mentioned missions can be found on the Authority's website (www.eftasurv.int).

5 Main findings and conclusions

5.1 Applicable EEA legislation and national 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.

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[1] This adaptation is provided for in Joint Committee Decision no. 95/2008 Article 1(2), and was subsequently inserted into adaptation text point A of point 12 in Part 7.1 of Chapter 1 of Annex I to the EEA Agreement

[2] The application was submitted to the Authority in accordance with Article 6(1b) and Point 7.1 of Chapter A, Part I of Annex III to Regulation 999/2001, as adapted to the EEA Agreement by Protocol 1 thereto

[3] EFSA Journal 2013;11(2):3119

[4] Veileder om fôring av dyr med hensyn til forebygging av, kontroll med og utryddelse av overførbare spongiforme encefalopatier (TSE), available on NFSA's website: http://www.mattilsynet.no/om_mattilsynet/gjeldende_regelverk/veiledere/

Findings

According to information provided by Norway in its reply to the pre-mission document of the Authority, the EEA legislation falling within the scope of this mission has been implemented into the internal Norwegian legal order by several national acts and regulations.

Regulation (EC) No 999/2001 has been transposed into the internal Norwegian legal order by Norwegian Regulation No. 595/2004[5], which entered into force on 1 April 2004 and having its legal basis in several national legal acts. NFSA head office is responsible for issuing the necessary administrative provisions to facilitate the implementation of the Regulation and NFSA district offices are empowered to control compliance and carry out official control in accordance with the provisions in the Regulation and related legislation.

Provisions concerning notification of BSE suspects, fallen stock and imported animals sent for slaughter and legal basis for NFSA district offices to enforce restrictions and control measures are laid down in Norwegian Regulation No. 732/2002[6], which entered into force on 1 August 2002 and having its legal basis in several national legal acts.

Conclusions

The relevant EEA legislation has been made part of the Norwegian legal order, as required by Article 7 of the EEA Agreement.

5.2 Competent Authorities[7]

5.2.1 Designation, coordination and co-operation between competent authorities involved.

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(5) of Regulation (EC) No 882/2004 states that when more than one competent authority or unit within a competent authority is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units and competent authorities.

Article 3(1) of Regulation (EC) No 882/2004 states that Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency.

Article 8(3) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to verify the effectiveness of official controls that they carry out and to ensure that corrective action is taken when needed.

Findings

[5] Forskrift om forebygging av, kontroll med og utryddelse av spongiforme encefalopatier (TSE) av 30. mars 2004 nr. 595

[6] Forskrift om bekjempelse av dyresjukdommer av 27. juni 2002 nr. 732

[7] 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.eftasurv.int/internal-market-affairs/fields-of-work/food-safety/country-profiles/

Part 1 of the country profile for Norway concerning the competent authority system, describes the overall organisation of the Norwegian competent authorities in the areas of food and feed safety, animal health and animal welfare. The competence, organization and management of NFSA and the control system for TSE are described in chapter 3.2 and chapter 4.9 respectively of the Multi-Annual National Control plan for Norway 2011-2014, available on the NFSA website[8].

In general NSFA district offices have the responsibility for implementing TSE controls according to instructions issued by the central NFSA under supervision of NFSA regional offices.

The mission team noted some indications of lack of a harmonized approach of official controls related to BSE between NFSA districts. Some districts visited had taken initiatives that were not seen in other districts. For example, in one district, a letter demanding corrective actions, had been sent out to all farms where discrepancies had been detected between information in the domestic animal database and the population statistics submitted annually by the farmers. Additionally, different practices were observed between districts concerning timing of registration in the domestic animal database in case of fallen stock. In one district this was done when the result of BSE tests was received, in another, it was done at the time of the BSE sampling.

According to information provided by Norway in its reply to the pre-mission document of the Authority, the number of healthy slaughtered animals sampled for BSE has not been according to the annual monitoring program in recent years. Furthermore, the mission team noted, during the mission that not all animals in other sub-populations that should be sampled as a part of active BSE surveillance are sampled (see chapter 5.3.3). The mission team was not provided with evidence that these discrepancies had been addressed by NFSA and it was noted that the central NFSA had not established any notification routines to inform regional or district NFSA offices on possible deviations from the number of samples reported compared to the target(s) set according to the annual BSE sampling program.

NFSA central representatives explained to the mission team that samples according to the official monitoring program for determination of constituents of animal origin in feed are taken randomly from lorries during loading at the feed mills. Therefore the sampling of feed for ruminants for presence of fishmeal above the national tolerance level of 0.15% is not targeted or risk based. The mission team also noted lack of central NFSA guidelines to the district offices on how to handle cases when fishmeal or meat and bone meal (MBM) was detected in official feed samples.

Conclusions

Norway has designated competent authorities responsible for the official controls 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.

[8] *http://www.mattilsynet.no/om_mattilsynet/multiannual_control_plan_norway_2011__2014.8609/BINARY/Multi-Annual%20Control%20Plan%20Norway%202011%20-%202014*
The web-link has been updated in this final report according to remarks made by Norway in its reply to the draft report. (See comments from Norway in Annex 4, page 25)

Efficient and effective coordination and cooperation between the different units within the competent authority involved in official controls as required in Article 4(5) of Regulation (EC) No 882/2004, is largely complied with by Norway although it is not fully ensured that official controls are carried out on a risk basis as required by Article 3(1) of Regulation (EC) No 882/2004.

It is not fully ensured by the competent authority that procedures are in place to verify the effectiveness of official controls that are carried out and that corrective action are taken when needed in accordance with Article 8(3) of Regulation (EC) No 882/2004.[9]

5.2.2 Training of personnel involved in the control system

Legal Requirements

Article 6(a)-(b) of Regulation (EC) No 882/2004 lays down requirements for training of staff performing official controls, to be ensured by the competent authority.

Article 10(1) of Regulation (EC) No 999/2001 states that Member States shall ensure that staff of the competent authority, official veterinarians, veterinary practitioners, slaughterhouse personnel and animal breeders, keepers and handlers have been given training in the clinical signs relating to TSEs.

Findings

According to information provided by NFSA in its reply to the pre-mission document of the Authority, training of NFSA officials or other involved actors specifically addressing BSE has not been organised in recent years although fact sheets and general information on BSE have been readily available for all interested parties for several years. Limited confirmation of specific training of relevant staff end other actors involved in the BSE monitoring program in all districts visited could be provided to the mission team. In relation to ABP the training of relevant NFSA staff is secured through the NFSA National ABP Controls Network. Staff from the central NFSA which attends the EU Better training for Safer Food program subsequently distributes the information gathered to the regional and district level through the ABP network.

In the annual letter of assignment regarding the national monitoring and control programmes which is prepared by the central NFSA, district offices are asked to communicate to farmers and other stakeholders the mandatory notification of BSE. However, limited indication of any training or awareness activities for relevant actors on clinical signs and epidemiology of BSE was observed by the mission team. In one farm visited, it was noted that the responsible farmer had not received any training in the clinical signs relating to BSE and was not aware of any initiatives taken by or on behalf of NFSA to raise awareness on the clinical signs relating to BSE. It shall nevertheless be mentioned that on the farm visited, evidence of close cooperation with the private veterinary services was noted in case of any out of the ordinary symptoms in the holding animals.

The Norwegian Veterinary institute and NFSA have in 2013 prepared a guideline aimed at informing staff on sampling procedures in relation to fallen stock and clinical suspects. The guideline also includes information concerning diagnosis of clinical suspects.

[9] *See comments from Norway in Annex 4 (page 26)*

Conclusions

Training of NFSA staff performing official controls is in general ensured by the competent authority. However it appears that training in the clinical signs relating to BSE is not fully ensured as concerns all NFSA staff, veterinary practitioners, slaughterhouse personnel and animal breeders, keepers and handlers, as required by Article 10(1) of Regulation (EC) No 999/2001.[10]

5.3 BSE epidemio-surveillance

5.3.1 Bovine identification and registration

Legal Requirements

Regulation (EC) No 1760/2000 establishes a system for the identification and registration of bovine animals. The said identification and registration is essential for BSE control measures concerning monitoring and eradication, as outlined in Annex III and Annex VII to Regulation (EC) No 999/2001.

According to Article 7(1) of Regulation (EC) No 1760/2000 animal keepers shall report all movements to and from the holding and all births and deaths of animals on the holding, along with the dates of these events, to the competent authority within a period of between three and seven days of the event occurring.

According to Article 22(1) of Regulation (EC) No 1760/2000 Member States are required to take all the necessary measures to ensure compliance with the provisions of this Regulation.

Findings

The Norwegian Regulation No. 1131/2010[11] describes requirements on registration and identification of bovines in Norway and incorporated Regulation (EC) No 1760/2000 into the Norwegian internal legal order. According to information provided by NFSA in its reply to the pre-mission document of the Authority, 5% of the bovine holdings are annually inspected by NFSA with regard to fulfilment of the requirements in this regulation. Anyone keeping cattle is obliged to register such in the domestic animal database which is an integral part of NFSA's computerized control system. The domestic animal database records the identity, origin, movement and disposal of all cattle. NFSA and other actors, such as animal keepers, slaughterhouse- and dairy organizations, keep the database updated by web based reporting. The NSFA is responsible for the general data maintenance.

Some weaknesses concerning registration and information in the domestic animal database were identified by the mission team. It was noted that when fallen stock older than 24 months is notified to NFSA for pre-approval of collection of this category of animals, information provided by the farmer is not consistently crosschecked by NFSA with information in the domestic animal database before the approval is issued. For fallen stock younger than 24 months, the concerned farmer directly calls the company collecting fallen stock. The mission team noted that the companies visited during the mission collecting fallen stock did not have access to the domestic animal database and therefore could not

[10] *See comments from Norway in Annex 4 (page 26)*

[11] Forskrift om sporbarhet og merking av storfe og storfekjøtt mv av 9. juli 2010 nr. 1131

check if the information provided by the farmers were in accordance with information in the domestic animal database. It was also confirmed by NFSA that there are no technical barriers built in the domestic animal database that prevents farmers from deregistering animals older than 24 months. The mission team noted that NFSA district or regional offices do not cross-check the numbers of fallen stock collected with the number of fallen stock as indicated in the domestic animal database.

The mission team noted that the domestic animal database indicates if a holding is under movement restrictions. However, no warnings are automatically issued to other stakeholders when holdings are placed under restrictions and registration of animal movements is not blocked in the database.

Different routines were observed by the mission team in the various NFSA district offices visited concerning at what point information in the domestic animal database was updated when registering fallen stock, and a delay of status update for this category of animals was observed in some instances surpassing the 7 day limit as required. On a farm visited by the mission team it was noted that some animals sent to slaughter for human consumption were registered as fallen stock in the domestic animal database and some animals in the holding were registered as belonging to the holding where they had been last transferred from and where the notification deadline was not respected. According to information provided by the management in a slaughterhouse receiving emergency slaughtered animals only, the animal status was updated in the domestic animal database at invoicing approximately 2 weeks after receiving the carcass. According to information provided by NFSA, approximately 70% of events are reported into the domestic animal database within the 7 day limit as required.

The system of approving healthy bovines for slaughtering was explained to the mission team by representatives of the establishments visited. Animals were notified for slaughtering electronically by the farmer but the farmer could also call in his notification, e.g. in cases where the animals was not to be found in the domestic animal database. In those cases the slaughterhouse made a provisional booking but demanded that the farmer registered his animals in the domestic animal database prior to slaughter. It was noted by the mission team that when collecting animals for slaughter, the transporter could alter the prepared list of animals to be collected manually in case of addition of animals or a change in the number of animals to be slaughtered. If manually altered lists arrive with the animals, the lairage staff would update the list of animals to be slaughtered.

Conclusions

The system in place in Norway on registration of bovine holdings and the identification of bovine animals in general appears to meet the requirements of the EEA legislation although the use of the domestic animal database as a tool to implement BSE control measures concerning monitoring and eradication, as outlined in Annex III and Annex VII to Regulation (EC) No 999/2001, can be improved.

Compliance with Article 7(1) of Regulation (EC) No 1760/2000 is not fully ensured as the mission team identified several shortcomings concerning the updating of the domestic animal database within the required time limit.[12]

[12] *See comments from Norway in Annex 4 (page 26)*

5.3.2 Passive surveillance and measures following suspicion/confirmation of BSE

Legal Requirements

Article 11 of Regulation (EC) No 999/2001 sets out the requirements for the notification of BSE suspect cases. Article 12 of Regulation (EC) No 999/2001 sets out measures to be taken with respect to suspect animals. Article 13 of Regulation (EC) No 999/2001 sets out measures to be taken following confirmation of the presence of BSE.

Findings

According to information provided by NFSA in its reply to the pre-mission document of the Authority, the central NFSA department of controls has the overall responsibility for the maintenance of TSE control programmes and their implementation. The NSFA district offices, under NFSA regional office supervision, have the responsibility for implementing TSE controls according to issued instructions and standard operational procedures. The Norwegian Regulation No. 732/2002[13] on control of animal diseases transposes several of the requirements laid down in Regulation (EC) No 999/2001 into the Norwegian legal order and establishes the obligation for private veterinary practitioners to notify any clinical suspect animal detected while carrying out veterinary work. It also establishes equivalent obligations for animal keepers, transporters or other relevant persons responsible for animal handling. An action plan in case of suspicion or confirmation of BSE in Norway has been prepared.

According to information provided by NFSA in its reply to the pre-mission document of the Authority, the Norwegian monitoring programme for TSE states that all cattle showing clinical signs of BSE shall be examined and euthanized, irrespective of age, ,on the spot and carcasses brought to an incineration plant after removing the relevant material for diagnostic purposes. Holdings with susceptible animals are subject to movement restrictions.

A case of BSE has never been confirmed in Norway and only three clinical suspect cases have been reported since 2006.

Conclusions

The requirements laid down by Article 11 and 12 of Regulation (EC) No 999/2001 concerning notification of suspect cases and measures to be taken with respect to suspect animals appear to be complied with by the Norwegian competent authorities.

5.3.3 Active surveillance

Legal Requirements

Article 6 of Regulation (EC) No 999/2001 sets out requirements to the monitoring systems of BSE.

Findings

According to information provided by NFSA in its reply to the pre-mission document of the Authority the following sub-populations of bovines should be tested in the context of

[13] Forskrift om bekjempelse av dyresjukdommer av 27. juni 2002 nr. 732

BSE active surveillance in Norway and according to the national surveillance and control programme for BSE in 2012[14]:

- all cattle older than 24 months of age, which have died or been culled, but not slaughtered for human consumption
- all emergency slaughtered cattle older than 24 months
- all cattle older than 24 months, with abnormal findings at ante-mortem examination, rejected for human consumption, or which died at the abattoir or during transport (referred to as ante-mortem animals)
- all slaughtered cattle with unknown age or origin irrespective of age
- all slaughtered imported cattle from any country irrespective of age

In addition a random selection of 10.000 normally slaughtered animals over 30 months of age shall be sampled annually.

The mission team noted that the system for fallen stock collection is in general well organized in Norway. Some NFSA district offices have entered into agreements with rendering plants and collection centres and, in some cases, the latter stands for sampling of fallen stock under NFSA district supervision. According to staff met during mission visits and collecting fallen stock, animals older than 24 months are only collected if NFSA has issued a document confirming the identification of the animals to be collected. The farmer should notify NFSA of fallen stock older than 24 months and, following a confirmation of the age of the animal, NFSA issues the above mentioned document and the carcass will be collected. The mission team noted that no cross checks are carried out by the NFSA to verify that all fallen stock over 24 months of age is notified as such. Finally, the mission team also noted that all animals that were notified directly to the companies visited by the mission team, collecting fallen stock were collected without any assessment of the age performed by the staff of these companies of animals collected. According to information provided by NFSA approximately 40% of fallen stock as indicated in the domestic animal database for 2012 has not been sampled.

A company was visited which collects and processes material of all ABP category types from an area encompassing eleven NFSA districts. In November last year the company and NFSA signed an agreement where sampling of fallen stock was referred to the company collecting fallen stock within a defined area. In the agreement, which was shown to the mission team, reference was made to the different obligations of the involved parties and it was indicated that the company could not be held responsible for any failure of sampling or cases where sampling could not be performed because of autolysis or other reasons for non sampling. In the agreement it was furthermore stated that NFSA was responsible for training of staff performing sampling. It was noted by the mission team that the training of staff involved in the sampling was documented by NFSA. During this visit, as well as during a visit to another collection centre in a different NFSA region, it was noted that not all collected animals older than 24 months were sampled, for example because of autolysis of sampling material or because the sampling material was not accessible due to frost. It was further stated by representatives of both companies visited that animals that could not be identified were not sampled.

The mission team visited an establishment receiving emergency slaughtered animals only. It was noted that animals were not collected unless there was a prior issuing of an emergency slaughter certificate issued by a veterinarian containing information

[14] http://www.vetinst.no/eng/content/view/full/8936/(language)/eng-GB

concerning tentative diagnose and animal identification. The document accompanied the animal when collected and the official veterinarian in the establishment confirmed that the information written in the document corresponded to the ear tag accompanying the animal wrapped in plastic bag attached to the carcass. In that establishment all animals over 24 months of age were sampled.

In another slaughterhouse visited it was noted by the mission team that not all animals with observations at ante mortem inspections over 24 months were sampled. According to information provided by the responsible NFSA veterinarian only animals that showed clinical signs that could be indicative for BSE were sampled. The mission team noted that according to information provided by the NVI, only 7 animals classified as animals with observations at ante mortem inspections, in total for all Norway, had been sampled and tested in 2012.

According to information provided by NFSA, farm slaughtering of cattle is not common in Norway and according to statistics in the domestic animal database approximately 90 % of animals which were registered as slaughtered on farms are less than 30 months of age. The NFSA organizes no sampling in relation to animals that are slaughtered on farms.

Concerning sampling of healthy animals over 30 months of age, different practices were observed by the mission team in relation to the selection of animals to be sampled. In one establishment the three last carcasses on each day of slaughtering were sampled. In another slaughterhouse, sampling of healthy slaughtered animals was not always perceived to be random as bulls slaughtered at the beginning of each day and destined for hot deboning were left out of the sampling plan all together according to information provided by the management. It was noted by the mission team that non identifiable animals were not sampled in the establishments visited.

According to information provided by NFSA in its reply to the pre-mission document of the Authority, healthy slaughtered animals over 30 months of age were excluded from the Norwegian surveillance program for BSE in year 2010[15]. The number of tested animals in this sub-population of animals was 7862 in year 2011 and 8734 in year 2012.

Conclusions

The requirements for BSE monitoring laid down by Article 6 of Regulation (EC) No 999/2001 are not complied with as not all animals of the relevant sub-populations are sampled.[16]

5.4 Specified risk material

Legal Requirements

Article 8 and Annex V to Regulation (EC) No 999/2001 sets out the requirements for removal and disposal of specified risk material (SRM).

[15] *See comment from Norway in its reply to the draft report (Annex 4, page 25)*
Remark from ESA concerning comment:In its reply to the pre mission questionnaire, Norway in its answers to point 3.4 of the questionnaire, included a web-link to NVI annual reports, including the 2011 annual report for the surveillance and control programme for BSE in Norway. According to the second footnote to table 1 on page 4 of the referred to document, healthy slaughtered animals were excluded from the surveillance program in year 2010.
[16] *See comments from Norway in Annex 4 (page 26)*

Article 3(1) of Regulation (EC) No 1774/2002 requires that ABPs and products derived there from shall be disposed of in accordance with that Regulation.

Findings

According to information provided by NFSA in its reply to the pre-mission document of the Authority, removal of SRM is verified as part of general and targeted official controls in the respective establishments. The central NFSA has issued an official guideline on SRM in connection with official controls related to prevention, control and eradication of TSEs. The guideline was adopted in September 2011 and last amended in October 2012, describing in detail relevant provisions aimed at informing NFSA district officers how to perform official controls.

In the slaughterhouses visited the mission team noted active official control systems in place concerning SRM although frequencies of specific SRM controls varied between the establishments based on individual risk assessments. In one slaughterhouse visited SRM controls were seen not performed according to the set frequencies for that establishment.

In general SRM removal and handling was perceived as satisfactory by the mission team, but in one slaughterhouse it was noted that the vertebrae was not removed in those cases when carcasses were delivered back to farmers. The NFSA took immediate actions and all districts were instructed by the central NFSA to ensure that this issue was followed up on in all relevant establishments. The mission team noted that not all carcasses were marked consistently with a blue strip on the label if younger than 30 months. Furthermore, some carcasses that were marked as containing SRM were observed marked with a blue strip on the same label as well. Carcasses without any marking indicating their SRM status were also spotted by the mission team.

Conclusions

The requirements of Article 8 and Annex V to Regulation (EC) No 999/2001 are for the most part complied with, however some discrepancies were observed regarding labeling of carcasses and the removal of SRM when carcasses were returned to farmers.

5.5 Feed ban

Legal Requirements

Article 7 of Regulation (EC) No 999/2001 prohibits the feeding of products of animal origin to farmed animals in accordance with the conditions set out in its Annex IV, requiring competent authorities to carry out checks throughout the chain in order to control compliance with that Regulation. The principles for the organization of these controls are laid down in Article 3 of Regulation (EC) No 882/2004.

Regulation (EC) No 181/2006 lays down the requirements concerning organic fertilizers and soil improvers.

Findings

In Norway, the production of ruminant feed may take place in facilities not physically separate from facilities that also produce feed for non-ruminant species containing fishmeal, as long as the different productions are separated in time. Furthermore, a

contamination of the ruminant feed of up to 0,15% of fishmeal is tolerated in Norway (see chapter 4)

According to information provided by the NFSA in its reply to the pre-mission document of the Authority, it is the NFSA which is the sole responsible body for feed ban monitoring planning and risk analysis. The mission team noted that the Norwegian feed ban monitoring program for constituents of animal origin only includes sampling of feed domestically produced for land animals. All consignments of imported fishmeal are tested for the presence of meat and bone meal (MBM) according to information provided by the NFSA. The number of feed samples to be analyzed for constituents of animal origin in 2011 and 2012, as part of official controls according to the NFSA annual monitoring plan for feed for land animals, are presented in table 2.

Table 2: Number of official feed samples to be analyzed in 2011 and 2012
(Type of analyzes indicated in parenthesis)

Feed type:	Year / No of samples	
	2011	2012
Ruminant feed (MBM and fishmeal)	60	40
Swine feed (MBM)	30	10
Poultry feed (MBM)	30	10
Fish meal (MBM)	10	-

Sampling for the presence of MBM in fishmeal was not included in the 2012 annual monitoring plan as presented to the Authority. All official sampling is done by NFSA staff and all official samples are analyzed at the visited National Reference Laboratory (NRL).

It was noted that the NRL for analysis of presence of constituents of animal origin in feed is not allowed to inform NFSA directly of positive results in private samples. NFSA has in March 2013 updated the Feed ban guideline to include the obligation for the respective companies to report to the respective NFSA district office any private sample results above the Norwegian set limit of carryover of fish meal, including corrective measures taken. It was described by NFSA central and district representatives that the only possibility to check if positive samples were not reported was through regular inspections of feed businesses. The mission team noted limited focus on this issue in inspection reports seen and it was indicated by NFSA that it is not consistently checked if feed businesses sampling is targeted. No instructions or guidelines could be provided concerning actions to be taken by NFSA in cases when fishmeal was detected above the set limit of 0.15%. No evidence of NFSA enforcing the limit of 0.15 % could be presented to the mission team (see also chapter 5.2.1).

According to information provided by NFSA in its reply to the pre-mission document of the Authority, all organic fertilizers and soil improvers must be registered prior to import and/or marketing in Norway. Most of the products are marketed as organic fertilizers, the remaining products are marketed as soil improvers/growing media.

According to information provided by NFSA in its reply to the pre-mission document of the Authority, imports of MBM have been prohibited in Norway since January 2001 unless destined for pet food or fur animal feed. The feed industry supplies NFSA regularly with information concerning farmers receiving MBM to be used as fertilizer. A list of recipients of MBM is distributed to NFSA district offices and is used to target controls on farms concerning proper storage, use and record keeping. The mission team was provided

with evidence that the list is used to target such farms, and that sampling was conducted for testing of the presence of MBM in feed at such farms.

Conclusions

Full compliance with the feed ban as laid down in Article 7(1) and Annex IV to Regulation (EC) No 999/2001, is not ensured insofar as Norway allows production of ruminant feed in facilities not physically separate from facilities that also produce feed for non-ruminant species containing fishmeal, and in Norway fishmeal contamination of ruminant feed of up to 0,15% is tolerated.[17]

5.6 Laboratory services

5.6.1 Sampling and laboratory testing for BSE

Legal Requirements

Article 19(1) and Chapter A of Annex X to Regulation (EC) No 999/2001 sets out some of the required functions and duties of national reference laboratories for BSE. Article 20(1) and Chapter C of Annex X to the same Regulation lay down the requirements for sampling and laboratory testing for the presence of BSE.

Findings

According to information provided by NFSA in its reply to the pre-mission document of the Authority, The Norwegian Veterinary Institute (NVI) is the National Reference Laboratory (NRL) for TSE. BSE samples are analysed in two NVI laboratories and both laboratories are accredited, and checked by the Norwegian body for accreditation annually. They also participate in annual ring trials for the tests used, organised by the respective European Union Reference Laboratories (EURLs). Reports from participation in ring trials were provided to the mission team for the years 2011 and 2012, with good performance reported.

An ELISA test, TeSeE from Bio-Rad, is used for detection of PrPSc in cattle. Positive samples are analysed further by Western-blotting in one of the NVI laboratories, and that laboratory participates in the annual ring trials for the method used for BSE testing. It was noted by the mission team that laboratory staff regularly attends relevant meetings organised by the EURL.

An updated agreement on the cooperation between NFSA and the NVI was observed by the mission team, signed in January 2013. The agreement includes a description of the NVI's responsibilities as an NRL. The NRL reports monthly to NFSA concerning the progress in sampling and will also report to the relevant NFSA district office if samples received are unsuitable for analysis. According to the NVI, the central NFSA has the responsibility of ensuring that a sufficient number of samples are collected and sent to the NVI. It was noted by the mission team that NVI does not have access to the domestic animal database but according to a staff member of the NVI, access has been requested.

[17] *See comments from Norway in Annex 4 (page 26)*

Conclusions

NFSA has designated a NRL for TSE and the designated NRL appears to carry out analyses of samples taken during official controls on BSE in line with Article 20(1) and Chapter C of Annex X to Regulation (EC) No 999/2001.

5.6.2 Sampling and laboratory testing for determination of constituents of animal origin[18]

Legal Requirements

Regulation (EC) No 152/2009 sets out the analytical method for the determination of constituents of animal origin for the official control of feeding stuffs.

Point F of Annex IV to Regulation (EC) No 999/2001 requires competent authorities to verify, on a regular basis, the competence of laboratories carrying out analyses for official controls on the total feed ban, in particular by evaluating the results of ring trials.

Findings

The mission team visited the designated Norwegian NRL for analysis of constituents of animal origin in feed. An updated contract between the laboratory and NFSA has recently been signed. The laboratory is accredited according to the ISO standard 17025 by the Norwegian body for accreditation and participates regularly in EURL ring trials. The laboratory uses a microscopic method although the method is not accredited.

The total number of feed samples analyzed for MBM and fish meal in 2011 and 2012, according to information provided by the laboratory management, are presented in table 3.

Table 3: Number of feed samples analyzed for MBM and fish meal in 2011 and 2012 (number of official samples thereof in parenthesis)

Year	Total MBM	Total Fish meal
2011	229 (131)	286 (127)
2012	204 (99)	224 (73)

According to information provided by the management, if fish meal is detected in a sample of feed for ruminants, the sample is analyzed for further estimation of approximate content according to an in-house calibration curve based on addition of fish meal with 8 % content of bone as described by the management. The laboratory provided information concerning the calibration curve but no baseline study of the average composition of Norwegian fishmeal could be provided.

According to information provided by NFSA in its reply to the pre-mission document of the Authority, for samples taken in 2011 and 2012 in which the presence of fish meal was detected, the results of analysis were reported with different quantification units indicated for presence of fishmeal found (below 0,15% / approx. 0,2% / between 0,15 and 0,5% / up to 0,5%). When going through examples of reports of analyses it was noted that there was no reference made to the method used in the analytical reports issued. It was further noticed by the mission team that it was indicated in one report, addressed to a private company, that the method used was not accredited. This was not indicated in the reports of

[18] *See comment from Norway in its reply to the draft report (Annex 4, page 28)*

analyses seen and addressed to NFSA. It was also noted that these reports did not contain the laboratory accreditation logo.

It was noted by the mission team that ring trial results indicated some under performance by the laboratory and that NFSA does not verify on a regular basis the competence of the laboratory, nor does it evaluate the results of ring trials regularly.

Conclusions

Norway has designated a NRL for the determination of constituents of animal origin and the designated NRL carries out analyses based on the analytical methods set out in Regulation (EC) No 152/2009. However, the method used is not accredited and expression of results seen was not fully in line with the requirements of Annex III (C)(3) of Regulation (EC) No 152/2009.

Evidence was found of under performance by the NRL in EURL organized ring trials, and verification on a regular basis by the competent authority of the competences of the laboratory for controls on the total feed ban, including evaluation of results of ring trials, were not conducted, as required by point III.F of Annex IV to Regulation (EC) No 999/2001.

6 Final meeting

A final meeting was held on 19 April in Oslo with representatives from NFSA, the NVI and the Ministry of Health and Care services. 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 could be included in the report.

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
1	Norway should ensure that official controls within the scope of this mission are carried out on a risk basis as required by Article 3(1) of Regulation (EC) No 882/2004 and also ensure that procedures are in place to verify the effectiveness of official controls carried out, and that corrective action is taken when needed as required by Article 8(3) of Regulation (EC) No 882/2004.
2	Norway should ensure that relevant NFSA staff, veterinary practitioners, slaughterhouse personnel and animal breeders, keepers and handlers are given training in the clinical signs relating to BSE, as required by Article 10(1) of Regulation (EC) No 999/2001.

3	Norway should ensure that the registration of events in the domestic animal database is performed within the time limits laid down in Article 7(1) of Regulation (EC) No 1760/2000.
4	Norway should ensure that the requirements for BSE monitoring laid down in Article 6 of Regulation (EC) No 999/2001 are complied with as regards sampling and testing of fallen stock, animals with observations at ante mortem inspection and also that 10.000 healthy slaughtered animals older than 30 months of age are sampled in accordance with Norway's current adaptation to Regulation (EC) No 999/2001, as provided for in Joint Committee Decision no. 95/2008 Article 1(2).
5	Norway should ensure full compliance with Article 7(1) and all conditions set out in Annex IV to Regulation (EC) No 999/2001, in particular points I(b) and II(B) thereof, ensuring that that the ban on feed containing fishmeal to ruminants is fully respected.
6	Norway should ensure that the competence of laboratories carrying out official controls related to the feed ban, in particular by evaluating the results of ring trials, is verified on a regular basis as required by point III.F of Annex IV to Regulation (EC) No 999/2001.

Annex 1 - BSE epidemio-surveillance data for Norway (2011 / 2012)[19]

HEALTHY SLAUGHTERED ANIMAL						
	> 30 months					
	Healthy slaughter					
	2011			2012		
Region	ampled anima	Tested	Positives	ampled anima	Tested	Positives
Finnmark og Troms	398	398	0	410	410	0
Nordland	544	543	0	568	568	0
Trøndelag, Møre-og Romsdal	1919	1915	0	2315	2310	0
Hordaland, Sogn og Fjordane	790	790	0	810	810	0
Rogaland og Agder	2034	2031	0	2096	2093	0
Buskerud, Vestfold og Telemark	904	896	0	974	972	0
Oslo, Akershus og Østfold	401	401	0	514	514	0
Hedmark og Oppland	888	888	0	1057	1057	0
Total national	7878	7862	0	8744	8734	0

EMERGENCY SLAUGHTERED ANIMALS						
	> 24 months					
	Emergency slaughtered					
	2011			2012		
Region	ampled anima	Tested	Positives	ampled anima	Tested	Positives
Finnmark og Troms	203	202	0	216	216	0
Nordland	474	471	0	438	438	0
Trøndelag, Møre-og Romsdal	2416	2408	0	2120	2117	0
Hordaland, Sogn og Fjordane	490	490	0	479	478	0
Rogaland og Agder	1502	1491	0	1695	1683	0
Buskerud, Vestfold og Telemark	407	407	0	280	280	0
Oslo, Akershus og Østfold	498	497	0	422	420	0
Hedmark og Oppland	1251	1250	0	1175	1175	0
Unknown region	0	0	0	16	16	0
Total national	7241	7216	0	6841	6823	0

FOUND SICK AT ANTE MORTEM						
	> 24 months					
	Found sick at ante mortem					
	2011			2012		
Region	ampled anima	Tested	Positives	ampled anima	Tested	Positives
Finnmark og Troms	0	0	0	1	1	0
Nordland	2	2	0	0	0	0
Trøndelag, Møre-og Romsdal	13	13	0	5	5	0
Hordaland, Sogn og Fjordane	5	5	0	0	0	0
Rogaland og Agder	2	2	0	1	1	0
Buskerud, Vestfold og Telemark	0	0	0	0	0	0
Oslo, Akershus og Østfold	0	0	0	0	0	0
Hedmark og Oppland	1	1	0	0	0	0
Total national	23	23	0	7	7	0

FALLEN STOCK						
	> 24 months					
	Fallen stock					
	2011			2012		
Region	ampled anima	Tested	Positives	ampled anima	Tested	Positives
Finnmark og Troms	92	90	0	100	94	0
Nordland	155	147	0	169	162	0
Trøndelag, Møre-og Romsdal	1087	1054	0	1092	1039	0
Hordaland, Sogn og Fjordane	204	195	0	218	206	0
Rogaland og Agder	781	714	0	705	656	0
Buskerud, Vestfold og Telemark	205	193	0	195	190	0
Oslo, Akershus og Østfold	181	176	0	183	172	0
Hedmark og Oppland	367	347	0	251	238	0
Unknown region	6	5	0	22	20	0
Total national	3078	2921	0	2935	2777	0

[19] According to information provided by NFSA in its reply to the pre-mission document of the Authority

Annex 2 - List of abbreviations and terms used in the report

ABP	Animal by-product as defined in Article 2 of Regulation (EC) No 1774/2002
Authority	EFTA Surveillance Authority
BSE	Bovine Spongiform Encephalopathy
Domestic Animal Database	A central database which is an integral part of NFSA's computerized control system and where origin, identity, movement and disposal of all cattle are registered.
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EFSA	European Food Safety Authority
EURL	European Union Reference Laboratory
Feed ban	The prohibition of feeding products of animal origin to farmed animals and exemptions applicable to this ban as laid down in Article 7 and Annex IV of Regulation (EC) No 999/2001
MBM	Meat and bone meal
NFSA	Norwegian Food Safety Authority
NRL	National Reference Laboratory
NVI	Norwegian Veterinary Institute
SRM	Specified risk material as defined in Article 7 and Annex V of Regulation (EC) No 999/2001
TSE	Transmissible Spongiform Encephalopathy

Annex 3 - Other relevant legislation

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

a) The act referred to at Point 7c of Subchapter 1.1 of Chapter I of Annex I to the EEA Agreement *Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97*, as amended

b) The Act referred to at Point 11 of Subchapter 1.1 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, as corrected and amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

c) Act referred to at Point 12 of Subchapter 1.1 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption*, as corrected and amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

d) The Act referred to at Point 9b of Subchapter 7.1 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption*, as corrected and as amended;

e) The Act referred to at Point 12 of Subchapter 7.1 of of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

f) The Act referred to at Point 17 of Subchapter 7.2 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 1326/2001 of 29 June 2001 laying down transitional measures to permit the changeover to the Regulation of the European Parliament and of the Council (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, and amending Annexes VII and XI to that Regulation*, as amended;

g) The Act referred to at Point 40 of Subchapter 7.2 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 1192/2006 of 4 August 2006 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards lists of approved plants in Member States*

h) The Act referred to at Point 43 of Subchapter 7.2 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 79/2005 of 19 January 2005 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the use of milk, milk-based products and milk-derived products, defined as Category 3 material in that Regulation*;

i) The Act referred to at Point 44 Subchapter 7.2 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 181/2006 of 1 February 2006 implementing Regulation (EC) No 1774/2002 as regards organic fertilisers and soil improvers other than manure and amending that Regulation*;

j) The Act referred to at Point 41b of the Section on *Acts of which the EFTA States and the EFTA Surveillance Authority shall take due account* under Chapter 7 of Chapter I to Annex I to the EEA Agreement, *Commission Decision 2009/719/EC of 28 September 2009 authorising certain Member States to revise their annual BSE monitoring programmes*, as amended;

k) The Act referred to in Point 31m of Chapter II of Annex I to the Agreement on the European Economic Area (EEA Agreement), *Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene*, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

l) The Act referred to at Point 31o of Chapter II of Annex I to the EEA Agreement *Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed*, as amended.

Annex 4 - Reply from Norway to the draft report

EFTA Surveillance Authority
Rue Belliard 35,
B-1040 Brussels
Belgia

Att. Karl Karlsson

Your ref: 72977
Our ref: 2013/29392
Date: 18.06.2013
Org.nr: 985 399 077

Norwegian Food Safety Authority

Mattilsynet

Answer to draft report, ESA mission to Norway from 15 to 19 April 2013 regarding application of EEA legislation related to bovine Spongiform Encephalopathy (BSE) epidemio-surveillance

Dear Sir / Madam,

Thank you very much for the draft report. Please find enclosed our answers and comments to the recommendations.

At first, a few comments on the content:

Page 7: the second paragraph under Legal Requirements reference is made to Regulation No 882/2004. The number is misprinted (822 for 882).
Page 8: Internet link in the foot note (8) Multi-Annual National Control Plan for Norway 2011 - 2014
Page 14: The statistics in the pre-mission questionnaire covered 2011 and 2012. Thus, the information concerning the surveillance program for BSE in 2010 must come from another source.

The other answers/comments are in way of a table, with one enclosure, from the laboratory visited, name of laboratory and persons are deleted.

ESA Action plan

Yours Sincerely,

Solfrid Amdal
Head of Section

Copy: Ministry of Agriculture and Food

www.mattilsynet.no

Norwegian Food Safety Authority
Head Office, seksjon for landyrhelse og dyrehelsepersonell

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Action plan BSE ESA mission 15. – 19. April 2013

No	Recommendations/Subjects	Comments/Actions	Time schedule
1	Norway should ensure that official controls within the scope of this mission are carried out on a risk basis as required by Article 3(1) of Regulation (EC) No 882/2004 and also ensure that procedures are in place to verify the effectiveness of official controls carried out, and that corrective action is taken when needed as required by Article 8(3) of Regulation (EC) No 882/2004.	The NFSA control systems are in general risk based. Courses are held in order to update the control staff on new rules, and to ensure uniformity in controls. Effectiveness is ensured/ surveyed through our system Mats, with points for control within the different areas. Some points of control are mandatory; other points can be controlled when the inspector finds it relevant/necessary. The statistics from Mats and other reports allows for having an up to date survey of the different areas. This allows for effective corrective actions when needed. Concerning the progress in the annual sampling of different categories in the BSE monitoring program, we monthly make public reports presenting monthly and accumulated data on the monitoring, see BSE report April 2013. These reports also include regional targets.	
2	Norway should ensure that relevant NFSA staff, veterinary practitioners, slaughterhouse personnel and animal breeders, keepers and handlers are given training in the clinical signs relating to BSE, as required by Article 10(1) of Regulation (EC) No 999/2001.	In April 2013 NFSA issued a brochure concerning scrapie, clinical signs, notification and the results of the surveillance. The brochure was distributed to members of The Norwegian Association of Sheep and Goat Farmers (NSG). A similar brochure might be appropriate concerning BSE and cattle farmers and other stakeholders.	
3	Norway should ensure that the registration of events in the domestic animal database is performed within the time limits laid down in Article 7(1) of Regulation (EC) No 1760/2000.	Improving the domestic animal database is a continuous project. Sometimes additional initiatives are taken, e.g., in 2014 a nationwide campaign related to the Regulation (EC) No 1760/2000 establishing a system for the identification and registration of bovine animals focusing on enforcement measures will be carried out.	
4	Norway should ensure that the requirements for BSE monitoring laid down in Article 6 of Regulation (EC) No 999/2001 are complied with as regards sampling and testing of fallen stock, animals with observations at ante mortem inspection and also that 10.000 healthy slaughtered animals older than 30 months of age are sampled in accordance with Norway's current adaptation to Regulation (EC) No 999/2001, as provided for in Joint Committee Decision no. 95/2008 Article 1(2).	We assume that the reason why we do not achieve the required number of samples taken from healthy slaughter animals might be due to a too low sampling frequency (yearly every tenth animal among a eligible subpopulation of about 100 000 bovines) in the sampling plan described in the central NFSA's instructions to the NFSA district offices. This will be evaluated and if necessary adjusted for in the BSE surveillance instruction for 2014. By the end of April 2013 more than 3400 healthy slaughtered animals have been sampled, see BSE report April 2013. As far as ante mortem animals are concerned, our understanding is that the monitoring requirement applies to animals with ante mortem observations relevant for BSE.	
5	Norway should ensure full compliance with Article 7(1) and all conditions set out in Annex IV to Regulation (EC) No 999/2001, in particular points I(b) and II(B) thereof, ensuring that that the ban on feed containing fishmeal to ruminants is fully respected.	Our guidelines on feeding of animals…. (Veileder om fôring av dyr med hensyn til forebygging av, kontroll med og utryddelse av overførbare spongiforme encefalopatier (TSE)) http://www.mattilsynet.no/om_mattilsynet/gjeldende_regelverk/veiledere/veileder_om_foring_av_dyr_med_hensyn_til_forebygging_av_kontroll_med_og_utryddelse_av_overforbare_spongiforme_encefalopatier_tse.2275/BI	The dot points are put in action. NFSA sharpened routines

		NARY/Veileder%20om%20f%C3%B4ring%20av%20dyr%20med%20hensyn%20til%20forebygging%20av,%20kontroll%20med%20og%20utryddelse%20av%20overf%C3%B8rbare%20spongiforme%20encefalopatier%20-TSE now includes the following elements: • Sampling is to be performed targeted, i.e. from the first batch of feed for ruminants produced after feed with fish meal. • Findings under 0,15 % shall in any case lead to examination of routines and measures in order to prevent cross contamination • All findings, also below 0,15 % of fish meal should be reported to NFSA. The operator shall describe corrective measures that will be/is implemented. The NFSA routines will be altered to include targeted sample taking of official samples. Our administrative routines in case of none compliance will be examined, aiming at sharp and consequent actions.	to be introduced by October 2013
6	Norway should ensure that the competence of laboratories carrying out official controls related to the feed ban, in particular by evaluating the results of ring trials, is verified on a regular basis as required by point III.F of Annex IV to Regulation (EC) No 999/2001.	**Please see comments from laboratory on page 28.**	

Comments to Draft report EFTA Surveilance Authority mission to Norway
June 14th 2013

1) **Page 18 about reporting analytical results:**
The microscopy method is not accredited as ESA mentioned in the report. When MBM/FM by the microscopy method is the sole analysis performed on the received sample, it is correct procedure that the report does not include the laboratory accreditation logo. This procedure implies that the method used in analyzing the sample is not an accredited method. In such cases (as with the NFSA reports), the laboratory is not allowed to use the accreditation logo. The reporting is performed according to rules set by Norwegian Accreditation. This procedure ensures that there is no doubt in the accreditation status of the method. In our understanding, the reporting procedure is undertaken in a correct manner.

   Some samples are analyzed for other components in addition to the MBM/FM using methods that are accredited (content of water, protein, fat, vitamins, minerals etc.). In such cases the report include analytical results performed by methods where the laboratory is accredited in addition to the unaccredited microscopy method (this was the case for the report belonging to a private company). It is correct procedure and according to procedure set by the Norwegian Accreditation to use the accreditation logo on the report in such cases, and the report shall include a footnote if some of the analysis includes results that are performed using unaccredited methods, as was undertaken by the NRL in the report example handed over to the ESA at the day of visit.

2) **Reference to the method in reports:**
The reference to the microscopy method is included in the reporting procedure, this was implemented post ESA visit. In addition, the reporting routines of results regarding MBM and FM in samples, is performed according to the regulations 152/2009, as translated to Norwegian text. As soon as EU 51/2013 is fully implemented in Norwegian legislation later in 2013, the reporting text will be changed according to the phrases used in the commission regulation.

3) **About skilled staff to perform the microscopic analyses:**
The laboratory acknowledge that this particular method has a requisition for experience, training and testing of competence. To date there are two staff members that are trained in the microscopic method for MBM and FM.

   The laboratory participates in ring trials at regular intervals. Since 2007, the laboratory has been tested in a total number of 31 samples through participation in ring trials. A total of 3 samples were not in coherence with the true value in the ring trial, resulting in false positive samples.

   NFSA and NRL perform annual meetings regarding contract work outsourced to the NRL. In order to improve the NFSA control of NRL we suggest the results of ring trials could be a fixed theme during the predetermined annual meeting, and reported in the annual activity reports made by the NRL to the NFSA.