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Final report

EFTA Surveillance Authority's Mission to

Norway

on Feeding stuffs and animal nutrition

from 4 to 13 April 2016

Please note that comments from Norway to factual errors in the draft report are referred to in foot notes in this final report. All comments and information on the corrective actions taken or planned by Norway are included in Annex 3.

Executive Summary

This report describes the outcome of a mission carried out by the EFTA Surveillance Authority in Norway from 4 to 13 April 2016.

The objective of the mission was to verify that official controls related to feed hygiene were carried out in compliance with the European Economic Area (EEA) legislation.

The mission team found that the relevant EEA legislation has been incorporated into the national legislation. The responsible competent authority is designated and has legal powers to enforce this legislation. A risk-based system for official controls ensuring appropriate frequencies of controls has been implemented as required by Article 3 of Regulation (EC) No 882/2004.

The task to carry out official controls in specific areas (sampling of feed material of plant origin at import in harbours) has been delegated to The Norwegian Marine and Cargo Survey (NMCS), an independent, private inspection company. The mission team noted that the NMCS is not accredited in accordance with the relevant European Standard EN as required by Article 5(2)(c) of Regulation (EC) No 882/2004. Also, there had been no supervision from the NFSA to cross check if sampling routines of the NMCS were in accordance with Regulation (EC) No 152/2009. This delegation had at the time of the mission not been notified to the EFTA Surveillance Authority.

There is room for improvement in the execution of certain official controls notably those related to following points:

Official controls did not always ensure that the relevant requirements concerning cross-contamination and homogeneity are fully complied with at feed establishment level. In particular, the official controls do not fully assess whether measures put in place by the feed business operator to minimise cross-contamination are sufficient to comply with the maximum levels of residues of coccidiostats in feed for non-target species.

Although official control revealed non-compliances at feed business operators level the follow-up in order to enforce the requirements of the relevant legislations was in some cases lacking or not timely executed.

It was noted by the mission team that feed business operators did not always notify the activities of each establishment under their control with a view to registration, and that certain types of operators (home compounders) did not consistently notify their activities to the competent authority as required by the legislation

One of the laboratories designated to analyse official samples of feed did not have all analytical methods accredited.

The mission team found it positive that an internal audit on the feed sector was carried out in 2015. The audit report included several findings (non-compliances and observations) related to guidance documents, registration in NFSA database and planning of controls. The internal audit had uncovered many of the findings observed by the mission team. It was explained to the mission team that a meeting was planned in April 2016 in order to address those issues described in the internal audit report.

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.

Table of contents

1 Introduction

The mission took place in Norway from 4 to 13 April 2016. The mission team comprised two inspectors from the EFTA Surveillance Authority (the Authority), a national expert and an observer from the DG Health and Food Safety of the European Commission.

The opening meeting was held with representatives of the Norwegian Food Safety Authority (NFSA), the Ministry of Trade, Industry and Fisheries and the Ministry of Agriculture and Food on 4 April 2016 at the NFSA head office in Oslo. At the meeting, the mission team confirmed the objectives and the itinerary of the mission and the Norwegian representatives provided additional information to that set out in the reply to the Authority's pre-mission document.

Throughout the mission, a representative from the head office of the NFSA accompanied the mission team. In addition, representatives from the regional level of the NFSA participated during meetings to the regional offices and departments and during visits to the different types of establishments.

A final meeting was held at the NFSA head office in Oslo on 13 April 2016, at which the mission team presented its main findings and preliminary conclusions from the mission.

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

2 Scope and objective of the mission

The main scope of the mission was to assess the application by the Norwegian competent authorities of:

- Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene;
- Directive 2002/32/EC of the European Parliament and the Council of 7 May 2002 on undesirable substances in animal feed;
- 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.

The main objective of the mission was to evaluate the control system in place for production and use of feed for farmed animals, in particular by assessing the following main issues:

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

This assessment was carried out based on, and related to, the legislation referred to in Annex 2 to this document. The mission covered all stages of the feed chain from primary production to the use of feed for farmed animals, including traceability.

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 demonstrate the normal control procedures adopted and measures in place to ensure that necessary corrective actions are taken when necessary.

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

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

	Number	Comments
Competent authorities	3	An initial meeting and a final meeting between the mission team and the Norwegian competent authority, the Ministry of Trade, Industry and Fisheries and the Ministry of Agriculture and Food. A sum up meeting with representatives from the head office of the NFSA.
	7	Meetings between the mission team and representatives of the regional offices of the NFSA in three different regions.
	1	Meeting with an officially delegated control body.
Feed mills	3	A feed mill producing feed for ruminants and non-ruminants using both fishmeal and coccidiostats for non-ruminant feed. A feed mill producing feed for non-ruminants using coccidiostats A feed mill producing fish feed non-medicated feed only.
Producer and importer of premixes and additives	1	Production of premixes for complementary feeds, trading of additives to the feed industry, importing additives to use in own production.
Fish meal factory	1	Production of fishmeal and fish oil.
Grain dryer	1	Corn silo dryer using propane gas as heating source.
Home compounder	1	A farm holding ruminants for dairy production and broilers. Using premixes and bread to mix into the feed for the ruminants.
Surplus food recycler	1	An establishment receiving surplus food stuffs (including dairy products) and processing into feed.

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*;

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*.

Legislation referred to in this report is listed in Annex 2.

4 Background

4.1 Previous missions

A previous mission on feed hygiene was carried out in October 2010. The report from that mission included a number of conclusions and recommendations addressed to the Norwegian competent authority aimed at rectifying the shortcomings identified. Subsequently the Norwegian competent authorities notified the Authority of corrective measures taken or planned to be taken. The final report from this mission can be found on the Authority's website (www.eftasurv.int).

The Authority also carried out a mission to Norway on Transmissible Spongiform Encephalopathies and the feed ban in 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, on feed safety in October 2010 and on BSE epidemio-surveillance in April 2013. During these missions it was noted that in Norway the production of ruminant feed was allowed to take place in facilities not physically separate from facilities that also produced feed for non-ruminant species containing fishmeal, as long as the different productions were separated in time. The Authority initiated infringement proceedings in relation to this matter and delivered a reasoned opinion to Norway in December 2013. Norway subsequently informed the Authority that it had changed its practice to comply with Regulation (EC) No 999/2001 and the case was closed in March 2015.

4.2 Information of the feed sector in Norway

According to information provided by the NFSA in its reply to the pre-mission document of the Authority, the yearly production in feed mills in Norway has been around Two million tonnes per year for the last three years. No data was available on production on farms (home compounders), the information received on quantity produced was limited to feed for terrestrial animals[1].

[1] This is due to a misunderstanding. We understood that was clarified during e-mail correspondence before we submitted the information, that the information requested was limited to land animals due to the recent fact finding inspection on aquaculture.

Table 2: Number of operators in the feed sector according to national list of approved and registered feed companies.

Type of operators (main activity)	Number of operators (2015)
Primary producers of feed	41.174
Producers of additives	6
Producers of pre-mixtures of additives	9
Producers of compound feeding stuffs.	36
Home compounders	59
Transporters of feed	315

5 Findings and conclusions

5.1 Legislative and implementing measures

Legal Requirements

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

Findings

According to information provided by the NFSA in its reply to the pre-mission document of the Authority, national Regulations incorporating the relevant EEA legislation into the Norwegian legal order are in place. According to same information the NFSA is responsible for drafting the national Regulations.

The mission team noted some delays in the incorporation into the Norwegian legal order of recent amendments to the EEA legislation relevant for the mission. A letter of formal notice had been issued in one instance (concerning the incorporation of Regulation (EU) No 2015/786, compliance date 1 November 2015). However, at the time of the mission, the relevant national legislation had entered into force.

Conclusions

The relevant EEA legislation concerning the production, use and placing on the market of feed and feed materials had been made part of the Norwegian internal legal order in line with Article 7 of the EEA Agreement.

5.2 Competent authorities

5.2.1 Organisation, planning and implementation of official controls

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for the official controls set out in the Regulation. It also lays down operational criteria for the competent authorities.

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. Controls shall be carried out at any of the stages of the production and processing chain.

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

Article 9 of the said Regulation requires that the competent authority draws up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the feed business operator concerned.

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units.

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 and has the legal powers to carry out official controls and implement measures to ensure feed safety and that feed business operators act in accordance with the EEA legislation. The NFSA operates under the auspice of the Ministry of Trade, Industry and Fisheries, the Ministry of Agriculture and Food and the Ministry of Health and Care Services.

Medicated feed is under the jurisdiction of the Norwegian Medicines Agency. For more information regarding communication and cooperation between the NFSA and the Norwegian Medicine Agency a reference is made to the Authority's report on control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products, available on the Authority's webpage: http://www.eftasurv.int/

The NFSA consists of two administrative levels, the head office and the regional level. The head office's responsibilities are the safe protection of audit data and ensuring the compliance of the regions. The head office acts as an appeal body for decisions made by the regions. The regions plan and carry out official controls of feed business operators.

For more detailed description of the structure and organisation of the NFSA a reference is made to the Authority's mission on fishery products carried out in March 2015, available on the Authority's webpage: http://www.eftasurv.int/

The head office of the NFSA uses the annual Budget Disposal Letter (BDL) and a five year supervision horizon (five year plan) to set priorities for official controls for the regions. The BDL is issued annually, and sets priorities for the following three years.

According to the five year plan for the period 2016 - 2020 the set priorities in the feed sector for 2016 were:

- the legal requirements applying to feed establishments regarding internal controls, in particular regarding undesirable substances, cross contamination and homogenisation;

- the legal requirements applying to feed business establishments receiving animal by-products (ABPs) for processing into feed.

The mission team noted that the BDL for 2015 -2017 only mentions undesirable substances and does not specify cross-contamination and homogenisation as focus areas. A representative of the NFSA head office explained that due to limited space in the tables in the BDL they were not able to include as much information as in the five year plan. It was evidenced that the priorities set out in the above mentioned documents were taken into consideration when developing the inspection plans in the regions visited.
The NFSA head office has issued guidelines for the inspectors according to which establishments are put into risk classes and inspection frequency is determined. Further guidelines have been issued in relation to conduction of official controls in the various types of feed establishments. The inspectors met during the mission were in general aware of the guidance documents and made use of them when conducting official controls. However, the mission team made some observations related to the issuing and the use of guidelines:

- in one of the region the staff of a department was not aware of the guideline for Salmonella in fish feed (Retningslinje for håntering av salmonella i fiskeforvirksomhet). According to an internal audit report from 2015 this particular guideline was not part of the quality manual of the NFSA in 2014 (see also chapter 5.3.6 Internal audits);
- in another region the department visited had moved one type of feed business operators (primary producers of feed, including those mixing feed for the exclusive requirements of their own holdings when using additives or pre-mixtures of additives) from risk class 2 to risk class 4, consequently reducing the inspection frequency from once every two years as a minimum, to inspection on ad hoc basis. No documented justification could be provided for the change of risk classification.

The mission team noted that the policy of the head office was that the NFSA should be more visible. This was done by increasing the number of visits to the establishments by carrying out more inspections and less in-depth audits. According to representatives of the NFSA head office a visit made in order to collect samples can count as an inspection[2]. The inspectors met explained that when collecting samples in the establishments they also included some inspection activities to the establishments.

The mission team noted that official controls were carried out regularly and the planned frequency was in most cases respected. However in one region the mission team was presented with overview of control activities to four of the largest feed business operators under the auspice of the department. It was noted that all the establishments were audited in 2015 however in 2013 and 2014 no audits had been carried out to the establishments. According to the control plan in the department these operators should be audited once and inspected twice every year. Numerous inspections had been carried out in 2013 and 2014 to these establishments.

Reports are drawn up after each inspection/audit, the reports contain the relevant legislation included in the scope of the inspection as well as the main findings and conclusions of the inspection/audit.

[2] This must be a misunderstanding. When inspectors plan a visit to an establishment they must go through a pathway in MATS. They pick a few "kravpunkt" (check points) and conduct a limited inspection together with the sampling during the same visit.

In one of the regions the mission team noted delays in reporting. An audit to a feed mill was carried out in October 2014, however, the report was dated June 2015. In another department in same region a report from an audit to fishmeal factory was issued in March 2016 when the audit was carried out in January 2016.

To ensure coordination and cooperation between the different units within the NFSA there are several mechanisms in place, such as:

- Regular meetings are established with groups of case handlers, legal officers and/or experts, representing all regions. In these meetings, cases of interest are discussed and best practices are identified. Relevant case handlers from the head office participate as observers. The mission team was presented with minutes and agenda from meetings in two of the regions visited. The meetings covered organisation of official controls and sampling of feed and official controls of establishment collecting and using animal by-products in fish feed.
- The head office sends out cases to the regions, accompanied by a questionnaire asking for the assessment of the case and proposals of actions. The results from these case-tests ("ring tests") are evaluated and measures are taken if the results reveal non-conformities. This case-test system is still in development, at the time of the mission no such case-test had been carried out in the feed sector.
- An internal audit was carried out in 2015 with the objective to assess if official controls in the feed sector in Norway were in accordance with applicable legislation, guidelines, internal procedures in particular the instructions given in the BDL of 2014 (see chapter 5.3.6 Internal audits).

Conclusions

The requirements for organisation and responsibilities of competent authorities laid down by Article 4 of Regulation (EC) No 882/2004 are complied with.

Official controls are risk based, carried out regularly and the inspection frequency is in general in accordance with planned arrangement as required in Article 3 of Regulation (EC) No 882/2004.

Official controls are in general carried out in accordance with instructions and guidelines contained in the quality manual of the NFSA in line with the requirements of Article 8 (1) of Regulation (EC) No 882/2004. Reports are drawn up in accordance with Article 9 of Regulation (EC) No 882/2004.

Measures to ensure coordination between the different levels of competent authorities involved in the official controls of production and use of feed are in place, as required by Article 4(3) of Regulation (EC) No 882/2004.

5.2.2 Registration and approval of feed business establishments

Legal Requirements

Article 9 of Regulation (EC) No 183/2005 requires feed business operators to notify to the competent authority of any establishments under their control, active in any of the stages of production, processing, storage, transport or distribution of feed, in the form required by the competent authority with a view to registration, and to provide the competent authority with

up-to-date information on any establishments under their control. The competent authority shall maintain a register or registers of establishments.

Article 10 of the same Regulation requires feed business operators to ensure that establishments under their control and covered by this Regulation are approved by the competent authority where they carry out certain defined activities such as manufacturing or placing on the market of certain feed additives.

Article 19 of Regulation (EC) No 183/2005 requires the competent authority to record in a national list all registered and approved establishments. Approved establishments shall be recorded under an individual identifying number. Furthermore, the Article requires Member States to keep updated the records of establishments in the lists referred to above.

Findings

According to information provided by the NFSA in its reply to the pre-mission document of the Authority, establishments falling under Annex I of Regulation (EC) 183/2005 (primary producers) are registered automatically via the already existing register maintained by the Norwegian Agricultural Authority (Administration of farm subsidies/grants).

Establishments falling under Annex III of the same Regulation (feed users) are registered in the central farm animal register, and in the register of fish-farmers. Feed users feeding animals not entering the food chain falling under Annex III are registered through an NFSA web-based registration system.

Operators falling under Annex II (feed businesses other than at the level of primary production) of the same Regulation are registered through web-based routines at the NFSA. Application for approval is also web based, and is followed up by onsite inspection prior to granting of approval.

For establishments which produce feed for non-ruminants using fish meal, therefore falling under Annex IV of Regulation (EC) No 999/2001, the NFSA has established a specific system for approval. The approval system also applies for other relevant provisions in the before mentioned Annex, such as use/storage of fish meal for non-ruminants on farms also holding ruminants.

The mission team noted that a list of all registered and approved feed business operators (except primary producers of feed) is available at the NFSA webpage. According to the reply to the pre-mission document, the NFSA cannot use the list to identify feed business carrying out certain activities.

- food business operators which supply food stuffs to feed business operators with the intention to recycle into animal feed;
- feed business operators whose activities consists in collecting, handling and/or processing food industry co-products before eventually supplying them as feed to other feed business operators;
- feed business operators drying feed material, as well as heat sources used for drying, were not identified.

For the identification of those above mentioned operators the NFSA relies on local knowledge of the inspectors. In addition, the mission team noted that very few farmers were registered with activities falling under the requirements of Annex II to the Regulation (i.e.

mixing feed for the requirements of their own holding using additives or pre-mixtures of additives).

- In one of the regions, the department visited had 20 farmers registered with activities falling under requirements of Annex II of the Regulation. In other regions visited the number of those farms was lower. In one of the regions the inspectors used information from a local producer of additives and premixes to identify such farmers[3].
- In another region, the department visited had six farmers registered with the activity mixing own feed, the inspectors acknowledged that many of the approximately 500 farmers in the region were of unknown status in that regard. In another department of the region, the inspectors had planned visits to a number of farmers in order to identify the status regarding "Annex I or Annex II registration". The mission team observed an inspection to one such farm (see chapter 5.5.1).

Apart from an initiative in 2010 to encourage farmers to register their activities regarding use of feed materials there had at the time of the mission been no further attempts from the head office to identify those farms. It was explained to mission team that the NFSA relied on local inspectors to have the knowledge and overview of such operators in their region.

In addition the mission team noted that in the official lists of feed establishments, the activity codes allocated to the listed establishments did not always reflect actual activities and that feed establishments in different locations could have the same approval number as long as the ownership of the establishments was the same. It was also noted that individual establishments appeared on the list multiple times in some cases, although activity codes, registration/approval number and address were the same.

Conclusions

Although lists have been drawn up and registers are kept, different establishments under the control of the same operator were not always registered separately. Moreover, it was not ensured that establishments mixing feed for the exclusive requirements of their own holdings using additives or pre-mixtures of additives, notified those activities to the competent authority with a view to be registered. Consequently, full compliance with Article 9 of Regulation (EC) No 183/2005 could not be ensured.

In addition, full compliance with Article 10 of Regulation (EC) No 183/2005 could not be ensured since the codes for the activities allocated to the approved establishments did not always reflect actual activities carried out.

5.2.3 Official controls and action taken in case of non-compliance

Legal Requirements

Article 54 of Regulation (EC) No 882/2004 requires the competent authority upon identifying non-compliances to take action to ensure that the operator remedies the situation. When deciding which 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.

[3] The region reports that they do not use this procedure as a method to identify the farmers, the information is however used to check that they have the correct information/overview regarding the registered primary producers.

Findings

According to information provided by the NFSA in its reply to the pre-mission document of the Authority, legal powers and procedures of the NFSA related to infringement procedures are described in "Virkemiddelbruk ved tilsyn" (administrative provision concerning infringement procedures). This document describes the types of actions which can be taken and sanctions which can be imposed by the competent authority. For more information regarding enforcement measures in place within the NFSA a reference is made to the report on fishery products carried out in 2015.

The mission team visited several types of feed business operators that were subject to official controls by the NFSA. In some of the establishments the mission team noted non-compliances not previously pointed out by the NFSA, as well as non-compliances previously identified by the NFSA without finding evidence for the follow up.

- In one establishment, no tests had been carried out by the operator to determine the effectiveness of the measures in place to prevent cross-contamination with coccidiostats of non-targeted feed (flushing). This had not been pointed out by the NFSA (see also chapter 5.4.3)
- At a surplus food recycling establishment processing foodstuffs into pig feed the lack of risk analyses at the point of reception of raw material was noted by the mission team. The same had been noted in an inspection report from the NFSA in 2012. However no evidence of the subsequent follow-up was seen[4].
- In another region a report from an audit carried out in October 2014 identified serious non-compliances related to sourcing of raw material, lack of homogenisation and lack of preventive measures for cross-contamination of coccidiostats feed and feed for non-target animals. The report was issued June 2015 and at the time of the mission no follow-up audit/inspection had been carried out. The responsible inspector explained the reason for the delay was lack of time.
- One establishment had only been audited once since its approval in 2012. The audit was carried out in January 2016, the audit report was issued in March 2016. The findings in the report described non-compliances related to the update of the HACCP system, flow charts and risk analyses. A deadline was set in June 2016 for the operator to remedy the situation.
- Samples taken to verify effectiveness of measures to prevent cross contamination of coccidiostats to non-target feed were not targeted on the feed produced immediately after the feed with coccidiostats, but were taken on a random basis (see also chapter 5.4.3). The mission team visited a feed manufacturer which was involved in an investigation following the detection of residues of Narasin in eggs. The local authorities considered the measures to prevent cross-contamination acceptable based

[4] The region reports that it is a misunderstanding that the finding from 2012 have not been followed up. An inspection was carried out 16/1/2012. The NFSA made a decision on the owh check system regarding hazard analyses and the point of reception of feed materials. NFSA conducted a new inspection 6/3/12 after the NFSA had received the report from the establishment. A new inspection (6/3/12) concluded that there still was non-compliance. The decision was maintained and a new time limit was given. After a new inspection 4/5/12 the case was closed. During an inspection carried out 25/102013 it was concluded that the establishment had a HACCAP based own check system in place that included the evaluation of the reception of feed materials. During the inspection in 2016 it was observed that the written procedures on reception of feed materials and the control on reception was not updated. No decision was made, but the establishment has forwarded the updated version to NFSA. During the ESA inspection in 2016 the establishment was not able to document the hazard analyses at reception of feed materials. The region will follow up this finding in future inspections.

on results of the operator's own controls and those of the official samples taken randomly from the final products.

In addition to the above the mission team noted that a number of reports were issued up to two months after the inspection took place.

Conclusions

Although non-compliances were identified, described in reports and corrective actions were requested by the competent authority, evidence of follow up were often not found. Therefore full compliance with Article 54 of Regulation (EC) No 882/2004 could not always be ensured.

5.2.4 Resources and training of staff

Article 4(2) of Regulation (EC) No 882/2004 requires the competent authority to ensure that they have access to a sufficient number of suitably qualified and experienced staff.

Article 6 of the said Regulation requires the competent authorities to ensure that staff receives appropriate training, and are kept up-to-date in their competencies.

Findings

According to information provided by the NFSA in its reply to the pre-mission document of the Authority, the NFSA spends 15 full-time equivalents per year on competence development.

In order to establish and maintain supervisory competence the NFSA's School of Supervision (Tilsynsskolen) was established in 2013. The goal is to ensure common basic knowledge for staff carrying out official controls. The School of Supervision now consists of the foundation courses in administrative law, control methodology and communication during inspections.

New inspectors receive their initial training by working together with a trained inspectors during inspections. The NFSA feed inspectors have also attended Better Training for Safer Food (BTSF) courses. The number of staff attending BTSF feed law/feed hygiene courses in recent years is approximately 15. The NFSA head office has annually arranged one or two day courses/meetings on feed legislation and feed inspection. The mission team was presented with agenda and attendant list for courses held in the period 2013 to 2015. These training courses concentrated on: changes in legal requirements, experience of official controls with the aim to identify best practices, the use of guidance documents, audits of HACCP systems in the feed sector. The list of participants included representatives from all of the regions visited.

The mission team noted that the staff met was in general motivated and willing to develop their competence. However, in two of the regions visited some of the inspectors were inexperienced in the feed sector and in one case the set inspection frequency was not respected due to lack of time (resources).

- In one of the departments of a region visited the staff responsible for the feed sector had only recently (one year) been allocated the responsibility for the feed sector. Individual inspectors acknowledged the need for training in the area. The training so far was in the form of inspections with more experienced staff.

- In another department in the same region the inspectors were experienced and able to demonstrate adequate knowledge of the feed legislation and requirements made to feed operators. However, one of the inspectors explained to the mission team that due to work overload it had not been possible to carry out audits to one of the establishments in accordance with planned arrangements. Inspections had regularly been carried out, but only one in-depth audit had been carried out since the approval of the establishment in 2012.
- In another region the mission team noted considerable delays in reporting, period of months passed since audit was carried out until an audit report was issued. The responsible inspector stated that this was due to work overload.

Furthermore the mission team noted that within the NFSA there is no system in place to assess the need for training of the staff.

Conclusions

There are several mechanisms in place and effort is made to meet the requirements for training of the staff of the NFSA, as is required in Articles 4(2) and 6 of Regulation (EC) No 882/2004.

5.2.5 Delegation of specific tasks related to official controls

Legal Requirements

Article 5 of Regulation (EC) No 882/2004 sets out the scope of possible delegation of specific tasks to control bodies, the criteria for delegation, and the minimum criteria which must be met by control bodies. Where such delegation takes place, the delegating competent authority must organise audits or inspections of the control bodies as necessary. The Authority must be notified about any intended delegation.

Findings

According to information provided by the NFSA in its reply to the pre-mission document of the Authority, certain specific tasks have been delegated to the Norwegian Marine and Cargo Survey (NMCS) which is an independent, private inspection company. NMCS performs sampling according to existing international regulations, contractual agreements and customer requests. The NMCS has a management system certification of NS-EN ISO 9001:2008 and is regularly audited against this standard by a Norwegian certification body (Teknologisk Institutt).

The NFSA has an agreement with the NMCS on sampling of feed material of plant origin at import in harbours where NMCS is present, and/or upon request from the local department of the NFSA. According to the agreement, all communication regarding sampling of feed or feed materials takes place via e-mails from NFSA head office, and copies of sampling requests are sent to the relevant region of the NFSA[5].

According to a representative of the NMCS the current number of samples taken by the control body is around 50 samples per year.

[5] There is a small misunderstanding regarding the communication between NFSA and NMCS, the last sentence should be: According to the agreement, all communication regarding sampling of feed or feed materials take place via emails from NFSA regional offices/departments to the head office of NMCS. NMCS head office then notifies their relevant sample taker, for sample taking.

During the mission, the mission team did not have the opportunity to observe sampling activities carried out by the NMCS. However, the mission team visited NMCS main office in Oslo. The following observations were made by the mission team:

- According to the agreement, NMCS is delegated this task according to Article 5 of Regulation 882/2004. The agreement includes a clause stating that NMCS is deemed to fulfil the criteria for accreditation by being certified by the Grain and Feed Trade Association (GAFTA). However, the NMCS is not accredited in accordance with European Standard EN 17020/2012.
- The agreement states that samples shall be taken in line with the requirements of Regulation (EC) No 152/2009. The mission team noted that the NMCS is a member of GAFTA and that samples are taken in accordance with GAFTA Sampling Rules No 124. The NFSA had not carried out any assessment of whether the conditions of the GAFTA Sampling Rules No 124 are in line with the requirements of Regulation (EC) No 152/2009.
- Furthermore the mission team noted that the NFSA had not carried out an assessment of the competency of the staff at the NMCS nor the conditions/validation of the sampling apparatus which in most cases are owned by the feed business operators.

At the time of the mission the Authority had not been notified about the delegation of these task of the NMCS.

Conclusions

Compliance with all requirements of Article 5 of Regulation (EC) No 882/20045 is not ensured since the control body is not accredited in accordance with the relevant European Standard and no audits or inspections of the control body had been organised by the competent authority. Norway has not notified the Authority of the delegation of those specific controls tasks.

5.2.6 Internal audits

Legal Requirements

Article 4(6) of Regulation (EC) No 882/2004 requires competent authorities to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Findings

According to information provided by the NFSA in its reply to the pre-mission document of the Authority, internal audits are conducted by an internal auditor and teams of specialists, selected from the relevant units of the NFSA. Internal audits are carried out yearly in accordance with documented procedures included in the quality management system of the NFSA. These documents are developed taking account of relevant EEA legislation and guidance-documents regarding internal audits.

The reply to the Authority's pre-mission questionnaire included a report from an internal audit that was carried out on the official control of the feed sector in Norway in 2015. Three out of five regions in Norway were subject to the audit. The objective of the audit was to assess if official controls on the feed sector in Norway were in accordance with applicable

legislation, guidelines, internal procedures and international standards. In particular the implementation of the instructions given in the BDL 2014 was assessed.

The overall conclusion of the audit in 2015 was that the instructions of the BDL were generally followed by the regions and their local departments. The shortcomings indicated in the report from the audit were related to the guidance/instruction documents (in the NFSA quality manual), the planning of controls and registration in NFSA database, MATS. It was also stated in the report that the shortcomings were not of systematic nature.

The report includes the following non-compliances (avvik) and observations (merknad):

Non-compliances

- Guidance documents regarding controls of *Salmonella* in fish feed and additives/premixes in feed were not part of the quality manual of the NFSA in 2014.
- Another guideline was published in 2015, but was not part of the quality manual of the NFSA and it was also considered not to follow the NFSA's basic requirements for guidance documents.
- The distribution of guidelines was incidental and some personnel were unsure of the status and version of the documents.

Observations

- Not all departments of the NFSA considered the BDL as a binding document for prioritising official controls.
- Some establishments such as bakeries that provide food to feed establishments are registered in different ways in different departments. Consequently the risk classification and inspection frequencies can vary.
- Some establishments are according to national legislation obliged to notify findings of *Salmonella*. These notifications are handled and archived in a different way in different departments of the NFSA.
- Guideline on production and placing on the market of feeding stuffs is not followed by all departments.
- Different level of involvement from the regional coordinator in planning and follow-up on official controls in different regions.

At the opening meeting a representative of the NFSA head office stated that the results will be reflected in the BDL for 2016 to 2018. Further, it was acknowledged that the general conclusion might be questioned as the report describes systemic failures such as staff in the regions not using the correct guidelines, expressing lack of support and knowledge, uncertainties regarding MATS, planning, how to work with the BDL, etc.

Together with the reply to the pre-mission questionnaire, the NFSA submitted copies of several guidelines for official control on the feed sector. Some of those were lacking signature for approval and it was unclear if all were part of the quality manual of the NFSA. As a consequence the versions and status of the documents was unclear.

The mission team was informed of a meeting planned for 14 April 2016 to discuss the results of the audit in 2015. It was stated at the opening meeting that some guidelines have been updated and that the guideline for *Salmonella* in fish feed had been incorporated in the

quality manual of the NFSA. A guideline had also been issued for the inspectors to address the registration problems in MATS.

The mission team visited a department in a region that was not subject to the audit in 2015. The representatives of that department were not aware of the audit or its results. In the same department the representatives had not been using a guideline that was missing in the NFSA quality manual (guideline for *Salmonella* in fish feed).

Conclusions

An internal audit on the feed sector was carried out in 2015 in line with the requirements of Article 4(6) of Regulation (EC) No 882/2004. The report from the audit described many of the shortcomings also identified by the mission team, and a meeting has been planned to analyse the problems and to take corrective measures.

5.3 Sampling and laboratory analysis

Legal Requirements

Article 12 of Regulation (EC) No 882/2004 requires the competent authority to designate laboratories that may carry out analysis of samples taken during official controls. It also lays down accreditation criteria for laboratories so designated.

Article 33 of the Regulation requires competent authorities to designate national reference laboratories and it further specifies the responsibilities of these laboratories.

Findings

According to information provided by the NFSA in its reply to the pre-mission document of the Authority, three laboratories have been appointed by the NFSA as National Reference Laboratories (NRL) for the feed sector in Norway. The feed relevant parameters analysed by the NRLs were: *Salmonella*, *Listeria monozytogenes*, animal protein in feeding stuffs (microscopic method and PCR method), and additives in feed.

Two of the NRLs are the main laboratories analysing samples taken according to the annual sampling program on feed for food producing land animals. One laboratory is mainly analysing samples taken according to the annual sampling program on fish feeds. The laboratories can use subcontractors upon agreement with NFSA.

The NRLs do not in general arrange ring tests, but participate in ring tests arranged by the EU Reference Laboratory (EURL). The one of the NRL's (Norwegian Veterinary Institute) reports that they have participated in ring tests on *Salmonella* and *Listeria monocytogenes* in 2015 with satisfactory results.

Following a tendering process in 2013 (renewed in 2015) the NFSA made agreements with private laboratories to carry out analysis of official samples. Consequently six private laboratories have been designated to handle all official samples taken in Norway. These six laboratories are accredited (by a Norwegian accreditation body) according to the international standard EN ISO/IEC 17025 on the general requirements for the competence of testing and calibration of laboratories.

One of the official laboratories handles all samples for fish feed. The other five laboratories analyse samples for: additives, heavy metals, animal protein (microscopic method), pesticides, microbiological parameters, mycotoxins in feed for terrestrial animals.

According to the same information one of the laboratories was not using accredited methods for all of their analyses such as: Clostridium perfringens, anaerobe sporiform, E.coli and total bacteria count. All of the methods mentioned are quantitative.

The mission team noted that the head office of NFSA creates sampling plans for feed for terrestrial animals and for fish feed. The sampling plans are issued yearly. The sampling plan for terrestrial animal for 2016 lays down the number of samples and substances to be analysed for different types of feed to be taken in each region. Instructions regarding packing and sending of samples were also included in the sampling plan. The mission team found that the range of analyses planned ensures adequate covering of undesirable/prohibited substances and microorganisms that might be contained in the feed.

The mission team was presented with a report from 2015 on the official sampling of fish feed and results for the year 2014. The main conclusions of the report are outlined below:

- With the exception of one non-compliant feed ingredient containing the pesticide hexachlorobenzene (HCB), the results for 2014 show that all samples of feed and feed ingredients are compliant with regards to the levels of heavy metals and organic contaminants.
- Several of the complete feeds were above the maximum limit with respect to Vitamin D3 and selenium. One complete feed was above the maximum limit with respect to cobalt, copper, manganese, iodine and zinc. Based on current methodologies it is not possible to consider if Vitamin D3, selenium cobalt, copper, manganese, iodine and zinc are added or contributed as part of the feed ingredients.
- No samples examined during 2014 harboured bacteria in the genus *Salmonella*, and the hygienic conditions as measured by the presence of bacteria in the family *Enterobacteriaceae*, were generally satisfactory.

A report on trends and sources of zoonosis for the year 2014 was also presented to the mission team. The report stated that in 2014 16 samples were analysed *Salmonella* positive. The mission team noted this contrast to the before mentioned report, the explanation given in the report was that the positive samples where own samples from feed operators.

It was observed by the mission team that in the regions visited, the sampling plans as laid down by the head office were followed with regard to substances to be analysed and sampling frequency. However, it was also noted that samples taken in order to monitor cross-contamination in feed mills using coccidiostats were taken randomly from final products and were not targeted on the lot produced immediately after the coccidiostats containing feed (see also chapter 5.4.3)[6].

[6] Samples taken according to the sampling plan laid down by the head office are not targeted samples. They are not taken on suspicion, to verify results in the own check system or to demonstrate violation breaks. These samples are taken and analyzed to gather information on certain substances, in order to follow the development in feed production, or to gather information on new substances. The inspectors may take samples for other purposes as part of the official control.

Conclusions

The competent authority has designated laboratories that may carry out the analysis of samples taken during official controls in line with Article 12 of Regulation (EC) No 882/2004, however, full compliance with that Article could not be ensured since not all methods used are accredited.

National Reference Laboratories responsible for parameters related to official controls of feed have been designated a required by Article 33 of Regulation (EC) No 882/2004. Since none of these laboratories were visited during the mission, no further assessment in relation to their compliance were made.

5.4 Compliance with requirements for feed hygiene as laid down in Regulation (EC) No 183/2005

5.4.1 Facilities and equipment

Legal Requirements

Article 5(1) of Regulation (EC) No 183/2005 establishes that for operations at the level of primary production and other associated operations, feed business operators shall comply with the provisions in Annex I to the said Regulation.

Article 5(2) of Regulation (EC) No 183/2005 establishes that for operations other than those referred to in paragraph 1 of the said Article (operations at the level of primary production and other associated operations, including home compounding of feed using additives or pre-mixtures of additives), feed business operators shall comply with the provisions in Annex II to that Regulation; Annex II lays down the requirements for the feed businesses concerned as regards, among others, facilities and equipment.

Findings

In one of the regions the mission team observed an inspection to a farm holding ruminants and poultry (broilers). It was noted by the mission team that this farm had not been inspected before in relation to feed production. The responsible inspector of the NFSA explained that the purpose of the visit was to verify if the farm should be registered as “Annex I or Annex II producer” under Regulation (EC) No 183/2005.

The two animal species at the farm and the correlating feed were held in separate buildings. The broilers were fed with complete feed sourced from an approved feed mill. The feed for the ruminants consisted of own produced silage mixed with additives from an approved feed mill and in addition bread from a local bakery that was also registered as feed supplier. At the time of the mission no information was available on the level of the additives, consequently the inspector was not able to conclude on the spot if the operator should be approved by the competent authority in accordance with Article 10 of Regulation (EC) 183/2005.

In relation to the hygienic conditions at the farm, the mission team noted the presence of non-feed material such as machinery and fertilizers in the area which the bread was stored and processed. Packaging materials was visible in the bread ready to be used as feed material. No attempt were seen to prevent pests or other animals from entering this area. Furthermore there was no clear evidence of the proper use of the mixing machine because no records of these activities were available.

These shortcomings were also noted by the inspector and discussed with the operator on the spot. The mission team had not received the corresponding inspection report at the time of drafting this report[7].

In most of the feed manufacturing establishments visited the mission team found facilities and equipment in adequate hygienic conditions, pest controls were in place and layout of production lines constructed to avoid cross contamination. However, there were some shortcomings identified that had not been addressed by the NFSA in previous inspection reports.

In two establishments located in different regions, producing feed with coccidiostats, the mission team noted that raw material was stored in non-dedicated areas. In one of those establishments, final products were found in the area dedicated for reception and storage of raw material, there was no clear separation visible indicating where which material should be stored. In addition the mission team found unlabelled products both in the storage area as well as in the processing area. In the processing area the mission team noted the presence of non-processing specific material such as wooden and plastic pallets, high production pollution was evident on the floor and machineries.

Conclusions

Official controls generally ensure compliance with the requirements of Article 5 of Regulation (EC) 183/2005.

5.4.2 Risk management, sourcing and traceability

Legal requirements

Article 5(2) of Regulation (EC) No 183/2005 provides that the requirements set out in its Annex II shall be met for operations other than those regarding primary production; these requirements concern, among others, records for traceability.

Article 5(6) of Regulation (EC) No 183/2005 establishes that feed business operators and farmers shall only source and use feed from establishments which are approved or registered in accordance with this Regulation.

Article 6 of Regulation (EC) No 183/2005 requires feed business operators to put in place, implement and maintain, a permanent written procedure or procedures based on the HACCP principles.

Article 7 of the same Regulation requires feed business operators to provide the competent authority with evidence of their compliance with Article 6 and to ensure that any documents describing the procedures developed in accordance with Article 6 are up-to-date at all times.

Findings

The mission team noted that all operators visited had appropriate traceability arrangements in place. Most of the operators met verified the system on a regular basis as part of their internal control procedures. Records concerning incoming and outgoing consignments were available and the operators kept archive samples of incoming and outgoing feed.

[7]The missing report is probably due to communication challenges. We would have provided this report if we have understood that the mission team requested it. We submitted a lot of information during and after the inspection

The mission team noted that official controls include verification of traceability arrangements at feed establishments such as manufacturers of feed additives, feed materials, pre-mixtures, compound feed and feed intermediaries.

Apart from one establishment, HACCP based own check systems were implemented where relevant. HACCP teams were established, the relevant hazards had in most cases been identified, critical limits decided and corrective actions were established. Sampling plans based on HACCP criteria were in place. Furthermore, monitoring and recording requirements were in general satisfactorily implemented.

However the mission team noted some weaknesses that had not been pointed out by the inspectors of the NFSA during official controls.

- In an establishment drying grains the storage of grain in boats which could last for two months in some cases was not included in the HACCP plan.
- In an establishment producing fish meal for the feed industry, the storage of some of the final product took place in another establishment outside the factory (in a different region), and was not part of the HACCP plan. In the same establishment the HACCP plan lacked the procedure for taking samples.
- In two other establishments the mission team noted unlabelled products in storage and processing areas.

The mission team noted that most of the establishments visited sourced their raw material only from approved/registered establishments that were able to provide guarantees of the safety of their products. In a majority of cases these requirements were adequately verified during official controls. However, some shortcomings were detected by the mission team. A surplus food recycler could not provide guarantees from the supplier about the origin of cooking oil and the type of products that the cooking oil had been used for (e.g. animal products or not). In the same establishment a HACCP based system for own-controls was not implemented. Furthermore, there was no risk assessment carried out for incoming raw materials which ranged from: dairy products in form of milk, whey, yogurt and cheese; bread and pastry from a local bakery; potato peelings from the chips industry; used cooking oil and more. Although an inspection report from 2012 pointed out the lack of risk analyses, there had not been any follow-up to enforce the corrective actions[8].

In a feed mill producing feed with coccidiostats, the HACCP plan had not been updated to take into account measures that were put in place to prevent cross-contamination of Narasin to non-targeted feed. The feed mill was also receiving surplus coccidiostats containing feed from the farmers to process into newer batches of feed, however, this process was not included in the HACCP plan.

[8]This is the same establishment and case that is described in Chapter 5.2.3, p 13 and has been followed up according to the description from the region.

Conclusions

Official controls can ensure that requirements concerning traceability laid down by Article 5(2) of Regulation (EC) No 183/2005 and in its Annex II are largely complied with at most feed establishments.

In most establishments, official controls can ensure that feed operators only source feed from registered or approved feed establishments as required by Article 5(6) of Regulation (EC) No 183/2005.

With few exceptions, the official controls on risk management and HACCP based procedures generally ensure that the requirements of Articles 6 and 7 of Regulation (EC) No 183/2005 are met.

5.4.3 Coccidiostats in non-target feed and other undesirable substances

Legal requirements

Article 5(2) of Regulation (EC) No 183/2005 provides that the requirements set out in its Annex II shall be met for operations other than those regarding primary production; these requirements concern, among others, cross-contamination, homogeneity as well as undesirable substances.

Directive 2002/32/EC sets out maximum permitted levels of residues of coccidiostats in non-target feed.

Findings

In one feed mill the risk of cross-contamination of coccidiostats (Narasin and Monensin) in non-target species was managed by considering the first mixer run (approximately 3-4 tonnes) after stopping the addition of coccidiostats, as part of the same batch containing coccidiostats. No further measures had been put in place by the feed business operator to determine the actual level of carry-over in feed for non-target species and to determine the homogeneity of the final products. According to the feed business operator, the usual size of a batch is about 55 tonnes. The inspector in charge of official controls identified the above-mentioned practice as not acceptable during an audit carried out in September 2014. However, the report of the audit was not sent to the operator until June 2015. At the time of the mission no further actions had been taken by the feed business operator to address this shortcoming.

In another feed mill the risk of cross contamination with coccidiostats (Narasin and Monensin) to feed for non-target species was managed by flushing the line with 750 Kg of limestone after the use of the coccidiostats. The flushing batch was then stored and used for batches of feed containing the same coccidiostats. However, no carry-over tests had been carried out to determine the effectiveness of these preventive measures.

The mission team visited a feed manufacturer which was involved in an investigation following the detection of residues of Narasin in eggs sampled in a farm which used feed manufactured by this feed operator. The local authorities carried out a number of controls (an audit and a number of samplings) to address the problem. During the visit the business operator explained to the mission team the measures in place to prevent cross contamination. These consisted in production sequencing and flushing of the line with two charges of corn (800 + 500 Kg). These flushing batches were then stored in dedicated silos and used for

batches of feed containing the same coccidiostats. The local authorities considered such measures acceptable on the basis of the favourable results of the operator's own controls and those of the official samples taken from the final products. However, the mission team noted that the official did not target the samples to the feed produced immediately after the feed containing coccidiostats, rather, these samples had been taken randomly in batches of 30-40 tonnes.

Conclusions

Official controls cannot fully ensure that the relevant requirements laid down by Article 5(2) of Regulation (EC) No 183/2005 and in its Annex II concerning cross-contamination and homogeneity are fully complied with at feed establishment level. In particular, the official controls do not fully assess whether measures put in place by the feed business operator to minimise cross-contamination are sufficient to comply with the maximum levels of residues of coccidiostats in feed for non-target species set out by Directive 2002/32/EC.

5.4.4 Dioxin monitoring

Legal requirements

Article 5(2) of Regulation (EC) No 183/2005 indicates that the requirements set out in its Annex II shall be met for operations other than those regarding primary production; these requirements concern, among others, arrangement for monitoring dioxins in fats, oils or products derived thereof.

Findings

In all the compound feed manufacturers as well as in the fish meal factory visited the mission team noted that animal fats consignments were accompanied by periodic analytical reports for dioxins and dioxin-like PCBs. The mission team checked a number of consignments in the relevant establishments and noted that most of them were linked with an appropriate certificate of analysis of an aggregate sample which always listed the identification-code of every consignment to which the analysis belonged. All analytical reports were not always available on the spot, however, those outstanding were received during the drafting of the report.

In the feed mills visited dioxin monitoring was included in the HACCP plans. The mission team noted that in one of the establishments producing fish meal and fish oil, the sample batches of the final product sometimes exceeded (by 100 Kg) the size limit of 1000 tonnes laid down in Annex II of Regulation (EC) No 183/2005.

Conclusions

In all feed manufacturers visited oils and fats requiring dioxin monitoring were tested either by the suppliers or directly by the feed manufacturers, in general, in line with the requirements laid down by Annex II to Regulation (EC) No 183/2005.

6 Final meeting

A final meeting was held on 13 April 2016 at the NFSA central office in Oslo with representatives from the NFSA, the Ministry of Trade, Industry and Fisheries and the

Ministry of Agriculture and Food. 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 recommendations could be included in the report.

The Norwegian representatives did not indicate any disagreement with the observations and preliminary conclusions presented by the mission team.

7 Recommendations

In order to facilitate the follow-up of the recommendations hereunder, Norway should notify the Authority no later than 9 September 2016, of additional corrective actions planned or taken other than those already indicated in the reply to the draft report of the Authority. In case no additional corrective actions have been planned, the Authority should be kept continuously informed of all changes made to the already notified corrective actions and measures, including changes of the deadlines indicated for completion and also the completion of the measures included in the timetable.

No	Recommendation
1	The competent authority should ensure that when non-compliances are identified and corrective actions are requested, a timely follow up is carried out to the relevant operators in order to remedy the situation as required by Article 54 of Regulation (EC) No 882/2004.
2	The competent authority should ensure that control bodies that have been delegated specific task of official controls are accredited in accordance with the relevant European Standard and that such control bodies are supervised by the competent authority. In addition such delegation should be notified to the Authority as required by Article 5 of Regulation (EC) no 882/20045.
3	The competent authority should ensure that laboratories analysing official samples use only accredited methods for such analyses as required by Article 12 of Regulation (EC) No 882/2004.
4	The competent authority should ensure that all feed establishments are registered or approved according to the activities actually carried out, as required by Articles 9 and 10 of Regulation (EC) No 183/2005. Also, the competent authority should ensure that feed business operators notify the competent authority of any establishment under their control with a view to registration, as required by Article 9(2).
5	The competent authority should ensure that measures put in place by feed business operators to minimise cross-contamination meet the requirements of Article 5(2) of Regulation (EC) No 183/2005 and in its Annex II, and are sufficient to ensure compliance with the maximum levels of residues of coccidiostats in feed for non-target species set out by Directive 2002/32/EC.

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

Authority	EFTA Surveillance Authority
BDL	Budged Disposal Letter
BTSF	A Commission initiative aimed at organising a Community (EU)/EEA training strategy in the areas of food law, feed law.
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EN 17020/2012	The standard specifies requirements for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities.
EN ISO/IEC 17025	The standard specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.
EU	European Union
EURL	European Reference Laboratory
GAFTA	The Grain and Feed Trade Association, a worldwide trade association for the grain and feed industry
Lovdata	Electronic legal database of Norway
MANCP	Single integrated multi annual national control plan
MATS	The operative system for official controls in the NFSA
NFSA	Norwegian Food Safety Authority
NRL	National Reference Laboratory

Annex 2 - Relevant legislation

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

a) The Act referred to at Point 7.1.9b of Chapter I of Annex I to the EEA Agreement, *Commission 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 amended;

b) 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;

c) The Act referred to in Point 1a of Chapter II of Annex I to the EEA Agreement, *Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition*, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

d) The Act referred to at Point 1zq of Chapter II of Annex I to the EEA Agreement, *Commission Regulation (EC) No 1334/2003 of 25 July 2003 amending the conditions for authorisation of a number of additives in feedingstuffs belonging to the group of trace elements*, as corrected and amended;

e) The Act referred to at Point 31aa of Chapter II of Annex I to the EEA Agreement, *Council Directive 98/68/EC of 10 September 1998 laying down the standard document referred to in Article 9(1) of Council Directive 95/53/EC and certain rules for checks at the introduction into the Community of feedingstuffs from third countries*;

f) The Act referred to at Point 31j of Chapter II 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 by the sectoral adaptations referred to in Annex I to that Agreement;

g) The Act referred to at Point 31l of Chapter II of Annex I to the EEA Agreement, *Commission Decision 2006/677/EC of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules*;

h) The Act referred to in Point 31m of Chapter II of Annex I to 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 amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

i) The Act referred to at Point 31n of Chapter II of Annex I to the EEA Agreement, *Commission Decision 2007/363/EC of 21 May 2007 on guidelines to assist Member States in preparing the single integrated multi-annual national control*

plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council;

j) 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 official control of feed*, as amended*;*

k) The Act referred to at Point 33 of Chapter II of Annex I to the EEA Agreement, *Directive 2002/32/EC of the European Parliament and the Council of 7 May 2002 on undesirable substances in animal feed*, as amended;

l) The Act referred to at Point 40 of Chapter II of Annex I to the EEA Agreement, *Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC*, as amended;

m) The Act referred to at Point 41 of Chapter II of Annex I to the EEA Agreement, *Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

n) The Act referred to at Point 47 of Chapter II of Annex I to the EEA Agreement, *Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on certain feed and foods of non-animal origin and amending Decision 2006/504/EC*¸ as amended*;*

o) The Act referred to at Point 47a of Chapter II of Annex to the EEA Agreement, *Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed;*

p) The Act referred to at Point 48 of Chapter II of Annex I to the EEA Agreement, *Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market* and *use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC* , as amended*;*

q) The Act referred to at Point 51 of Chapter II of Annex I to the EEA Agreement, *Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials* ;

r) The Act referred to at Point 145 of Chapter II of Annex I to the EEA Agreement, *Commission Regulation (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification processes applied to products intended for animal feed as provided for in Directive 2002/32/EC of the European Parliament and of the Council.*

Annex 3 – Reply to draft report, suggested corrective actions

ROYAL NORWEGIAN
MINISTRY OF AGRICULTURE AND FOOD

EFTA Surveillance Authority
35 Rue Belliard
BE 1040 Brussels

Your ref	Our ref	Date
CNo 78469 DNo 804327	15/1104-	21.06.2016

Subject: EFTA Surveillance Authority's mission to Norway regarding feed safety from 4 to 13 April 2016

Please find enclosed the Norwegian Food Safety's response to the draft report from the mission to Norway regarding feed safety from 4 to 13 April 2016.

Yours sincerely,

Cathrine Steinland
Deputy Director General

Anne Felde Doser
Adviser

This document has been signed electronically and therefore it is not signed by hand

Enclosures: 3

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Your ref: Case No 78469
Our ref: 2016/25488
Date: 14.06.2016
Org.no: 985 399 077

Norwegian Food Safety Authority

Mattilsynet

EFTA SURVEILLANCE AUTHORITY'S MISSION TO NORWAY REGARDING FEED SAFETY - COMMENTS TO DRAFT REPORT

Please find enclosed our comments on the factual contents and other elements of the draft report. Annex1 includes the comments on the factual contents of the report and Annex II refers to plans for action that we will take and those already taken, in response to your recommendation.

Yours Sincerely

Lise Rokkones
Head of section

This document has been electronically approved, and sent without signature.
Documents that require a signature will also be sent as a paper copy.

Annex II Plans for actions that we are going to take and those already taken in response to your recommendations

No	Recommendation
1	The competent authority should ensure that when non-compliances are identified and corrective actions are requested, a timely follow up is carried out to the relevant operators in order to remedy the situation as required by Article 54 of Regulation (EC) No 882/2004. We will have to come back to you on this point as it involves much more than the feed hygiene regulation. A solution to the challenge that has been identified here, demands involvement from the director General and the management staff.
2	The competent authority should ensure that control bodies that have been delegated specific task of official controls are accredited in accordance with the relevant European Standard and that such control bodies are supervised by the competent authority. In addition such delegation should be notified to the Authority as required by article 5 of Regulation (EC) no 882/2004. Accreditation The Norwegian Marine & Cargo Survey (NMCS) are delegated sampling tasks according to Article 5 of Regulation (EC) No 882/2004. The delegated tasks include sampling of feed materials of plant origin at import in harbours where NMCS is present. The NMCS are accredited in accordance with ISO standard 2000:2008. They are also certified by the Grain and Feed Trade Association (GAFTA). After the visit from ESA in April, the NMCS has compared the European Standard EN 17020/2012 with the requirements in their existing quality control system. Their conclusion after this comparison is that the current quality control system at the NMCS covers the requirements in the European Standard EN 17020/2012. The NFSA will carry out a similar comparison of the existing quality system at the NMCS with the European Standard EN 17020/2012. - If we come to the same conclusion as the NMCS, i.e. that the existing quality system fulfills the requirements in EN 17020/2012, we will conclude that the requirements of Article 5 of Regulation (EC) No 882/2004 are fulfilled. The basis for this conclusion is that Article 5 of Regulation (EC) No 882/2004 says that "the control body works and is accredited in accordance with European Standard EN 45004 "General criteria for the operation of various types of bodies performing inspection" and/or another standard if more relevant to the delegated tasks in question. " - If the conclusion is that the current quality system does not fulfill the requirements in EN 17020/2012, we will have to consider the way we have

	organized the sampling, including whether we shall withdraw the tasks that are delegated to the NMCS or not. Suggested closing date: October 1st 2016. Supervision Article 5 of Regulation (EC) No 882/2004 says that competent authorities delegating specific tasks to control bodies shall organize audits or inspections of control bodies as necessary. The NFSA has, as the ESA correctly has pointed out, not performed such supervision activities at the NMCS yet. The NFSA will consider which supervision activities that are necessary to perform in the future, and make a plan for these activities. The activities will at least include an assessment of whether the conditions of the GAFTA Sampling Rules No 124 is in line with the requirements of Regulation (EC) No 152/2009. Suggested closing date: October 1st 2016. Notification The NFSA will notify the EFTA Surveillance Authority about the delegation of tasks to the NMCS. Suggested closing date: July 1st 2016.
3	The competent authority should ensure that laboratories analysing official samples use only accredited methods for such analyses as required by Article 12 of Regulation (EC) No 882/2004. We are of the opinion that the Control Regulation 882/2004 does not require all analysis to be accredited. Article 12 lists the options if the methods are not accredited, and NFSA accept non-accredited analyzes if the analyzes follow the options specified in Article 12 or quality criteria mentioned in the Annex to Article 12 in the Control Regulation That it is validated methods; the laboratory has participated in ring tests, etc.
4	The competent authority should ensure that all feed establishments are registered or approved according to the activities actually carried out, as required by Articles 9 and 10 of Regulation (EC) No 183/2005. Also, the competent authority should ensure that feed business operators notify the competent authority of any establishment under their control with a view to registration, as required by Article 9(2). In our BDL (Budget Disposal Letter) for 2016 point 6.5 data quality is mentioned: Continuous and correct registration of inspections and inspection results, and administrative follow-up is a prerequisite for good data quality, correct data for directing and effective reporting. Regarding feed, we have made a document in order to support updating and clearing up in MATS. (PMQ, document5.4.2). The regions are to go through their

	respective feed business operators for correctness according to this document, as stated on our intranet pages on prioritizing for this year. Registration of home mixers: KSL, Kvalitetssystem i landbruket, Quality System in Agriculture (QSA) is a «standard» used by 95 – 98 % of the farmers in Norway. Please see the QSA standard (PMQ, point 5.5). The standards for the different productions have instruction manuals and check lists to be used in self-auditing performed each year (The QSA system also includes external audits). Until now, the instruction manuals on respectively swine and ruminants have a thorough passage on criteria for registration according to Annex II in 183/2005. Thus, in practice all affected farmers are informed. In addition, we have now asked the editors of the QSA standards- instructions and checklists, to include a checkpoint on possible registration according to Annex II of 183/2005. Checkpoints will be included in the respective checklists in next year's QSA documents.
5	The competent authority should ensure that measures put in place by feed business operators to minimise cross-contamination meet the requirements of Article 5(2) of Regulation (EC) No 183/2005 and in its Annex II, and are sufficient to ensure compliance with the maximum levels of residues of coccidiostats in feed for non-target species set out by Directive 2002/32/EC. One of the national priority areas on feed control for 2016 (Budget Disposal Letter) is to control the FBO's own check system regarding their control plan on undesirable substances, cross contamination and homogenous mixing of additives. Please see the guideline (PMQ, point 5.5.2) We anticipate that the regions carry out controls as described. The results of the controls for 2016 will give us valuable information on how the FBOs deal with these issues. Based on this information together with information on the use of coccidiostats and other relevant information we can decide the priority of this point in future controls.