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Final report

EFTA Surveillance Authority mission to

Norway

27 January to 5 February 2014

regarding the application of EEA legislation

related to control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products

Please note that comments from the Norwegian competent authorities to factual errors in the draft report have been included in *underlined italic print* in the body of the report. Comments and information on the corrective actions already taken and planned by the Norwegian competent authorities are included in Annex 3 and referred to in footnotes in *underlined italic print*.

Executive Summary

This report describes the outcome of a mission carried out by the EFTA Surveillance Authority (the Authority) in Norway from 27 January to 5 February 2014 regarding application of EEA legislation related to control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products.

The main legal framework for the National Residue Control Plan and use and distribution of veterinary medicinal products, i.e. Council Directive 96/23/EC and associated legislation including Commission Decision 2002/657/EC concerning validation of analytical methods for residues, Council Directive 2001/82/EC on controls on the distribution and use of veterinary medicinal products and Council Directive 90/167/EEC on use of medicated feed has been transposed into Norwegian legislation.

There have been no changes in the designation and responsibilities of the competent authorities since the last mission was carried out by the Authority in 2009. The distribution and use of veterinary medicinal products in food producing animals is overall effectively controlled through official inspections at wholesalers, pharmacies, veterinary practices and primary producers. These controls are supported by a central database of veterinary treatment records that has been compulsory to use in Norway since January 2011 for aquaculture animals and since January 2012 for terrestrial animals. Veterinary medicinal products are generally prudently used. Official recommendations on the prudent use of antibiotics have been published and animal health professionals are aware of these. Some areas for improvement include the discipline of veterinarians and farmers to maintain the (electronic) records and the retention of copies of veterinary prescriptions at pharmacies and farms.

The effectiveness of the controls on the distribution and use of veterinary medicinal products is reflected in the outcome of the residue monitoring plan. In the years since the previous mission was carried out by the Authority in 2009, there have been no findings indicating the use of illegal substances and very few instances where the maximum residue limits have been exceeded. Follow-up investigations were thorough and effective, with the exception of investigations in relation to repetitive findings of excessive levels of a feed additive in eggs.

The residue monitoring plans and their implementation are overall in line with EEA requirements. The scope of testing in terrestrial animals has significantly improved in 2014 relative to previous years. Areas for improvement include the turnaround times of aquaculture samples, storage and transport of samples and targeting of samples in cattle and horses. The satisfactory performance of the laboratories involved in the 2014 residue plan provides confidence in the analytical results.

The report makes a number of recommendations to the Norwegian competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.

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1 Introduction

The mission took place in Norway from 27 January to 5 February 2014. The mission team comprised two inspectors from the EFTA Surveillance Authority (the Authority), a national expert and an observer from the European Commission's Food and Veterinary Office (FVO).

The opening meeting was held with representatives from the Ministry of Health and Care Services, the Ministry of Trade, Industry and Fisheries, the Norwegian Food Safety Authority (NFSA), the Norwegian Medicines Agency (NoMA) and the National Institute for Nutrition and Seafood Research (NIFES) on 27 January 2014 at the NFSA head office in Oslo. At the meeting the competent authorities added information to the reply to the pre-mission questionnaire.

Throughout the mission a representative of the head office of NFSA accompanied the mission team. In addition, representatives of NoMA accompanied the mission team during visits to the regional offices, to the pharmacy, to the wholesaler of veterinary medicinal products (VMPs) and to the feed mill producing medicated feed. Furthermore the relevant district offices of NFSA participated during meetings at the regional/district offices and at the visits to the different farms and the slaughterhouse.

A final meeting was held on 5 February 2014 at the NFSA's office in Oslo, 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 Objectives of the mission

The objective of the mission was to assess the application by the Norwegian competent authorities of *Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products* ("Directive 96/23/EC") and other relevant EEA legislation in the field of control of residues in live animals and animal products, including the controls on the distribution and use of VMPs and feed additives, the use of which may give rise to residues in such products.

This assessment was carried out based on, and related to, the legislation referred to under Chapter 3 and Annex 2 to this document. Furthermore, the mission team followed up certain aspects of the Authority's mission on control of residues and VMPs carried out in 2009 (see Chapter 4 on Background).

The meetings with the competent authorities and the visits to establishments and farms during the mission are listed in Table 1:

Table 1: Competent Authorities, establishments, laboratories and farms visited during the mission

	Number	Comments
Competent Authorities	**5**	An opening and a closing meeting at the NFSA head office with representatives from the Ministry of Health and Care Services, the Ministry of Trade, Industry and Fisheries, NFSA, NoMA and NIFES. In addition, meetings with representatives of three regional offices of NFSA.

Laboratories	**1**	One laboratory analysing samples for the National Residue Control Plan for aquaculture samples and functioning as National Reference Laboratory
Slaughterhouse	**1**	One slaughterhouse slaughtering cattle, pigs, sheep and horses
Wholesaler	**1**	One wholesaler distributing veterinary medicinal products to pharmacies and veterinarians
Pharmacy	**1**	One pharmacy specialised in veterinary medicinal products
Farms	**4**	One pig farm, one broiler farm, one dairy farm (cattle) and one aquaculture farm (salmon)

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 21 of *Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC and*

e) Article 45 of *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules,* as amended.

The EEA legislation relevant for the mission is listed in Annex 2.

4 Background

In 2006 and 2009 the Authority carried out missions to Norway regarding the residue plans and the competent authorities application of Council Directive 96/23/EC as well as regarding the distribution and use of VMPs as set out in Directive 2001/82/EC and medicated feed as set out in Directive 90/167/EC.

Information on the quantities of food commodities of animal origin produced in Norway in 2011 (which created the basis for the planning of the residue plan for 2013, see section 5.3.) was provided by NFSA as follows:

Commodity	**Animal population**
	2011
Bovine	305.595
Sheep/goats	1.204.348
Swine	1.580.311

Wild game	107.658
Equine	1.610

Commodity	**National production (metric tonnes)**
	2011
Aquaculture products	1.118.341
Milk collected by dairies	1.499.660
Eggs	59.480
Poultry	84.699
Farmed game	2.025
Honey	850

5 Main findings

5.1. Transposition and application of relevant legislation

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.

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

Findings

The legislation providing the legal basis for official controls carried out by NFSA relating to food production and food safety is the Food Act (Act 2003-12-19, No 124).

The relevant acts where NoMA has competence are: the Pharmacy Act (Act 2000-06-02 no 39) and the Medicinal Products Act (Act 1992-12-04 No 132) .

The mission team noted that:

- The relevant EEA legislation including later amendments on residues monitoring and sampling, maximum residue limits (MRLs), forbidden substances, pesticides, contaminants, medicated feed, additives and VMPs had been transposed to Norwegian legislation.
- A national regulation (Regulation 3 July 2009 No 971 regarding reporting of information about distribution and use of medicines on animals) requires pharmacies, medical feed mills, veterinarians and fish health biologists to report their use of VMPs in food producing animals to the NFSA into a database called the veterinary medicine register (VETREG). According to the information received this system has been in place for terrestrial animals since 1 January 2012 and for aquaculture animals since 1 January 2011 (see also section 5.5.2).

Conclusions

The national legislation is in line with the EEA agreement according to information provided by the NFSA head office and legal powers are in place to enforce the legislation.

5.2. Competent authorities

5.2.1. Designation of competent authorities and cooperation and coordination between competent authorities

Legal requirements

Article 4(1) and (2) of Regulation (EC) No 882/2004 require Member States to designate the competent authorities responsible for official controls, provide for efficient and effective co-ordination and cooperation between and within competent authorities and require that staff carrying out official controls are free from any conflict of interest.

Findings

Controls on the production, distribution and use of VMPs are divided between two competent authorities, NFSA and NoMA.

NFSA is responsible for residues monitoring in live animals and animal products. In particular, NFSA is responsible for drawing up the national residue control plans (NRCP) for Norway according to Directive 96/23/EC and for the implementation and supervision (i.e. in order to verify the effectiveness of the official controls as required by Article 8 (3) of Regulation (EC) No 882/2004) of the plan (see also sections 5.2.3 and 5.3.2).

NFSA is also responsible for the application of Regulation (EC) No 37/2010 regarding MRLs (see section 5.5.1). In addition, NFSA is responsible for official controls of VMP usage on farms and veterinary practitioners distribution and usage of VMPs (see section 5.5).

NoMA is responsible for licensing and official controls on manufacture and distribution of VMPs from VMP producers, VMP wholesalers, pharmacies and feed mills producing medicated feed.

The mission team noted that:

- There have been no changes in the organisation of the competent authorities involved since the last mission regarding the NRCP and VMPs was carried out by the Authority in 2009.

- According to information received from both NFSA and NoMA, NFSA used input from NoMA regarding planning of the NRCP. In the planning process NFSA used telephonic consultations with NoMA and the relevant laboratories. In addition, included in the planning of the NRCPs are data on VMP use in aquaculture/terrestrial animals on substances and amounts used in Norway from yearly reports issued in March each year by the Public Health Institute (Folkehelseinstituttet) with data for the previous year.

- Following the change in the laboratory network (see also section 5.3.2), the mission team noted that no clear strategy or procedures were established by the head office of the NFSA and communicated to all district offices on how to ensure timely and appropriate packaging and sending of samples to the laboratory from 1 February 2014. Regarding official controls on distribution and use of VMPs from

pharmacies and their obligation to register use and distribution of VMPs to NFSA in VETREG, the coordination of the NFSA and NoMA as well as the interface between databases could be improved (see also section 5.5).

Conclusions

Norway has designated competent authorities responsible for the official controls of residues and contaminants in live animals and animal products including controls on VMPs and, in general, cooperation and coordination within and between the competent authorities involved were, with minor shortcomings detected, in line with the with the requirements of Article 4 of Regulation (EC) No 882/2004.

5.2.2. Adequacy of personnel involved in the control system

Legal requirements

Article 4(2)(c) 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 same Regulation requires the competent authorities to ensure that staff receives appropriate training and keep the staff updated in their area of competence.

Findings

According to the information received from NoMA five inspectors at central level are in charge of all inspections of manufacturers of VMPs, wholesalers of VMPs, feed mills producing medicated feed and pharmacies. There are no regional or district levels in NoMA.

According to the information received from NFSA two persons at central level (one for aquaculture and one for terrestrial animals), 19 at regional level (six for aquaculture and 13 for terrestrial animals) and 338 staff at district level (92 for aquaculture and 246 for terrestrial animals) are involved in the controls on residues in animals and products of animal origin and VMPs in NFSA. However, these staff have other duties as well and only part of their working time is specifically used for the NRCP and VMPs.

The mission team noted that:

- Concerning NoMA and their planned controls of wholesalers of VMPs all 23 wholesalers were planned to be inspected in 2011 and 2012, however only six (2011) and two (2012) had been inspected due to lack of resources. According to information received at the initial meeting NoMA is planning to hire additional inspectors to carry out all planned inspections to wholesalers of VMPs in the future.
- As regards pharmacies and producers of VMPs NoMA has no set frequency for inspections (there is no distinction between human and veterinary medicine in this regard). *Nevertheless, a few pharmacies in Norway have specialised in veterinary medicine. In 2011 NoMA planned 34 inspections, of which 30 were carried out*[1]. For feed mills producing medicated feed three such premises are licensed by NoMA, and the planned frequency for inspections of these feed mills is once every three years, which had been carried out.

[1] *See Annex 3 for comments from NoMA.*

- Concerning NFSA and their planned controls of veterinary practices dealing with food producing animals 446 such practices are registered. The number of veterinary practices planned to be inspected in 2011 was 108 of which 84 were carried out, and in 2012 129 inspections were planned, however, 293 were carried out, of which 290 were dealing with record keeping and medicines handling in veterinary clinics (see also section 5.5. concerning the national projects on VMPs from 2011 (aquaculture) and 2012 (terrestrial animals)).

Conclusions

The competent authorities have currently access to a sufficient number of suitably qualified and experienced staff in line with Article 4(2)(c) of Regulation (EC) No 882/2004.

5.2.3. Procedures, corrective action and enforcement

Legal requirements

Article 8 of Regulation (EC) No 882/2004 requires the competent authority to carry out official controls in accordance with documented procedures and to ensure that corrective action is taken when needed. Article 9 of the said regulation requires that the competent authority shall draw up reports on the official controls that it has carried out.

Findings

The mission team noted that:

- NoMA has issued several instructions on how to carry out inspections in producers and wholesalers of VMPs as well as in pharmacies. Written inspection reports were issued after each inspection carried out. Examples were seen of documented follow-up by NoMA, when deficiencies had been detected in a pharmacy, a wholesaler and a feed mill producing medicated feed.

- NFSA has issued instructions for taking samples for the NRCP for both terrestrial animals and aquaculture animals. The instructions include information on follow-up in case of positive samples and require in general an inspection at the farm of origin. Nevertheless, the mission team noted a few cases (e.g. narasin in eggs) where samples had tested positive in the NRCP, but no follow-up inspection had been carried out on the farm (see also section 5.3).

- Several examples of cases of follow-up by NFSA (decisions issued) were seen in the districts visited , where veterinarians did not fulfil their obligations in relation to keeping of veterinary registers and lack of entering relevant data on use of VMPs into the VETREG as required by national legislation (see section 5.1).

- A lack of supervision (i.e. verification of official controls) on the implementation of the NRCP as required by Article 8(3) of Regulation (EC) No 882/2004 and Article 4(2)(b) and (c) of Directive 96/23/EC was noted (see also section 5.3.2)

- As regards control by NFSA on use of VMPs on farms it is in general up to the district level to decide if controls on VMPs should be carried out, and there are no central instructions on how to carry out controls on the use of VMPs on farms. In the districts visited it was confirmed that some controls had been carried out on the use and registration of VMPs used, but in general these controls were not reported.

Conclusions

Instructions had been issued by the competent authorities concerning controls of VMPs, NRCP and in general reports were drawn up after inspections and examples of follow-up of deficiencies detected were seen as required by Article 8 and 9 of Regulation (EC) No 882/2004. Nevertheless, a lack of supervision on the implementation of the NRCP as required by Article 8(3) of Regulation (EC) No 882/2004 was noted.

5.3. National Residue Control Plan (NRCP)

5.3.1. Planning of the residue monitoring plan

Legal requirements

Article 5 of Directive 96/23/EC provides that the EEA EFTA Member States shall submit to the Authority a plan setting out the national measures to be implemented for the detection of residues or substances listed in Annex I to the Directive, and subsequently, Member States shall submit any update of residue monitoring plans previously approved on the basis of the experience of the preceding year or years, by 31 March at the latest of the year of the update. The following EEA legislation has a direct bearing on the elaboration/updating of the residue monitoring plan:

- Article 3 of Regulation (EC) No 882/2004 deals with the general obligations with regard to the organisation of official controls;
- Articles 3 to 7 of Council Directive 96/23/EC deal with the requirements for residue monitoring plans;
- Commission Decision 97/747/EC lays down levels and frequencies of sampling for residues.

5.3.1.1. Aquaculture

Findings

The Section for Seafood of the NFSA elaborates in the second half of the year the NRCP for the subsequent year, based on production data of the previous year in consultation with NIFES concerning the use of veterinary medicinal products in Norwegian aquaculture and the analytic parameters of the tests.

The Section for Seafood distributes the sample numbers over the regions relative to their production volume in the previous year. The regional offices subsequently distribute the samples over the districts depending on the number of production sites and processing plants. The district offices determine when and where samples should be taken.

The mission team noted that:

- The NRCP for 2014 was available to the regional and district offices before the start of the year, allowing sampling to commence in January 2014, which supports unforeseen sampling as required by Annex III to Directive 96/23/EC.
- Sample numbers in the 2013 and 2014 NRCP meet the requirements of Chapter 3 of Annex IV to Directive 96/23/EC.
- Because there have been no non-compliant results in the aquaculture NRCP since the mission carried out by the Authority in 2009, this has not been a factor in the planning process. Nevertheless, consideration is given to planning samples at

production sites where misuse or abuse of substances could be of therapeutic relevance, for example the use of dyes in hatcheries.

Conclusions

The planning process of the NRCP for aquaculture animals is in line with the requirements of Directive 96/23/EC.

5.3.1.2. Terrestrial animals and their products

Findings

The Section for Animal Products of the NFSA elaborates in the second half of the year the NRCP for the subsequent year, based on production data of the previous year and taking into consideration previous test results in Norway and other countries, subjective knowledge on the use of veterinary medicinal products and advice from scientific groups.

The Section for Animal Products of the NFSA distributes the sample numbers over the regions relative to their production volume in the previous year. The regional offices subsequently distribute the samples over the districts depending on the number of farms and processing establishments. The district offices determine on which date of the month and where samples should be taken.

The mission team noted that:

- The 2014 NRCP was available to the regional and district offices at the start of the year whilst sampling was to commence in February. There was no sampling scheduled in January due to a change in testing laboratories from 1 January 2014 (see section 5.4). This is not fully in line with Annex III to Commission Decision 96/23/EC. However, it was noted that samples had been scheduled and taken in every month in 2013, and samples had been scheduled for every month from February 2014 onwards.
- Sample numbers in the 2013 and 2014 NRCP generally meet the requirements of Chapter 3 of Annex IV to Directive 96/23/EC.
- The nature of the non-compliant test results of the NRCP of 2011, 2012 and 2013 did not warrant increased sampling levels, with the exception of the repetitive finding of narasin in eggs in 2011 and 2012. Whilst the mission team was not provided with evidence of a follow-up investigation and actions that would prevent recurrence (see section 5.3.4), the sampling levels for narasin were not increased in 2013 or 2014.
- The scope of testing, the number of substances within the substance groups, has significantly improved by increasing the number of substances for various species in the 2014 NRCP compared to 2013. For example, more non-steroidal anti-inflammatory drugs (NSAIDs) are being tested for as this was identified as an area where the scope of testing should be expanded in relation to the VMPs available.

Conclusions

The planning process meets the requirements of Directive 96/23/EC with one exception where sampling levels have not be adjusted following repetitive findings of narasin in eggs as would be justified in the context of Annex III to Directive 96/23/EC.

5.3.2. Implementation of the residue monitoring plan

Legal requirements

Articles 3, 4 and 12 of Directive 96/23/EC deal with aspects pertaining to the implementation of the residue monitoring plan. Article 4(2)(b) and (c) of Directive 96/23/EC lays down the requirements for central competent authorities in co-ordinating the activities of all bodies involved in residues controls. Commission Decision 97/747/EC lays down levels and frequencies of sampling for residues and Commission Decision 98/179/EC lays down the rules for official sampling under the residue monitoring plan.

Article 8(3) of Regulation (EC) No 882/2004 and Article 4(2)(b) and (c) of Directive 96/23/EC deals with obligations for the competent authorities to verify efficiency of official controls of the NRCP by e.g. supervision of implementation of it.

Findings

All sampling is carried out by staff of the district offices of NFSA.

The mission team noted that:

- Staff has access to written instructions and sampling forms which provide relevant information for the selection and taking of samples.
- NIFES provides adequate and tamper proof sampling materials to the district offices for aquaculture samples.
- The Norwegian Veterinary Institute provided until 31 December 2013 adequate and tamper proof sampling materials to the district offices for samples of terrestrial animals and products. As of 1 January 2014 the district offices should purchase the sampling materials from the contracted laboratory (see also section 5.4).
- In 2013 samples were spread over different aquaculture production sites, farms with terrestrial animals and processing establishments. Samples were traceable to individual producers and animals in the case of cattle. However, samples were not always traceable to individual units at aquaculture sites, although units could be at different stages of production and fed different feeds.
- Samples had been taken throughout the year, taking into consideration the seasonality of the commodity.
- Although samples were generally appropriately targeted, some mistakes were observed with regard to terrestrial animals. For example, two pigs from the same farm slaughtered on the same day were analysed for the same substance, a horse was sampled without checking whether it had been signed out of the food chain and some pregnant heifers were sampled in order to be tested for hormones.
- Every fortnight collected samples are to be sent for analysis. Pending shipment, samples are stored in a fridge/freezer of the district office. The temperature of freezers in the offices visited was not always controlled.
- Aquaculture samples are sent in containers with a freezing element by post to NIFES. Samples of terrestrial animal were similarly sent to laboratories in Norway until the end of 2013. However, at the time of the mission it was still unclear how the samples of the 2014 NRCP would be sent to the contracted laboratory outside Norway and who would pay for the transport costs. Central level of NFSA indicated that the task to organise this had been delegated to the districts, but the districts would not send samples without instructions on how to do it and without clarity on how the costs would be financed.
- Sampling staff and/or their direct supervisors and the district offices visited kept spreadsheets or logbooks of samples taken. However, these documents were on

some occasions incomplete and there was no systematic supervision on the implementation of the plan for terrestrial animals at regional or central level. Up to the end of 2013 laboratories did not report the results of compliant results of terrestrial samples to the NFSA, and it could thus not be supervised on an ongoing basis by the districts, regions or central level whether samples had arrived at the laboratory and had been analysed. However, there was no evidence of under-implementation of the NRCP. The central level indicated that the possibilities for supervision would be strengthened for terrestrial animals in 2014 as the laboratory would send all test results (both compliant and non-compliant) directly to the districts and in copy to central level. The central level also indicated that it would play a more pro-active role in 2014 in supervising implementation.

- Data seen by the mission team showed variable and relatively long periods (3 to 8 months) between sampling and reporting of results, both for terrestrial and aquaculture samples.

Conclusions

Notwithstanding a lack of supervision (i.e. verification of official controls) as required by Article 8(3) of Regulation (EC) No 882/2004 and Article 4(2)(b) and (c) of Directive 96/23/EC on implementation and some minor shortcomings in the targeting of animals, the 2013 NRCP has been largely implemented as foreseen and generally satisfies the requirements of Directive 96/23/EC. Changes to the system in 2014 have the potential to enable effective supervision on implementation, however, a lack of clarity on the transport of samples may delay the implementation of the 2014 plan and combined with uncontrolled storage conditions this may affect the quality of samples which have been taken which is not in line with Article 11(7) of Regulation (EC) No 882/2004. Long turnaround times of samples in the laboratories has the potential to the decrease effectiveness of follow-up in case of non-compliances as required by Articles 13 and 16 of Directive 96/23/EC.

5.3.3. Other residue control programmes

Legal requirements

In addition to the residue monitoring plan required by Article 5 of Council Directive 96/23/EC, Article 11 of the said Directive gives Member States the option of conducting other residues testing, particularly in relation to the detection of illegal treatment of food producing animals. Article 9 of the Directive foresees the application of own-checks by food business operators.

Findings

In addition to the NRCP, the NFSA runs a national control program for residues of antibacterial agents in slaughtered cattle, pigs and small ruminants. The Norwegian School for Veterinary Science performs a screening test on kidneys. Should a screening test show the presence of antibiotics, then a qualitative and quantitative determination of the residue is perform in a muscle sample. Approximately 950 and 850 samples were analysed in 2013 and 2012 respectively.

The dairy industry carries out routine analysis of antibiotics in milk samples taken from each tanker truck arriving at the plant. A milk sample is also taken at each farm from which the milk has been collected. Non-compliant test results should be reported to the NFSA at district level.

Conclusions

The official control program for antibiotics in red meat and the dairy industry's surveillance of antibiotics in milk provide additional assurances with regard to residue status of these commodities.

5.3.4. Follow up of non-compliant results

Legal requirements

The measures to be taken by the competent authorities in response to the finding of non-compliant residues results are described in Articles 13, 16, 17, 18, 19, 23, 24, 27 and 28 of Directive 96/23/EC. In addition Article 54 of Regulation (EC) No 882/2004 lays down the principles to be followed in the application of national enforcement measures and actions to be taken in cases of non-compliances.

5.3.4.1. Non-compliant results in the NRCPs for 2012 and 2013

There were no non-compliant test results reported in the NRCP for aquaculture since the mission carried out by the Authority in 2009. Concerning terrestrial animals there were a number of non-compliant test results and the mission team examined those of 2013 (as far as available), 2012 and 2011. These consisted mainly of findings of cadmium, lead and thiouracil in various animal species, 17-alfa-nandrolon and beta-boldenon in pigs and 17-alfa-nandrolon in bovines. There were no MRL violations for authorised antimicrobial substances.

The mission team noted that:

- The NFSA has procedures in place for the follow-up on non-compliant test results in terrestrial animals. For aquaculture there is no specific follow-up procedure. For food in general there is a national contingency plan. By far most non-compliant test results (195x) were the finding of cadmium above the limit in kidney and liver of bovines, pigs, sheep, farmed game and wild game.
- The NFSA indicated that cadmium is a problem in approximately 20% of the farmed animals. A report with a safety assessment of this situation has been awaited for three years, but has not been delivered yet as priority was given to other issues.
- The NFSA has a policy in place for dealing with findings of thiouracil. As the presence of this substance may be linked to certain feedingstuffs, only levels above 10µg/kg will trigger an investigation. This is in line with recommendations from the EU reference laboratory. All findings were below the threshold value.
- Cases of 17-alfa-nandrolon and beta-boldenon in pigs and 17-alfa-nandrolon in bovines examined by the mission team could be related to the potential natural presence of these substances in the type of animals sampled (boars and pregnant heifers).
- In one region narasin was found above the limit in eggs, both in 2011 and 2012. The investigation file examined by the mission team concluded that the non-compliant results could be the result of cross contamination in the feed mill. However, there was no evidence that the feed mill had been visited as part of the follow-up investigation in order to confirm the (suspected) cause and if necessary to enforce corrective measures to prevent recurrence. The mission team could not

find evidence that if in 2013 samples had been taken from egg producers purchasing feed from the concerned feed mill in order to monitor the situation.

- There was one finding of chloramphenicol in pig muscle in 2013. The NFSA demonstrated in the follow-up investigation that the sample had been very likely contaminated by the sampler, who had been in contact with chloramphenicol eye drops for human use around the time of the sampling. During a visit in one of the districts the mission team was informed that a similar case had occurred approximately in 2007. The 2014 sampling instruction has been updated to include a warning for samplers on the use of human medicinal products.
- The mission team examined a case where high levels of anthelmintics were found in goat milk. The matter had been thoroughly followed-up by the NFSA. The conclusion was that a sample had been taken on the farm from milk which was evidently not destined for the market.

5.3.4.2. Non-compliant results in other residue control programmes

The mission team noted that:

- Staff at the district offices visited had received notifications of antibiotic findings by the dairy plants. Some of these would be followed up by the district, either via a telephone call or by means of a visit. Usually the dairy plant would already have investigated the matter thoroughly.
- There had been no non-compliant test results in the NFSA antibiotic monitoring programme for red meat in 2013 and 2012.
- A consignment of salmon had been returned from a third country to Norway following the finding of crystal violet in 2009. The matter was thoroughly investigated by the NFSA. It could be demonstrated that live fish had not been exposed to this day, but that the fillets had been contaminated via the food contact material. Corrective measures were taken by the company with regard to the batch concerned and in order to prevent recurrence.

Conclusions

Overall, investigations of non-compliant test results have been thorough and effective in finding the cause. However, investigations into the repeated maximum limit violations of narasin in eggs were incomplete and it cannot be ensured that the situation has been remedied, which is not in line with Articles 13 and 16 of Directive 96/23/EC. With regard to the presence of environmental contaminant cadmium in a large part of the farmed and wild animals, a risk evaluation has not yet been completed and a policy on this matter has yet to be established by the NFSA. Accordingly, effectiveness of the follow-up of non-compliant results as required by Articles 13 and 16 of Directive 96/23/EC could not be ensured.

5.4. Laboratories

Legal requirements

Requirements for designating laboratories are laid down in Articles 12(1) and 33 of Regulation (EC) No 882/2004 and Article 14 of Council Directive 96/23/EC. Requirements pertaining to the capacity and capability of laboratories are described in Article 4(2)(c) of Regulation (EC) No 882/2004. Requirements for accreditation of laboratories are laid down in Point 1.2 of the Annex to Commission Decision 98/179/EC

and in Article 12(2) and (3) of Regulation (EC) No 882/2004. Requirements for the validation of analytical methods for residues of pharmacologically active substances and certain contaminants are laid down in Articles 3, 4, 5 and 6 of Commission Decision 2002/657/EC. Requirements for analytical methods are also laid down in the annexes to Commission Regulation (EC) No 252/2012 (dioxins and dioxin-like PCBs in foodstuffs), Commission Regulation (EC) No 333/2007 (chemical elements in foodstuffs) and Commission Regulation (EC) No 401/2006 (mycotoxins).

5.4.1. General description

NFSA has from 1 January 2014 reorganised the laboratory network for the performance of laboratory analysis of the samples falling under the NRCP as follows:

- Aquaculture: NIFES with one subcontracted laboratory in Norway and a sub-contacted private laboratory in an EU Member State (i.e. no changes since the previous mission carried out by the Authority in 2009).
- Terrestrial animals: A private laboratory in an EU Member State with one subcontracted laboratory in the same country (changed on 1 January 2014).

Previously the Norwegian Veterinary Institute was responsible for the reception, preparation and distribution of samples from terrestrial animals falling under the NRCP to the appropriate sub contracted laboratories.

From 1 January 2014 it is planned that the district offices of NFSA will be responsible for the collection of samples and their transportation to the contracted laboratory in an EU Member State of all samples taken from terrestrial animals. The contract between NFSA and this private laboratory gives the laboratory a period of up to a maximum of six weeks, from receiving a sample, to sending the results to the NFSA district office (turnaround time in the laboratory). Only non-compliant results are copied to NFSA headquarters.

During the mission, the mission team visited the NIFES laboratory, it being designated as a National Reference Laboratory (NRL) for NRCP aquaculture samples. The assessment by the mission team of the private laboratory in an EU Member State in charge of samples from terrestrial animals was based on information provided by the NFSA on specific request from the mission team.

National Reference Laboratories:

According to a list of designated NRLs in Norway, sent to the Authority as an attachment to the answer to the pre-mission questionnaire, the responsibilities of the laboratories relevant for residue controls were as follows:

- Norwegian Doping Control Laboratory. Oslo University Hospital is designated as NRL for compound groups A1, A3, A4, A5 and B2d;
- The National Veterinary Institute is designated as NRL for compound groups A2, and B3d, but not for B3c;
- The National Institute of Nutrition and Seafood Research (NIFES) is designated as NRL for groups B1, B2a, B2b, B2e, B3c and B3e.

However, the mission team was informed by the NFSA at the initial meeting, that these NRLs previously associated with the samples taken from terrestrial animals in the context

of the NRCP have refused to continue as NRLs after 1 January 2014. In addition, the mission team was informed at the initial meeting, that the main reason for the reluctance is because these NRLs will no longer be in charge of testing the samples taken from terrestrial animals in the context of the NRCP. Moreover, the mission team was informed at the same meeting, that the NFSA are in the process of finding new NRLs, although no deadline had been set for this process.

Contract Laboratory:

The NFSA conducted a tender for the laboratory analysis of veterinary residues and contaminants in terrestrial animals and products thereof during September 2013 under national legislation (*Lov 1999-07-16 No 69 om offentlige anskaffelser).* All relevant EEA legislation as amended concerning control on residues in terrestrial animals was assessed (see Annex 2). In addition, the following recommendations concerning control on residues were assessed:

- Guidelines for the validation of screening methods for residue of veterinary medicines 20.01.2010 (This guideline document supplements Commission Decision 2002/657/EC regarding the validation of screening methods). http://ec.europa.eu/food/food/chemicalsafety/residues/Guideline_Validation_Screening_en.pdf
- SANCO/2007/3131 Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed. http://www.eurl-pesticides.eu/docs/public/tmplt_article.asp?CntID=615&LabID=100&Lang=EN

The private laboratory in an EU Member State (with one subcontracted laboratory) was successful in the competition. Before the mission was carried, out the mission team requested the NFSA to provide specific documentation regarding the performance of the laboratory, including information on accreditation, validation of methods and results of proficiency testing, etc.

The mission team noted that:

- The private laboratory and its subcontractor both held ISO 17025 accreditation from Accreditation Services linked to the European Cooperation for Accreditation.
- The contracts stipulate the reserved capacity available for testing, a % tolerance on additional testing, for which substances, the preference method to be used, the detection/quantification/reporting limits, that must be achieved and the turnaround time for the analysis and reporting of results.
- The private laboratory had standard operating procedures (SOPs) for validation, which were based on Commission Decision 2002/657/EC. The laboratory also provided an example of a validation report to NFSA and forwarded to the mission team.
- The results for proficiency testing provided to the NFSA and forwarded to the mission team were successful and included some of the analyte/matrix combinations for which they will be responsible for in the NCRP.

5.4.2. On-the-spot visit in the laboratory

Findings

The mission team visited the NIFES laboratory and noted the following:

- The laboratory is accredited by a Norwegian Accreditation body. All methods used in the NRCP are included within the scope of accreditation.
- The laboratory has participated in a range of proficiency tests covering several of the analyte/matrix combinations for which they were responsible in the NCRP and with generally satisfactory results.
- Quality systems were established in the laboratory. A Quality Manager was designated responsible for the maintenance of the quality management system and for conducting audits as part of internal quality control. Vertical audits checking the whole process of performing analyses were performed twice per year.
- Quality documents e.g. quality manual, reviews, training manuals and standard operating procedures, were available for laboratory staff. The documents fulfilled the criteria for controlled quality management documents and staff were signed off as trained in their training records.
- The laboratory was well equipped with state-of-the-art equipment including gas chromatography-mass spectrometry (GC-MS), liquid chromatography-mass spectrometry (LC-MS) and liquid chromatography-tandem mass spectrometry (LC-MSMS). Staff were sufficiently qualified and experienced to satisfactorily perform their designated tasks.
- The laboratory had SOPs for validation design, presentation of the final validation report and validation performance based on Commission Decision 2002/657/EC.
- A validation file was checked by the mission team, i.e. nitrofuran metabolites (A6) in fish muscle by LC-MSMS. Necessary validation parameters were properly evaluated according to the requirements of Commission Decision 2002/657/EC. This validation included the repetition of a Food Analysis Performance Assessment Scheme (FAPAS) proficiency test with satisfactory results. The laboratory considered this validation file as the standard for future validation.
- LC-MS methods used before 2009, e.g. Florphenicol and Emamectin in fish muscle were not validated fully to the requirements of Commission Decision 2002/657/EC. For these methods only the molecular ion was monitored – increasing the risk of false positive results. The laboratory acknowledged that non-compliant results would be confirmed by their subcontracted laboratory.
- The subcontractor laboratories employed by NIFES both hold ISO 17025 accreditation from Accreditation Services linked to the European Cooperation for Accreditation.
- The laboratory received and accepted frozen samples in blue plastic bags bearing a signed tamperproof seal from the district offices. A label bearing a unique identification number was printed by the laboratory information management system (LIMS) and attached to the defrosted sample. Subsequently the sample was homogenised and divided into A and B samples together with on occasion a C sample for delivery to a contract laboratory. All three were labelled with the unique identification number produced from the LIMS. All samples are frozen and the B-samples are stored until they are needed. The A-samples are collected by the analyst who generates a work list from the LIMS before commencing a test. It was noted during processing of the samples, that the SOP did not demand the cleaning of the knife or the use of a new cutting surface between samples. This has the potential to cause cross contamination of veterinary drugs between samples.

Conclusions

After reorganisation of the laboratory network since 1 January 2014 in Norway, there is not yet designated a NRL for residues for terrestrial animals, as it is required by Article 33(1) of Regulation (EC) No 882/2004.

The contract laboratory was found to meet the requirements for a laboratory involved in the analysis of veterinary drug residues present in terrestrial animals and products thereof as set out in Articles 4(2)(c), 12(1), (2) and (3) of Regulation (EC) No 882/2004, Article 14 of Council Directive 96/23/EC, Articles 3, 4, 5 and 6 of Commission Decision 2002/657/EC and Point 1.2 of the Annex to Commission Decision 98/179/EC.

The laboratory visited was found to meet the requirements for a laboratory involved in the analysis of veterinary drug residues present in aquaculture animals as set out in Articles 4(2)(c), 12(1), (2) and (3) of Regulation (EC) No 882/2004, Article 14 of Council Directive 96/23/EC, Articles 3, 4, 5 and 6 of Commission Decision 2002/657/EC and Point 1.2 of the Annex to Commission Decision 98/179/EC and gave confidence in the reliability of the results generated.

5.5. Veterinary medicinal products (VMPs) and medicated feeding stuffs

5.5.1. Authorisation, distribution and use of VMPs

Legal requirements

Conditions governing the marketing of VMPs are laid down in Articles 5 to 15, 21 to 30, 58 to 62 and 83 of Directive 2001/82/EC. VMPs which are authorised for use in food producing animals may only contain pharmacologically active substances which are listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. Council Directive 96/22/EC prohibits the authorisation of hormones and beta-agonists for use as growth promoters in food producing animals. Conditions governing the distribution and use of VMPs are laid down in Articles 65 to 71 of Directive 2001/82/EC. Article 67(aa) of Directive 2001/82/EC requires that VMPs for food producing animals are only dispensed to the public under a veterinary prescription unless exempted under the conditions laid down in Article 2 of Commission Directive 2006/130/EC. The veterinary medicines record keeping requirements for stockowners are laid down in Article 69 of Directive 2001/82/EC, Article 10 of Council Directive 96/23/EC and Annex I, Part A III, point 8(b) to Regulation (EC) No 852/2004.

Findings

There are no major changes in the system for authorisation and distribution of VMPs, since the mission was carried out by the Authority in 2009. NoMA is responsible for authorisation of VMPs and all veterinary medicinal products for food producing animals are prescription only.

VMPs are sold from wholesalers to pharmacies. The pharmacies then dispense the VMPs to the end user following a prescription by a veterinarian/fish health biologist. Veterinarians may also buy VMPs from the pharmacy for use in their clinical practice. All VMPs for food producing animals are prescription only medicines. VMPs must be prescribed by a veterinarian or a fish health biologist (for aquaculture only) and must include information on withdrawal periods. The prescribed VMP must then be distributed to the farmer by a pharmacy or a medical feeding stuff company (when treating aquaculture animals medicated feed is mainly used).

Veterinarians may apply for special exemption, which is a special permission to request VMPs without a Norwegian marketing authorisation. Such applications are assessed according to the principles of cascade. The prescribers are responsible for setting adequate withdrawal periods for VMPs used under special exemption. These provisions including

established minimum withdrawal periods in line with Directive 2001/82/EC are included in the Regulation of 16 January 2007 on use of medicinal products in animals (responsible competent authority is NFSA).

All 767 pharmacies in Norway are obliged to dispense both human and veterinary medicine but a few of these are specialised in veterinary medicine. There are 23 wholesalers of VMPs (licensed by NoMA) that supply pharmacies (licensed by NoMA) and veterinary practices that at the same time run a veterinary pharmacy. There are 446 veterinary practices that are registered in Norway as working with food producing terrestrial animals.

Three feed mills in Norway are licensed by NoMA to produce medicated feed for aquaculture animals of which one is dealing with clinical trials. The Norwegian Regulation on medicated feed (*Forskrift 1996-06-28 no 693*) requires that the manufacturer also comply with the Good Manufacturing Practice (GMP) aspects of the regulations on manufacture and import of medicinal products. Combined these regulations require for Norwegian feed mills producing medicated feed validation of cleaning processes and equipment, manufacturing processes and analytical testing and equipments and other requirements for medicinal products.

The mission team noted that:

- One feed mill producing medicated feed (in a separate production mill) was visited by the mission team. It was confirmed that the license issued by NoMA covered manufacture of medicinal products. *The mission team noted, that the company had a manufacturing authorisation that expired 13 November 2013 and that the new authorisation was valid from 8 January 2014. According to the information received from NoMA, the company had not requested a new license before they were informed about the coming inspection from the Authority*[2]. Nevertheless, validation reports were in place for processes, homogeneity, cleaning etc, as required by national legislation. In addition, registers were kept for batches of medicated feed produced including veterinary prescriptions.
- In a pharmacy visited it was noted, that veterinary prescriptions were not kept by the pharmacy.
- In a wholesaler of VMPs visited copies of veterinary prescriptions were kept for ten years back.
- One pig farm, one poultry farm and one dairy farm were visited, where treatment records (*helsekort*) were available and most of the treatments, VMPs used and withdrawal times were recorded. Nevertheless, some examples were seen in the pig farm and the dairy farm, where not all treatments with VMPs and withdrawal times were noted in their registers or there was not a clear link between veterinary prescriptions and the treatment records.

Conclusions

The distribution of veterinary medicinal products to food producing animals is in line with Article 67(aa) Directive 2001/82/EC, that requires that VMPs for food producing animals are only dispensed to the public under a veterinary prescription including written instructions on withdrawal times. However, a pharmacy visited did not keep the veterinary prescriptions for five years, which is not in line with Article 66 of said Directive. In

[2] *See Annex 3 for comments from NoMA.*

addition, some deficiencies were noted in information in treatment records at farm level, which is not in line with Article 69 of the said Directive.

5.5.2. Official Controls on the distribution and use of VMPs

Legal requirements

Competent authorities have a general obligation under Article 80(1) of the Community code relating to VMPs (Directive 2001/82/EC) to carry out inspections throughout the distribution chain of VMPs in order to verify compliance with the provisions of the Directive 2001/82/EC. Specific obligations for competent authorities are laid down in Articles 65, 66, 68, 69 of this Directive. With regard to ensuring that the production of medicated feeding stuffs is in accordance with Council Directive 90/167/EEC, the rules governing control functions by the competent authorities are laid down in Articles 4, 9 and 13 of said Directive. The requirements for food chain information accompanying animals submitted for slaughter for human consumption are laid down in Annex II, Section III, point 3(c) to Regulation (EC) No 853/2004.

Findings

NoMA is responsible for the controls og manufacturing and distribution of VMPs and medicated feed until the retail level. The controls of VMPs in farms and veterinary practices is under the responsibility of NFSA.

The database VETREG is a new instrument, based on national legislation, launched on 1 January 2012 for terrestrial animals (for aquaculture animals the system has been in place since 1 January 2011), that can be used for the official controls of VMPs. Veterinarians and fish health biologists are obliged to report their use of VMPs on food producing animals to the database VETREG. According to the national legislation pharmacies and feed mills producing medicated feed are also obliged to report the distribution of VMPs and medicated feed to NFSA via VETREG.

The mission team noted that:

- NoMA carries out controls on the use of VMPs to wholesalers of VMPs (23 licenced) and pharmacies selling VMPs. However, according to the information received from NoMA due to lack of staff only a limited number of wholesalers had been inspected in recent years (see also section 5.2.2).
- In a pharmacy visited, it was noted that VETREG was not used. *According to the information received, the pharmacies register their sales of medicines in their own data system (the database Pharmapro). The pharmacies report the distribution of VMPs from Pharmapro to VetReg by activating a link between the two systems. According to the information received, the link between the two databases did not work properly at the time of inspection, however, according to the reply to the draft report received from NFSA recent improvements have solved this problem*[3].
- In the feed mill visited it was confirmed that VETREG was used to report use of VMPs to NFSA.
- Official recommendations on the prudent use of antibiotics have been published in Norway and animal health professionals were aware of these. Veterinary medicinal products are generally prudently used.
- In 2011 a national supervision project was carried out by NFSA in Norway covering animal health and the use of VMPs by veterinarians and fish health

[3] *See Annex 3 for comments from NoMA and NFSA.*

biologists in aquaculture animals. The final report concluded, that there were some deficiencies in registers of VMPs for the practicing veterinarians and fish health biologists. In the NFSA districts visited, the mission team confirmed that the districts had followed up on these non-compliances detected.

- In 2012 a national supervision project was carried out by NFSA in Norway covering the use of VMPs in terrestrial animals including the use of VETREG (see also section 5.1). The project focused on veterinarians dealing with terrestrial animals and their correct use of VMPs and registrations of use of VMPs both private registers and entering of data into VETREG. The project focused in particular on pig production. Inspections were carried out by NFSA to 290 practising veterinarians to check their registers and reporting systems. In addition, 105 practising veterinarians dealing with pig productions were inspected more comprehensively to check administration of VMPs. According to the project report issued in May 2013 in total 191 veterinarians had non-compliances detected regarding gaps in registers or lack of reporting the use of VMPs in VETREG etc., which amounted to 66 % of the veterinarians checked. According to the information received, follow-up has been done by the NFSA by way of decisions issued to the veterinarians to ensure compliance. This follow-up was confirmed in all districts visited with written decisions issued from the districts to veterinarians with non-compliances detected.
- The district offices of NFSA carry out controls on the use of VMPs to all farms with food producing animals primarily in connection with inspections targeted at other issues e.g. animal welfare or zoonoses monitoring.
- There is an appropriate system in place for food chain information covering all species of production animals. In the poultry farm, the pig farm and the dairy farm visited appropriate documents for food chain information were seen. However, in a slaughterhouse visited, it was noted that in some cases the documents for food chain information had been signed by the transporter of the animals instead of the farmer.

Conclusions

The distribution and use of veterinary medicinal products in food producing animals is overall effectively controlled through official inspections at wholesalers, pharmacies, veterinary practices and primary producers in line with the provision of Directive 2001/82/EC. These controls are supported by a central database of veterinary treatment records.

There is a system in place for food chain information in Norway in line with Section III of Annex II of Regulation (EC) No 853/2004.

6 Final meeting

A final meeting was held on 5 February 2014 at the head office of the NFSA in Oslo with representatives from the Ministry of Trade, Industry and Fisheries, NFSA, NoMA and NIFES. At the meeting, the mission team presented its main findings and the preliminary conclusions of the mission with reference to the relevant EEA legislation. 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.

The Norwegian representatives were given the opportunity to comment or ask for clarification during the meeting. The Norwegian representatives did not indicate any disagreement with the main findings and the preliminary conclusions presented. However,

the mission team was informed by the NFSA, that NIFES (who currently is functioning as NRL for samples taken from aquaculture animals) had provisionally accepted the task of NRL for samples from terrestrial animals taken in the context of the NRCP. In addition, NoMA confirmed that an additional inspector had just been hired and one more inspector was soon to be hired.

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 to include all non-compliant residue results in the planning process of the national residue control plan for terrestrial animals in order to adjust sampling levels in case of repetitive findings as set out in Articles 4, 5, 8(2) and Annex III in Directive 96/23/EC.
2	Norway should ensure that the sampling of terrestrial animals on farms is targeted in accordance with Points 2(1), 2(2) and 2(3) to the Annex of Decision 98/179/EC.
3	Norway should ensure transport and storage of samples of terrestrial animals in accordance with Points 2(6) and 2(9) to the Annex of Decision 98/179/EC, in particular as regards storage temperature, transport boxes and delivery times to the responsible laboratory.
4	Norway should ensure verification of effectiveness of official controls (i.e. by supervision) on implementation of the NRCPs from regional/central level to the district level in line with Article 8(3) of Regulation (EC) No 882/2004 and Article 4(2)(b) and (c) of Directive 96/23/EC.
5	Norway should ensure appropriate turnaround times of samples in the laboratories in order to ensure effectiveness of follow-up in case of non-compliances as required by Articles 13 and 16 of Council Directive 96/23/EC.
6	Norway should designate and communicate the name and address of each National Reference Laboratory for residues of veterinary medicine and contaminants to the Authority as required by Article 33(1), (4) and Annex VII (I.12) of Regulation (EC) No 882/2004 and should ensure that these laboratories fulfil the tasks as set out in Article 33(2) of the same Regulation.
7	Norway should ensure that pharmacies keep detailed records for veterinary medicinal products that are supplied on prescription for five years in line with Article 66 of Directive 2001/82/EC.
8	Norway should ensure that owners and keepers of food-producing animals maintain records of veterinary medicinal products used as laid down in Article 69 of Directive 2001/82/EC.

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

The Authority	EFTA Surveillance Authority
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EU	European Union
FAPAS	Food Analysis Performance Assessment Scheme
FVO	Food and Veterinary Office of the European Commission
GC-MS	Gas Chromatography- Mass Spectrometry
GMP	Good Manufacturing Practice
LC-MS	Liquid Chromatography- Mass Spectrometry
LC-MSMS	Liquid Chromatography- Tandem Mass Spectrometry
LIMS	Laboratory Information Management System
MRL	Maximum Residue Limit
NFSA	Norwegian Food Safety Authority
NIFES	National Institute for Nutrition and Seafood Research
NoMA	Norwegian Medicines Agency
NRCP	National Residue Control Plan
NRL	National Reference Laboratory
NSAIDs	Non-steroidal anti-inflammatory drugs
SOP	Standard Operating Procedures
VETREG	Veterinary Medicine Register in Norway
VMP	Veterinary Medicinal Product

Annex 2 - Relevant EEA legislation

The main EEA Acts regarding residues, contaminants and veterinary medical products relevant for this mission are:

a. The Act referred to at Point 7.1.13 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety,* as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

b. The Act referred to at Point 6.1.16 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs*, as corrected and amended;

c. The Act referred to at Point 6.1.17 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin*, as corrected, 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 1.1.11 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, as corrected and amended;

e. The Act referred to at Point 1.1.12 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, amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

f. The Act referred to at Point 1.2.128 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2005/34/EC of 11 January 2005 laying down harmonised standards for the testing for certain residues in products of animal origin imported from third countries*;

g. The Act referred to at Point 6.2.39 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 98/536/EC of 3 September 1998 establishing the list of national laboratories for the detection of residues*, as corrected and amended;

h. The Act referred to at Point 7.1.1 of Chapter I of Annex I to the EEA Agreement, *Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EC*, as amended;

i. The Act referred to at Point 7.1.2 of Chapter I of Annex I to the EEA Agreement, *Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC,* as amended;

j. The Act referred to at Point 7.1.10 of Chapter I of Annex I to the EEA Agreement, *Council Directive 90/167/EEC of 26 March 1990, laying down conditions governing the preparation, placing in the market and use of medicated feedingstuffs in the Community*;

k. The Act referred to at Point 7.2.13 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products*;

l. The Act referred to at Point 7.2.14 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 98/179/EC of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products,* as amended;

m. The Act referred to at Point 7.2.19 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results*, as corrected and amended;

n. The Act referred to at 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 adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

o. The Act referred to at Point 54zz of Chapter XII of Annex II to the EEA Agreement, *Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC*;

p. The act referred to at Point 54zzy of Chapter XII of Annex II 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;

q. The Act referred to at Point 54zzzl of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) 401/2006 of 23 February 2006 laying down the methods of sampling and analyses for the official control of the levels of mycotoxins in foodstuffs,* as amended;

r. The Act referred to at Point 54zzzp of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 333/2007 of 28 March 2007*

laying down the methods of sampling and analyses for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MPCD and benzo(a)pyrene in foodstuffs, as amended*;*

s. The Act referred to at Point 54zzzz of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs,* as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex II to that Agreement;

t. The Act referred to at Point 70 of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006*;

u. The Act referred to at Point 12 of Chapter XIII of Annex II to the EEA Agreement, *Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council,* as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex II to that Agreement;

v. The Act referred to at Point 13 of Chapter XIII of Annex II to the EEA Agreement, *Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin* as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex II to that Agreement;

w. The Act referred to at Point 15p of Chapter XIII of Annex II to the EEA Agreement, *Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products,* as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex II to that Agreement;.

x. The Act referred to at Point 15za of Chapter XIII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae;*

y. The Act referred to at Point 15zg of Chapter XIII of Annex II to the EEA Agreement, *Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food producing animals from the requirement of a veterinary prescription.*

Annex 3 – Reply to the draft report

ROYAL NORWEGIAN
MINISTRY OF AGRICULTURE AND FOOD

EFTA Surveillance Authority
Rue Belliard 35
B-1040

Your ref	Our ref	Date
CNo 74571 ENo 700716	13/1415-	25.04.2014

Subject: Mission to Norway from 27 January to 5 Febraary 2014 regarding the application of EEA legislation related to control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products - draft report

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

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: 5

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EFTA Surveillance Authority

Your ref: 74571
Our ref: 14/69498
Date: 08.04.2014
Org.nr: 985 399 077

Att.

Norwegian Food Safety Authority

Mattilsynet

Corrections to the Draft report related to control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products

These are the comments from the Norwegian Medicines Agency:

Page 8 fifth paragraph, second bullet point:
«Nevertheless, a few pharmacies (23) in Norway have specialised in veterinary medicine and 34 inspections to these specialized pharmacies were planned by Noma in 2011 off which 30 were carried out,….."

The yellow part we suggest altered to:
Nevertheless , a few pharmacies in Norway has specialized in veterinary medicines. In 2011 NOMA planned 34 inspections, of which 30 was carried out.

Explanation: The planned 34 inspection was not entirely for the specialized pharmacies, it was the total number for inspection of all pharmacies. We don't have an exact number of the pharmacies that have specialized in veterinary pharmacy, but the visited pharmacy is one of them. The number 23 refers to the number of wholesalers specialized in veterinary medicine (PMQ 5.3.8 annex 3)

Page 20 fourth paragraph, first bullet point:
"The mission team noted that:

- One feed mill producing medicated feed (in a separate production mill) was visited by the mission team. It was confirmed that the license issued by NoMA covered manufacture of medicinal products. The mission team noted that there had been no GMP license issued by NoMA, according to the information received from NoMA, because the company had not requested it.

The yellow part we suggest altered to:
The mission team noted that the company had a manufacturing authorization that expired 13. November 2013 and that the new authorization was valid from 8. January 2014. This gap was

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related to the fact that the company had not requested a new license before they was alerted by the inspection from ESA.

Page 21, fourth paragraph, second bullet point:

"In a pharmacy visited, it was noted that VETREG was not used. According to the information received, the pharmacies have instead another separate reporting system (the database Pharmapro), where the pharmacies report the distribution of VMPs. According to the information received there is not yet a link between the two databases. In addition, the input to Pharmapro had not been checked by the NoMA or NFSA, since they did not have access (see also section 5.2.1)."

The visited pharmacy had specialized in veterinary medicine and was run in coordination with a wholesaler also specialized in veterinary medicine. For this reason that pharmacy had an atypical way of reporting data. Pharmacies in general use PharmaPro to report to VETREG, but this reporting system is not functioning well yet. But the observation in the visited pharmacy is correct.

Comments from the NFSA:

Text on page 21 about VetReg :

In a pharmacy visited, it was noted that VETREG was not used. According to the information received, the pharmacies have instead another separate reporting system (the database Pharmapro), where the pharmacies report the distribution of VMPs. According to the information received there is not yet a link between the two databases. In addition, the input to Pharmapro had not been checked by the NoMA or NFSA, since they did not have access (see also section 5.2.1).

Our suggested text :
In a pharmacy visited, it was noted that VETREG was not used. According to the information received, the pharmacies register their sales of medicines in their own data system (the database Pharmapro). The pharmacies report the distribution of VMPs from Pharmapro to VetReg by activating a link between the to systems. According to the information received, the link between the two databases did not work properly at the time of the inspection
Recent improvements have solved this problem.

The last sentence we do not understand:
In addition, the input to Pharmapro had not been checked by the NoMA or NFSA, since they did not have access (see also section 5.2.1)

Is it the actual data that is not checked or is it if the data is coming in or not coming in that is not checked? And who is it that has no access? Is it NoMa (that is not supposed to have direct access), NFSA that has access and could have checked the data but has not done so because the data that came in were wrong. Or do you mean that it is Pharmapro/the visited pharmacy that had no access to report?

Yours Sincerely
Randi Edvardsen
Head of Section for Animal Products

Copy:

EFTA SURVEILLANCE AUTHORITY

EFTA Surveillance Authority

Your ref:
74571
Our ref:
14/69498
Date: 07.04.2014
Org.nr: 985 399 077

Att.

Norwegian Food Safety Authority

Mattilsynet

Comments to the Draft report on EFTA Surveillance Authority mission related to control of residues and contaminants in live animals and animal products, including medicinal products

Regarding the *Recommendations*:

1. *Norway should ensure to include all non-compliant residue results in the planning process of the national residue control plan for terrestrial animals in order to adjust sampling levels in case of repetitive findings as set out in Articles 4, 5, 8(2) and Annex III in Directive 96/23/EC.*

   This is something we try to achieve in the planning process, and we will have even more focus on this in the future. Regarding the findings of Narasin, we have increased the number of samples in the plan for 2014.

2. *Norway should ensure that the sampling of terrestrial animals on farms is targeted in accordance with Points 2(1), 2(2) and 2(3) to the Annex of Decision 98/179/EC.*

   This is already written into the instructions to our staff taking the samples, and this will be highlighted in courses and training for the staff.

3. *Norway should ensure transport and storage of samples of terrestrial animals in accordance with Points 2(6) and 2(9) to the Annex of Decision 98/179/EC, in particular as regards storage temperature, transport boxes and delivery times to the responsible laboratory.*

   We are working hard to ensure that this is fulfilled. There have been, and still is a substantial amount of contact between the Head office, Regional offices and District offices regarding this point. This is also an important part of the demands for the new contract on postal services that is negotiated for the NFSA this year.

4. *Norway should ensure verification of effectiveness of official controls (i.e. by supervision) on implementation of the NRCPs from regional/central level to the district level in line with*

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Article 8(3) of Regulation (EC) No 882/2004 and Article 4(2)(b) and (c) of Directive 96/23/EC

This is something we plan to do regularly. We have already planned a "ring-test" on the implementation on the NRCP in 2015. And we are also looking into other ways of ensuring that the official control is effective regarding the NRCP.

5. *Norway should ensure appropriate turnaround times of samples in the laboratories in order to ensure effectiveness of follow-up in case of non-compliances as required by Articles 13 and 16 of Council Directive 96/23/EC.*

   In terrestrial animals and animal products the changing of laboratory this year has reduced the turnaround time by many weeks.

6. *Norway should designate and communicate the name and address of each National Reference Laboratory for residues of veterinary medicine and contaminants to the Authority as required by Article 33(1), (4) and Annex VII (I.12) of Regulation (EC) No 882/2004 and should ensure that these laboratories fulfil the tasks as set out in Article 33(2) of the same Regulation.*

   Attached is the EURL – NRL table showing the NRLs for Residues in food of animal origin, see 12a), 12b), 12c) and 12d).

7. *Norway should ensure that pharmacies keep detailed records for veterinary medicinal products that are supplied on prescription for five years in line with Article 66 of Directive 2001/82/EC.*

   We intend to respond to this recommandation in connection with the final report.

8. *Norway should ensure that owners and keepers of food-producing animals maintain records of veterinary medicinal products used as laid down in Article 69 of Directive 2001/82/EC*

   We will follow up on this towards the farmers and our district offices during 2014 and 2015.

Other comments to the Draft report:

Regarding repeated findings of Narasin (5.3.1):

- The instructions to our District offices will clarify that non-compliant findings suspected to emerge from feed mills will have to be investigated more thoroughly to ensure that the feed mills are operating in accordance with the legislation and good manufacturing principles.

Regarding sampling in January (5.3.1): There have been taken samples in January 2014

Regarding sampling of two pigs (5.3.2): We have checked this finding and according to the District office in charge this mistake was detected and the samples in question were not sent.

Yours Sincerely

Randi Edvardsen
Head of Section for Animal Products

Community Reference Laboratories (KURL)/ National Reference Laboratories (NRL)

NORWAY FOR 2008-12-22 nr 1621: Kontrollforskriften, Vedlegg VII, I og II

Number Matrix/parameter	EURL	Name NRL Address	Head of NRL Name/e mail/tel/fax	Contact person (if different of Head NRL) Name/e mail/tel/fax	www
12a) Residues in food of animal origin Directive 96/23/EC Annex I Group B 3d)	Rijksinstituut voor Volksgezondheid en Milieu (RIVM) 3720 BA Bilthoven The Netherlands	**Group B 3d)** Norwegian Veterinary Institute Box 750 Sentrum NO-0106 Oslo Norway	Gudmund Holstad gudmund.holstad@vetinst.no Phone +47 23 21 63 00 Fax +47 23 21 60 01	Per-Erik Clasen Per-erik.clasen@vetinst.no Phone +47 23 21 62 22 Fax +47 23 21 60 01	www.vetinst.no
12a) Residues in food of animal origin Directive 96/23/EC Annex I Group A 1,3,4. Group B 2d)	Rijksinstituut voor Volksgezondheid en Milieu (RIVM) 3720 BA Bilthoven The Netherlands	**Group A 1,3,4. Group B 2d)** Oslo University Hospital Norwegian Doping Control Laboratory Trondheimsvn 235 NO-0514 Oslo	Peter Hemmersbach Peter.Hemmersbach@farmasi.uio.no Phone +47 22894368 Phone +47 90526895 Fax +47 22894151		www.uio.no
12a) Residues in food of animal origin Directive 96/23/EC Annex I Group A 2	Rijksinstituut voor Volksgezondheid en Milieu (RIVM) 3720 BA Bilthoven The Netherlands	**Group A 2** Norwegian Veterinary Institute Box 750 Sentrum NO-0106 Oslo Norway	Gudmund Holstad gudmund.holstad@vetinst.no Phone +47 23 21 63 00 Fax +47 23 21 60 01	Dag Grønningen dag.gronningen@vetinst.no Phone +47 23 21 60 68 Fax +47 23 21 60 01	www.vetinst.no
12b) Residues in food of animal origin Directive 96/23/EC Annex I Group B1 Group B3e) Carbadox Olakindox	ANSES — Laboratoire de sécurité des aliments ANSES – site de Fougères BP 90203 Frankrike	The National Institute of Nutrition and Seafood Research Box 2029 Nordnes NO-5817 Bergen Norway	Øyvind Lie oyvind.lie@nifes.no Tel +47 90 09 37 88 Fax +47 55 90 52 99	Rita Hannisdal rha@nifes.no Tel +47 95 79 54 86 Fax +47 55 90 52 99	www.nifes.no
12c)Residues in food of animal origin Directive 96/23/EC Annex I Group B2a), B2b), B2e)	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) D-12277 Berlin GERMANY	The National Institute of Nutrition and Seafood Research Box 2029 Nordnes NO-5817 Bergen Norway	Øyvind Lie oyvind.lie@nifes.no Tel +47 90 09 37 88 Fax +47 55 90 52 99	Rita Hannisdal rha@nifes.no Tel +47 95 79 54 86 Fax +47 55 90 52 99	www.nifes.no
12c)Residues in food of animal origin Directive 96/23/EC Annex I Group A5	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) D-12277 Berlin GERMANY	Oslo University Hospital Norwegian Doping Control Laboratory Trondheimsvn 235 NO-0514 Oslo	Peter Hemmersbach Peter.Hemmersbach@farmasi.uio.no Phone +47 22894368 Phone +47 90526895 Fax +47 22894151		www.uio.no
12d) Residues in food of animal origin Directive 96/23/EC Annex I Group B3c)	Istituto Superiore di Sanità (ISS) I-00161 Roma Italy	The National Institute of Nutrition and Seafood Research Box 2029 Nordnes NO-5817 Bergen Norway	Øyvind Lie oyvind.lie@nifes.no Tel +47 90 09 37 88 Fax +47 55 90 52 99	Heidi Amlund ham@nifes.no Tel + 47 95 41 17 51 Fax.: + 47 55 90 52 99	www.nifes.no