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Final report

EFTA Surveillance Authority's remote audit of Norway

from 22 February to 5 March 2021

to evaluate official controls on residues and contaminants in live animals and animal products

Information on the corrective actions planned by Norway are included in Annex 3 to the report.

Executive Summary

This report describes the outcome of a remote audit carried out by the EFTA Surveillance Authority in Norway from 22 February to 5 March 2021.

The objective of the audit was to evaluate the effectiveness of official controls related to residues of veterinary medicinal products (VMPs), pesticides and contaminants in live animals and animal products.

The mission team found that the competent authorities allocate significant resources to official controls related to residues of VMPs and contaminants in live animals and animal products. The planning process for the annual residue monitoring control plan (RMP) for both terrestrial and aquatic animals is well established. The plan is cascaded throughout the organisation in enough time to allow sample collection to begin at the start of the year. The final targeting of animals for sampling is left to the discretion of local staff at department level. Surveillance for detection of illegal administration of prohibited substances, abusive administration of approved substances and controlling compliance with maximum residue limits (MRLs) could be further strengthened in certain instances by changing certain aspects of the sampling strategy. These include sampling matrices, the location of sampling events, the type of animals delivered to slaughterhouses and keeping sampling visits unannounced.

A laboratory network is established for testing samples from live animals and animal products for residues and contaminants with appropriate designation of NRL in Norway. Sampling instructions are in place though samples are not always sent to the laboratories in a timely manner. Consequently, follow-up action where non-compliance is detected may be delayed.

Follow up of non-compliant test results is completed and generally takes the form of written correspondence between officials and herd owners with no on-site visits or repeat sampling considered necessary. Detailed guidance on what actions to take following certain non-compliant results is not available to assist staff in their decision making. Non-compliant results were not considered as a risk factor for planning subsequent residue monitoring at department level.

All sectors responsible for prescribing VMPs are subject to official controls and the responsibilities for undertaking such controls are well defined between Norwegian Medicines Agency (NoMA) and Norwegian Food Safety Authority (NFSA). These official controls have identified continued delays in reporting VMP use by some veterinary practitioners. One consequence is that staff do not always have access to all relevant information when selecting animals for residue sampling in slaughterhouses.

Staff interviewed were generally knowledgeable but, in some cases did not follow staff instructions, resulting in the wrong class of animal being sampled or delays in samples being sent to the laboratory.

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

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1 Introduction

The remote audit took place in Norway from 22 February to 5 March 2021. The audit team comprised two auditors from the EFTA Surveillance Authority ('the Authority') and an observer from Directorate F, Health and Food Audits and Analysis, DG Health and Food Safety ('DG SANTE') of the European Commission.

A pre-audit questionnaire was sent by the Authority to the Norwegian Ministry of Agriculture and Food on 11 December 2020. A reply ('the pre-audit document') was provided on 2 February 2021.

The opening meeting was held remotely with representatives of the Norwegian Ministry of Agriculture and Food, the Norwegian Ministry of Health and Care Services, the Norwegian Ministry of Trade, Industry and Fisheries and the Norwegian Food Safety Authority ('NFSA') on 22 February 2021. At the meeting, the audit team confirmed the objectives and scope of the audit and the Norwegian representatives provided additional information to that set out in the pre-audit document.

Throughout the audit, representatives from the head office of NFSA participated in all meetings.

A final remote meeting was held with the relevant competent authorities on 5 March 2021. At this meeting, the audit team presented its main findings and preliminary conclusions from the audit.

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

2 Objective and scope of the audit

The objective of the audit was to evaluate:

- The effectiveness of official controls related to residues of veterinary medicinal products, pesticides and contaminants in live animals and animal.

The scope of the audit included:

- Terrestrial and aquatic animals
- The planning process and implementation (at central, regional and department level) of the annual residue monitoring control plan in live animals and animal products;
- Follow up actions taken after non-compliances have been detected, including communication between the different authorities involved;
- The capacity and analytical capability of the laboratory network;
- The distribution and use of veterinary medicinal products.

The assessment was carried out based on the legislation referred to in Annex 2 to this report. The assessment was further based on the competent authorities ('CAs') response to the pre-audit questionnaire.

The evaluation included the gathering of relevant information and appropriate verifications. This was undertaken by means of interviews/discussions and the review of relevant documents and records in order to ascertain both the normal control procedures adopted and the measures in place to ensure that necessary corrective actions are taken when necessary.

The remote meetings with the competent authorities selected for documentary review of official controls during the audit are listed in Table 1.

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

	Number of meetings	Comments
Central competent authorities	2	An initial and final remote meeting between the audit team and the Norwegian competent authorities
Regional competent Authorities	2	4 departments
Slaughterhouse	1	Cattle, sheep and pigs
Laboratory	1	National Reference Laboratory (NRL) for residues (aquaculture).
Norwegian Medicines Agency	1	

3 Legal basis for the mission

The legal basis for the mission was:

a) Point 4 of the Introductory Part of Chapter I of Annex I to the EEA Agreement;

b) Article 1(e) of Protocol 1 to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice;

c) Article 116 of Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products ('OCR'), as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement.

Legislation relevant to this audit is listed in Annex 2.

4 Background - Previous missions

4.1 Background information

This audit was performed remotely due to the Covid-19 pandemic and consequential restrictions on travel. A programme of remote meetings and interviews was arranged with the competent authority (CA) involving central, regional and department staff. The findings and conclusions of this remote audit of CA performance are limited in certain aspects where the audit team was, for example, unable to verify fully the CA activities at establishment level. This verification may be necessary at a future date when travel is again permitted.

Each year the Authority conducts an assessment of the Norwegian residue monitoring control plan against the requirements of the relevant European Economic Area (EEA) legislation[1]. This includes an evaluation of the number of samples planned against the minimum number of samples required by relevant EEA legislation.

[1] Directive 96/23/EC, Commission Decision 98/179/EC and Commission Decision 97/747/EC. The Official Controls Regulation (EU) 2017/625, implemented in Norway on 7 April 2020, repeals Directive 96/23 (Article 146(1) of the OCR) but includes a transitional period during which States of the EEA must continue monitoring residues in accordance with the requirements of Directive 96/23/EC (Article 150 of the OCR).

4.2 Previous missions

The Authority carried out a mission to Norway from 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 VMPs. The final report can be found on the Authority's website (www.eftasurv.int).

5 Findings and conclusions

5.1 Competent Authorities

Legal Requirements

Articles 4, 5 and 6 of Regulation (EU) 2017/625

Findings

5.1.1 Personnel and staff training

1. The NFSA is organised into two administrative levels; the head office (the Central Competent Authority ('CCA')) and the regions. The head office carries out directorate and governance tasks. There are five regions, divided into thirty-one departments. Official controls are performed at regional level. The Director of each region is responsible for coordinating the official control activities performed by individual departments.

2. Training related to sampling is included in the syllabus for meat inspectors. At department level, all new employees have a training plan which includes sampling and staff met confirmed part of their training involved accompanying more experienced staff on sampling duties. In addition, staff have attended Better Training for Safer Food (BTSF) training related to VMPs and have access to internal videos and other reference materials on sampling.

5.1.2 Audits and verification / supervisory activities

3. According to the pre-audit document, the NFSA's internal audit system covers implementation of the residue monitoring control plan. However, no audits have been carried out in the last five years related to any aspect of residues control.

4. The NFSA confirmed that regional co-ordinators must provide the head office with an update on implementation of the residue monitoring control plan (RMP) every four months. In addition, the terrestrial programme co-ordinator receives a monthly summary of laboratory results and uses this to monitor and assess implementation of the RMP.

Conclusions

5. The competent authority allocates adequate resource to training staff in sampling duties related to the residue monitoring control plan. Implementation of the RMP is regularly monitored which helps ensure all sampling is completed.

5.2 Planning of residue monitoring

Legal Requirements

Article 5 of Directive 96/23/EC.

Findings

6. The NFSA is responsible for preparing and submitting the annual residue monitoring plans, collection of related samples and follow up of analytical results. Programme co-ordinators for terrestrial and aquatic animals and animal products at the CCA, draft the national residue monitoring plans and then distribute them to the regions/departments.

7. For terrestrial animals, the programme co-ordinator calculates the number of samples to be collected for each relevant substance, listed in Annex I of Directive 96/23/EC, based on production figures for each category of animal from two years earlier. The samples are then allocated for collection at farm or slaughterhouse. According to pre-audit documentation, the samples are then divided between the regions in accordance with the relative production volume of each category of animal in each region.

8. Regional co-ordinators allocate their annual quota of samples to the departments within their region using a template provided by CCA. For live animals, the template includes the responsible department, category of animal, substance group, species, matrix, laboratory performing tests and the scheduling of samples to be taken on a monthly basis for each substance. The template used by regional co-ordinators to allocate samples to slaughterhouses, wild game, egg and honey producers includes the specific slaughterhouses where samples must be collected. The regional plans are returned to the programme co-ordinators at the CCA for quality control before being finally issued to the departments.

9. The NFSA confirmed that departments select the farms / egg and honey producers / timing of sampling based on local knowledge. A sampling instruction for terrestrial animals (Document 99943333 dated December 2020) is available and includes criteria for risk-based sampling. These include targeting herds where animals have a good body condition, high milk yields, where there are indications of animal health or animal welfare problems or where animals are grazed near known sources of pollution.

10. In addition, one regional team co-ordinator for residues interviewed by the audit team considered a wider range of risk factors such as the number of animals on a holding, the presence of foreign labour (risk of illegal import of medicines), crop production (pesticide risk). In addition, the co-ordinator used VetReg (NFSA veterinary medicines/-prescription register) to evaluate on farm medicines use.

11. The audit team were able to review departments' previous years' residue sampling plans which recorded details of where samples had been taken. Departmental sampling plans reviewed for 2021 recorded, *inter alia*, the date and location of sampling events to date. The NFSA confirmed that the decision on which farms/establishments to sample is taken nearer to the sample date allocated in the regional sampling plan. Concerning slaughterhouses, this decision on which animals to sample is taken once food chain information has been received.

12. In one department interviewed, CA confirmed that the regional plan was received on 22 December 2020 and the final department level plan was issued to the department on 18 January 2021.

13. For aquatic animals, the programme co-ordinator calculates the number of samples to be collected for each relevant Group A and Group B substance, listed in Annex I of Directive 96/23/EC, based on production data from two years before the due sampling year. The production data is retrieved from the official statistics of the Directorate of Fisheries[2]. The NFSA confirmed annual production to be approximately 1.4 million tons of fish requiring 14,000 aquaculture samples *per annum*. These samples are divided between the Northern, Mid and South-West Regions in accordance with the relative production volumes in each region. The remaining two regions in Norway have very few aquaculture farms and are therefore not included in the residue monitoring control plan. Departments are notified by e-mail when the plan is finalised and available on the NFSA intranet.

14. The CCA confirmed that risk criteria considered during development of the aquatic residues plan include the sale of VMPs and the presence of any new VMPs on the market. This information is provided by the Norwegian Institute of Public Health by means of their annual report on the use of drugs in fish farming and by the Norwegian Medicines Agency (NoMA), respectively.

15. Departments perform the sampling according to the residue monitoring control plan and their local knowledge of sites. The NFSA confirmed that they do not generally visit aquaculture farms solely for residue sampling purposes. Rather, residue sampling is an additional task undertaken when an official control is being performed for animal health and welfare reasons.

16. Group A substances are allocated for collection at farm level and Group B substances are allocated for collection at slaughterhouses. The programme co-ordinator for aquaculture (rather than the regional co-ordinator) allocates samples to departments who are responsible for selecting at which specific aquaculture farms/slaughterhouses sampling will be undertaken.

17. In one department interviewed, the CA considered age of fish as a risk factor when sampling for substance subcategories Group B1 [antibacterial substances] and Group B(3)(e) [dyes]. It considered younger fish most likely to be treated with these substances and targeted sampling of such fish at land based operations. In addition, the department always sampled healthy fish to ensure they had eaten and consequently ingested any in feed medication that may have been provided.

Conclusions

18. The planning process for the annual residue monitoring control plan (RMP) for terrestrial and aquatic animals and animal products is well established. The plan is cascaded throughout the organisation in enough time to allow sample collection to begin at the start of the year with the final targeting of animals for sampling being left to the discretion of local CA staff.

[2] Total (fiskeridir.no)

5.3 Implementation of residue monitoring control plan

Legal Requirements

Article 5(2)(c) and Annexes III and IV of Directive 96/23/EC, Annex to Decision 97/747/EC and Annex to Decision 98/179/EC

Findings

19. A detailed sampling instruction for the 2021 aquaculture residue monitoring programme is available for CA staff. This includes guidance on:

    - sample size - portions from five fish originating in the same cage/batch constitute a sample;
    - how to package samples and prepare documentation;
    - transport - all samples should be frozen and sent to laboratory as soon as possible and no later than two weeks after sampling; and
    - avoidance of cross contamination - staff should ensure they do not pose a risk to the samples, for example, in connection with ongoing personal medication.

20. The sampling instruction for terrestrial animals (see paragraph 9 of this report) includes details on:

    - sample types including weight/volume required;
    - packaging requirements, the need to freeze samples and send them to the laboratory within 14 days;
    - the requirement, in principle, for urine samples from live animals to be taken on the farm but, to avoid risk or difficulties, the possibility to take urine samples at the slaughterhouse instead (post-mortem) and for these samples to be considered as meeting the requirement for urine samples scheduled to be taken from live animals at the farm; and
    - the need to avoid sampling pregnant animals when testing for substance A3 (steroids).

21. The NFSA staff interviewed were generally knowledgeable concerning sampling instructions and could competently describe procedures for sampling, sample preparation and dispatch.

22. The NFSA confirmed that samples are packaged in sealable bags and frozen prior to dispatch. They are stored in freezers kept within NFSA offices in slaughterhouses or department offices. Regarding security of samples, one NFSA slaughterhouse team acknowledged that it was possible to access official samples when no officials were present.

23. Relevant EEA legislation requires official sampling to be unforeseen and unexpected to ensure the element of surprise. The sampling instruction for terrestrial animals generally confirms this but, for practical reasons, sometimes permits the visit to be agreed in advance.

24. Officials interviewed confirmed they generally notified herdowners/aquaculture farms in advance of their visits to take samples. Justifications for this included the need for the NFSA to check that personnel at that establishment would be available given the long travel distances required for inspectors to reach the establishment and also the need to check that transport would be available to access sea cages (in the case of aquaculture). In the departments interviewed, notification ranged from one day to one week in advance of the official control being carried out. One notification involved an inspector telling a herdowner that the inspection was residues related and another involved sending a text message the day before the official control indicating that samples would be taken. This is not in accordance with Point 1. of Annex III (1) of Directive 96/23/EC and Point 2.1. of the Annex to Decision 98/179/EC.

25. For Group A substances having anabolic effect and unauthorised substances, relevant EU legislation requires half of the bovine samples to be taken from live animals on the holding.

26. In one slaughterhouse where the official control team were interviewed, bovine urine samples were scheduled to be taken at the slaughterhouse (post-mortem) the following month instead of from live animals at holding level.

27. The NFSA provided data (Table 1) for one region, for 2019 and 2020, relating to the number of urine samples in the residues monitoring control plan intended to be taken at holding level, the number of urine samples actually taken at holding level and the number taken at a slaughterhouse instead. Sampling bovines at the slaughterhouse, rather than at holding level, is not in accordance with the requirements of Point 1. of Chapter 1 of Annex IV of Directive 96/23/EC.

    Table 1.

Department	Number of urine samples planned to be taken on holding		Number of urine samples actually taken on holding		Number of urine samples taken at slaughterhouse	
	2019	**2020**	**2019**	**2020**	**2019**	**2020**
Nordfjord	13	15	13	15	0	0
Sunnfjord og Sogn	18	18	7	3	11	15
Bergen og omland	20	23	19	23	1	0
Sunnhordland og Haugalandet	20	20	0	0	20	20
Sør-Rogaland, Sirdal og Flekkefjord	36	38	0	0	36	38
Agder	15	17	12	1	3	16
TOTAL	**122**	**131**	**51**	**42**	**71**	**89**

28. European Reference Laboratories (EURLs) for residues evaluate residue monitoring control plans of EEA countries on an annual basis. This involves, *inter alia*, recommending the minimum number of analytes for the relevant substances listed in Annex I of Directive 96/23/EC, the screening and confirmatory method to be used and the recommend matrices for the different substances by species.

29. For one of the substance sub-groups reviewed by the audit team, the EURL recommended matrices were not used in the slaughterhouse samples scheduled in the 2021 residue monitoring control plan.

30. In the slaughterhouse where the official control team were interviewed, officials confirmed that the slaughterhouse receives two to three on farm emergency slaughter animals each day. In the last two years, there has been only one official residue sampling event involving this class of animal in this particular slaughterhouse. The CCA confirmed that in practice, on farm emergency slaughter animals were not considered as a risk factor in targeting residue samples.

31. NFSA has recently commissioned MAKKS (Mattilsynets kjøttkontrollsystem) in slaughterhouses (terrestrial animals). This is an electronic system used, *inter alia*, to receive food chain information (FCI) and record ante-mortem and post-mortem data. Officials use MAKKS to plan risk based residues sampling by reviewing the relevant data. This includes the age and type of animals presented, recent veterinary treatments (extracted from VetReg and FCI), adherence to withdrawal periods, the number of animals expected for slaughter and the date when animals are due to be presented for slaughter.

32. The NFSA confirmed that it is mandatory for all aquaculture slaughterhouses to have a slaughter plan by the Thursday preceding the week of slaughter. Officials use this information together with VetReg to target residue sampling undertaken during the following week.

33. As mentioned in paragraph 20, the staff instruction for sampling terrestrial animals highlights the need to avoid sampling pregnant animals when testing for substance A3 (steroids). However, in several of the non-compliant results for steroids reviewed by the audit team, bovines sampled were pregnant.

Conclusions

34. Sampling instructions are available for officials who are familiar with the content and generally follow their requirements.

35. Surveillance for the detection of prohibited substances illegally administered, approved substances abusively administered and official controls of compliance with maximum residue limits ('MRLs') could be further strengthened. The combination of announcing official control visits in advance, not always sampling EURL recommended matrices most likely to detect certain substances for the longest period post treatment and sampling at the slaughterhouse rather than on farm (when the sampling is not routine such that herdowners would not be expecting the sampling event) collectively reduce the chances of detecting non-compliances.

36. The general exclusion of on farm emergency slaughter animals from targeted sampling weakens the surveillance strategy. Slaughter of these animals is not anticipated and there is consequently an increased likelihood that they may be undergoing treatment with legal or prohibited substances when presented at a slaughterhouse.

5.4 Official sampling and laboratory analysis

Legal Requirements

Article 100 of Regulation (EU) 2017/625 and Annex to Decision 98/179/EC

Findings

37. The Institute for Marine research (IMR) and Wageningen Food Safety Research (WFSR) are the designated Norwegian National Reference Laboratories (NRLs) for residues in aquaculture and terrestrial animals respectively. Both are included on the list of NRLs published on the NFSA's website[3].

38. The NFSA confirmed that a co-operation agreement signed between the NFSA and IMR in early 2020 assigns IMR as the NRL for aquaculture and a contract between the two parties acts as a letter of designation.

39. IMR operates in accordance with EN ISO/IEC 17025 and is accredited in accordance with that standard by the national accreditation body Norsk Akkreditering. Accreditation includes the methods of laboratory analysis. The NFSA have not organised audits of the NRL, relying instead on their accreditation status. This is in compliance with Article 100(2) of Regulation (EU) 2017/625.

40. IMR subcontract some of their sample analyses responsibilities to a laboratory in Germany. This laboratory is accredited in accordance with EN ISO/IEC 17025 by the national accreditation body Deutsche Akkreditierungsstelle GmbH (DAkkS) and the relevant methods of laboratory analysis are included in the accreditation.

41. The NFSA confirmed that they had recently reached an agreement with Norsk Akkreditering to notify NFSA of any observed underperformance of IMR in proficiency tests (PTs) that they participate in. No such agreement is in place with Deutsche Akkreditierungsstelle GmbH (DAkkS).

42. WFSR has recently been designated as the Norwegian NRL for residues in terrestrial animals. According to pre-audit documentation, the WFSR is accredited for analysis of residues of all groups of veterinary medicines (without the need to subcontract other laboratories) and is also the NRL for The Netherlands. In addition, the contract between NFSA and WFSR requires the NFSA to be updated on WFSR's laboratory performance in PTs.

43. According to the sampling instructions for terrestrial animals and the sampling instructions for the 2021 aquaculture residue monitoring programme (see paragraphs 9 and 19), samples should be sent to the analytical laboratories no later than 14 days after the sampling event.

44. One NFSA department confirmed that they sometimes held samples for 3-4 months before sending them for analysis. In another case noted by the audit team, samples were not dispatched until seven weeks after the sampling date. Other samples reviewed by the audit team took approximately three weeks to transit within Norway.

45. The sampling instruction for the 2021 aquaculture residue monitoring programme describes a sample being constituted from portions from five fish from the same batch. In 2020, IMR rejected three samples on the basis that samples were made

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3 https://www.mattilsynet.no/om_mattilsynet/eurlnrls_food_and_feed_animal_health_and_live_animals.7671/binary/EURL-NRLs%20food%20and%20feed,%20animal%20health%20and%20live%20animals

up from less than five fish. Appropriate corrective action was taken by resubmission to IMR of samples constituted from portions from five fish from the same batch.

46. All aquaculture samples are initially sent to IMR. Samples destined for the sub-contracting laboratory in Germany (see paragraph 40) are removed from their sealed bag, homogenised and then repackaged in different containers prior to shipment. The NFSA confirmed that sample containers are not officially sealed following homogenisation as required by point 2.6 of the Annex to Decision 98/179/EC.

Conclusions

47. A laboratory network is established for testing samples from live animals and animal products for residues and contaminants with appropriate designation of the aquaculture NRL for Norway. Sampling instructions are in place. However, receipt of samples at the laboratories is sometimes delayed with the result that sample analysis results are not delivered in a timely manner. This will delay follow-up actions if non-compliance is detected in these samples. The absence of official seals on certain samples reduces sample integrity and traceability.

5.5 Follow up of non-compliant results

Legal Requirements

Article 138 of Regulation (EU) 2017/625

Article 4 of Delegated Regulation (EU) 2019/2090

Findings

48. The Institute of Marine Research (IMR), at the request of the NFSA, publish an annual report on the "Monitoring program for pharmaceuticals, illegal substance and contaminants in farmed fish." The two most recent reports for 2018[4] and 2019[5] conclude that:

    - No substances with anabolic effect were detected in any of the samples analysed.
    - None of the veterinary drugs were detected at levels exceeding the MRL established for fish.
    - For contaminants, no samples exceeded the EUs maximum limits, where such limits have been established.

    According to pre-audit documentation, preliminary results show no non-compliant results for residues in aquaculture in 2020.

49. According to information provided by the NFSA, there were a number of non-compliant results in terrestrial animals during the period 2018-2020. These were

[4] 2018 - https://www.hi.no/en/hi/nettrapporter/rapport-fra-havforskningen-en-2019-44

[5] 2019 - https://www.hi.no/en/hi/nettrapporter/rapport-fra-havforskningen-en-2020-26

detected in a range of species and consisted mainly of detection of cadmium, copper, 17α-19-Nortestosterone and α-Boldenone exceeding statutory MRLs or above the decision limit[6]. In addition, there were four non-compliant results for antimicrobial substances and two for non-steroidal anti-inflammatory substances, all detected in bovines.

50. The sampling instruction for terrestrial animals (see paragraph 9) contains procedures on follow up of non-compliant results. These include the requirement that competent authorities carry out an investigation in accordance with legislative requirements[7] and complete an investigation report.

51. The audit team reviewed a selection of non-compliant results with a focus on those detected in departments where staff were interviewed. For these cases, follow up action was completed and generally took the form of written correspondence between officials and herd owners with no on-site visits or repeat sampling considered necessary. The NFSA confirmed that non-compliant results were not considered as a risk factor in planning subsequent residue monitoring at department level.

52. In one 17α-19-Nortestosterone non-compliant case, the sample submission document recorded the cow as not pregnant at the time of sampling. However, the follow-up report concluded that the non-compliant result was probably due to the natural occurrence of hormones during pregnancy. The herdowner notified 'MATS' (NFSA's case processing and decision support tool) that the cow had delivered a calf one month after the report concluded. The NFSA was unable to explain how it was known at time of conclusion of the report that the cow was pregnant and consequently the basis for dismissing the non-compliant result.

53. The sampling instruction for terrestrial animals confirms that pregnant animals should not be sampled for hormone analysis. However, in a number of non-compliant 17α-19-Nortestosterone cases reviewed by the audit team, sample submission forms recorded that the cows in question were pregnant.

54. No instruction/guidance was available to staff to help them interpret the significance of 17α-19-Nortestosterone non-compliant results and what actions to take once the non-compliance was detected.

Conclusions

55. In some cases, sampling instructions are not followed in practice. Follow up action to non-compliant test results is taken and generally takes the form of written correspondence between officials and herd owners with no on-site visits or repeat sampling considered necessary for additional follow-up. Detailed guidance on what actions to take following certain non-compliant results is not available to assist staff in their decision making.

56. Non-compliant results are not considered as a risk factor in planning subsequent residue monitoring at department level to help target sampling.

[6] The limit at and above which it can be concluded with an error probability of α that a sample is non-compliant

[7] Article 4 of Delegated Regulation (EU) 2019/2090

5.6 Distribution and use of Veterinary Medicinal Products

Legal Requirements

Articles 65 to 70 and 80 of Directive 2001/82/EC

Article 10 of Council Directive 96/23/EC

Findings

57. Part 1 of the country profile[8] describes the organisation of control systems for VMPs and residues.

58. In summary, controls of the production, distribution and use of VMPs are divided between the Norwegian Medicines Agency (NoMA) and the NFSA. NoMA is responsible for licensing and official controls related to the manufacture and distribution of VMPs through wholesalers and pharmacies. The NFSA is responsible for official controls of VMP use by veterinary practitioners and on farms.

59. According to the pre-audit document, all medicines for terrestrial and aquaculture are prescription only. Only veterinarians can prescribe VMPs for terrestrial animals and only veterinarians or fish health biologists can prescribe VMPs for aquaculture use. Veterinarians treating terrestrial animals are not allowed to sell VMPs other than for initial treatment. Further VMPs must be obtained from a pharmacy using a veterinary prescription. A similar procedure is in place for aquaculture requiring that veterinarians/fish health biologists are only allowed to dispense VMPs in emergencies.

60. The NFSA confirmed that all treatments and prescriptions issued for food producing animals must be reported to 'VetReg' (the NFSA's veterinary medicines/prescription register).

61. The CCAs provided data on official controls carried out between 2017 and 2020 relating to distribution and use of VMPs. This included inspection of wholesalers and pharmacies dispensing VMPs, veterinarians and fish biologists registered as working with food producing animals and feed mills registered to produce medicated feed.

62. The largest number of inspections were carried out in veterinary practices registered to work with food producing animals. Of the 853 veterinary practices currently registered, 168, 83 and 9 official controls were performed in 2018, 2019 and 2020 respectively. These controls detected 53, 35 and 3 non-compliances in the respective years. The NFSA confirmed that 34 out of 35 non-compliances in 2019 related to veterinarians failing to comply with their obligation to report all VMPs used in food producing animals to VetReg (see paragraph 31) within the national requirement of seven days.

63. In one of the departments interviewed, the audit team reviewed the follow up of non-compliances related to veterinarian reporting obligations. This included issuing a Decision describing the non-compliance, a requirement for the veterinarian to retrospectively update VetReg with treatments for a given period and to establish routines for reporting all VMPs used in food producing animals within the national

[8] https://www.eftasurv.int/cms/sites/default/files/documents/gopro/Country%20Profile%20-%20Part%201%20-%20for%20web%20publishing.pdf

timeframe. A closure letter was issued once the relevant non-compliant veterinary practice confirmed that actions had been taken.

64. NoMA confirmed that the Norwegian market for VMPs is very small and many products are not available on the market. Consequently, VMPs marketed in other EEA countries are necessary for ordinary veterinary practice. Where a veterinarian wishes to use such VMPs, the veterinarian must make a justified application to NoMA for their supply. If successful, the product must be obtained from a pharmacy. NoMA confirmed that they receive approximately 10,000 justified applications each year.

Conclusions

65. All sectors responsible for prescribing VMPs are under official control and the division of responsibilities for official controls between the Norwegian Medicines Agency (NoMA) and the NFSA is well defined. Official controls have identified failure by some veterinarians to comply with their reporting obligations concerning treatments with VMPs. Consequently, official veterinarians in slaughterhouses do not always have access to the most up to date information to assist them in their selection of animals to target for residue sampling.

6 Final meeting

A final remote meeting was held on 5 March 2021 with representatives from the relevant ministries and competent authorities present. At this meeting, the audit team presented its main findings and preliminary conclusions. During this meeting, the CCAs did not express any disagreement with the findings and preliminary conclusions of the audit team.

7 Recommendations

In order to facilitate the follow-up of the recommendations hereunder, Norway should notify the Authority no later than 16 September 2021 of additional corrective actions planned or already taken other than those already indicated in the reply to the draft report of the Authority. In case no additional corrective actions have been planned, the Authority should be informed of this. The Authority should be kept continuously informed of such changes made to the already notified corrective actions and measures, including changes to the deadlines indicated for completion and also the completion of the measures included in the timetable.

No	Recommendation
1	The NFSA should ensure that official sampling for residues and contaminants is unforeseen and unexpected and that all precautions necessary to ensure the element of surprise in checks are maintained as required by Point 2.1 of the Annex to Decision 98/179/EC and Point 1. of Annex III (1) of Directive 96/23/EC. Recommendation based on conclusion at paragraph 35. Associated findings: paragraphs 23 and 24.

2	The NFSA should ensure that the residues sampling strategy is designed to maximise the detection of illegal treatments and controls compliance with the maximum residue limits for residues of veterinary medicinal products as required by Point 2.2 of the Annex to Decision 98/179/EC. Recommendation based on conclusions at paragraph 35 and 36. Associated findings: paragraphs 26, 27, 29 and 30.

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

Authority	EFTA Surveillance Authority
BTSF	Better Training for Safer Food
CA	Competent authority
CCA	Central competent authority
DAkkS	Deustche Akkreditierungsstelle GmbH
DG SANTE	Directorate-General for Health and Food Safety of the European Commission
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EU	European Union
EURL	European Union reference laboratory
FCI	Food chain information
IMR	The Institute of Marine Research
MAKKS (Mattilsynets kjøttkontrollsystem)	NFSA IT system for food chain information and meat control
MANCP	Single integrated multi annual national control plan
MATS	NFSA's case processing and decision support tool
MRL	Maximum residue limit
NFSA	Norwegian Food Safety Authority
NoMA	Norwegian Medicines Agency
NRL	National reference laboratory
OCR	Official Controls Regulation (EU) 2017/625
PT	Proficiency Test
RMP	Residue monitoring plan
VetReg	Veterinary medicines / prescription register
VMP	Veterinary medicinal product
WFSR	Wageningen Food Safety Research

Annex 2 - Relevant legislation

The following EEA legislation was taken into account in the context of the audit:

a) The Act referred to at Point 11b. of Part 1.1 of Chapter I of Annex I to the EEA Agreement, Regulation (EU) No 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC, as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to the EEA Agreement;

b) 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;

c) The Act referred to at Point 16 of Part 6.1. of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to the EEA Agreement;

d) 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;

e) The Act previously referred to at Point 2 of Part 7.1. 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 (repealed by Regulation (EU) No 2017/625 but remains relevant as per Article 150 of that Regulation);

f) The Act referred to at Point 13 of Part 7.2. 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*;

g) The Act referred to at Point 14 of Part 7.2. 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;

h) 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 as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex II to that Agreement;.

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Annex 3 - Plan for corrective measures and actions

Plan on corrective actions, EFTA Surveillance Authority remote audit to Norway from 22 February to 5 March 2021 to evaluate official controls on residues and contaminants in live animals and animal products				
No	**Recommendations/subject**	**Action**	**Time aspect**	**Enclosures**
1	The NFSA should ensure that official sampling for residues and contaminants is unforeseen and unexpected and that all precautions necessary to ensure the element of surprise in checks are maintained as required by Point 2.1 of the Annex to Decision 98/179/EC and Point 1. of Annex III (1) of Directive 96/23/EC. Recommendation based on conclusion at paragraph 35. Associated findings: paragraphs 23 and 24.	The Head Office will review and amend the sampling instructions so that it becomes clear that the sampling must be carried out unannounced. The instructions must also address in cases where NFSA must notify business operators for practical reasons, the notification should always be neutral and never indicate that samples would be taken. When the sampling instructions for 2022 are ready, the Head Office will conduct training sessions with the regional coordinators with emphasis on basic principles in the sampling instructions. The basic principles will include unannounced sampling, targeted sampling, secure depositing of the samples and transport to the laboratories.	31.12.2021 31.01.2022	
2	The NFSA should ensure that the residues sampling strategy is designed to maximise the detection of illegal treatments and controls compliance with the maximum residue limits for residues of veterinary medicinal products as required by Point 2.2 of the Annex to Decision 98/179/EC. Recommendation based on conclusions at paragraph 35 and 36. Associated findings: paragraphs 26, 27, 29 and 30.	Head Office will amend the instructions and conduct training of the region coordinators to target the sampling. This will also include less sampling at the slaughterhouse. Head Office will amend the instructions to ensure residue sampling of emergency slaughter animals. Head Office will amend matrices in the sampling plan to detect certain substances for the longest period post treatment.	31.03.2022	