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Final report

EFTA Surveillance Authority's audit to

Norway from 9 to 18 October 2023

to evaluate official controls related to Avian Influenza and Newcastle

Disease

In response to information provided by Norway, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote. Information on the corrective actions already taken and planned by the Norwegian competent authority are included in Annex 3 to the report.

Executive Summary

This report describes the outcome of an audit carried out by the EFTA Surveillance Authority (ESA) in Norway from 9 to 18 October 2023.

The objective of the audit was to verify compliance with the applicable EEA animal health legislation governing the control of highly pathogenic avian influenza (HPAI) and Newcastle disease (ND).

The audit team found that contingency plans are in place which describe what the Norwegian Food Safety Authority (NFSA) does in the event of an outbreak of a listed disease but the plans do not include all the information required to launch a rapid response. The plans do not address all control measures required or the ability of the NFSA to deal with multiple outbreaks at the same time. During outbreaks, the lack of comprehensive contingency plans delayed certain control and eradication processes. Despite these delays, the regional NFSA successfully managed the disease outbreaks using their own initiative along with advice from the NFSA's head office and the Norwegian Veterinary Institute (NVI).

National requirements for biosecurity are in place and poultry / captive bird owners met were generally aware of them. Despite being a priority for official controls in 2023, biosecurity measures in poultry establishments were not adequately verified by the NFSA. This reduces the NFSA's knowledge of biosecurity standards and restricts their ability to take enforcement action to improve them to reduce the risk of introduction and spread of HPAI in poultry establishments.

Surveillance programmes are in in place for HPAI and ND in commercial poultry flocks. The NFSA confirmed that not all breeding flocks were sampled for HPAI and ND in 2021 and 2022 as described in the surveillance programmes.

Surveillance programmes for HPAI in wild birds should act as an early warning for possible introduction of HPAI into commercial poultry flocks. The audit team observed many delays in reporting laboratory results from wild bird samples. This reduces the possibility for early intervention measures to control the disease.

The NFSA did not always conduct an immediate investigation to confirm or rule out the presence of a suspected category A disease. This delay in investigation can increase the risk of spread of the disease.

The NVI provides a rapid diagnostic service for suspect cases of HPAI in commercial poultry holdings which supports the NFSA in implementing control measures. However, there are regular delays in analysis of samples from suspect cases of HPAI in captive birds and wild birds. In case of positive results, this delay would hinder timely application of appropriate disease control measures.

The NVI also acts as an expert group for listed diseases and provides significant scientific and technical assistance to the NFSA related to disease control measures including the provision of many risk assessments and advice during outbreaks.

The audit team observed that notifications to the Animal Disease Information System (ADIS) of primary outbreaks of HPAI in wild birds in Norway are regularly delayed and on occasion, incomplete information is provided. This delays the possibility of timely implementation of risk management measures in other countries.

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

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1 Introduction

The audit took place in Norway from 9 to 18 October 2023. The audit team comprised two auditors from the EFTA Surveillance Authority (ESA). The audit team was also accompanied by an observer from the Health and Food Audits and Analysis Directorate (Directorate F) of DG Health and Food Safety (DG SANTE) of the European Commission.

ESA sent a pre-audit questionnaire to the Norwegian Ministry of Agriculture and Food on 4 July 2023 and received the reply ('the pre-audit document') on 22 September 2023.

An opening meeting was held with representatives of the Norwegian Ministry of Agriculture and Food and the Norwegian Food Safety Authority (NFSA) on 9 October 2023 in Oslo. At the meeting, the audit team confirmed the objective, scope and itinerary of the audit. The Norwegian representatives provided additional information to that contained in the pre-audit document.

Throughout the audit, a representative of the NFSA accompanied the audit team. In addition, representatives of other levels of NFSA participated during meetings at different sites and visits to the different type of establishments.

A final meeting was held with representatives of the Norwegian Ministry of Agriculture and Food and the NFSA in Oslo on 18 October 2023 at which the audit team presented its main findings and preliminary conclusions from the audit.

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

2 Objectives and scope of the audit

The objective of the audit was to verify compliance with the applicable EEA animal health legislation governing the control of highly pathogenic avian influenza (HPAI) and Newcastle disease (ND).

The scope of the audit includes:

- The implementation of the applicable contingency plans;
- The outbreaks of HPAI and ND in poultry and captive birds and confirmations of HPAI in wild birds, that occurred in Norway between 2020 - 2023;
- Animal health conditions governing the production chain for poultry;
- The effectiveness of the measures taken in the affected poultry and captive bird populations and when there is a suspicion and confirmation in wild birds;
- All levels of the national and regional administrations involved in the planning and application of prevention, surveillance and control measures for HPAI and ND;
- The operation of the official laboratory designated to carry out analyses, tests and diagnoses to detect and / or confirm the presence of HPAI and ND.

The findings and conclusions of the audit are based on the information provided in the pre-audit document, documents provided by the competent authorities during the audit, interviews with NFSA staff and interviews with representatives of the poultry industry during on-the-spot visits to establishments.

The meetings with the competent authorities and visits to establishments / sites during the audit are listed in Table 1.

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

	Number	Comments
Competent authorities	3	An initial meeting, clarification meeting and a final meeting between the audit team and the Norwegian competent authorities in Oslo.
NFSA Departments	3	One by video link
Laboratory	1	National Reference Laboratory for HPAI and ND
Commercial poultry holding	4	
Captive bird holding	2	
Meeting with poultry industry	1	

3 Legal basis for the audit

The audit was carried out under the general provisions of the EEA Agreement and relevant legislation, in particular Articles 116, 117 and 119 of 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 (the official control regulation), as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I thereto.

Legislation relevant to this audit is listed in Annex 2.

4 Background - Previous audits

4.1 Background information

In recent years, several epizootic waves of highly pathogenic avian influenza (HPAI) have had a major impact on the domestic poultry sector across Europe where they have caused significant direct and indirect economic and societal costs.

During the 2020-2021 epizootic in Europe, migratory wild birds were instrumental in the transmission of the HPAI virus to the poultry population. Since 2021, Norway has notified an increasing number of confirmed HPAI cases in wild birds.

In Norway, between November 2021 and May 2023, there have been four outbreaks of HPAI and one outbreak of ND affecting poultry establishments, two outbreaks of HPAI and one outbreak of ND affecting captive birds. Between January 2021 and September 2023, HPAI virus has been detected in over 190 wild birds.

EEA measures on control of HPAI[1] aim to prevent further transmission of the disease to poultry populations and stop its spread as soon as possible to ensure the safe placing on the market and export of EEA poultry and their products.

The last ESA audit to Norway related to HPAI and ND was in 2006 and since then the legal framework has changed (see preceding paragraph). The final report from this earlier audit can be found on ESA's website (www.eftasurv.int).

ESA approved Norway's disease-free status for ND virus without vaccination by its Decision 032/21/COL of 21 April 2021.[2]

Table 2 shows the poultry population in Norway in 2022 - data provided by the Norwegian Veterinary Institute (NVI).

Table 2: Poultry in Norway (2022)

Category	No. of flocks	No. of birds
Broilers	600	75 million
Layers	600 (>50 birds)	4.1 million
Turkeys	40	926.000
Ducks	10	350.000
Geese	1	2.500

5 Findings and conclusions

5.1 Findings on prevention

Legal Requirements:

Article 18 of Regulation (EU) 2019/2035

Articles 10, 18(1), 26, 43, 54, 60(c), 70, 84, 93 and 101 of Regulation (EU) 2016/429

Articles 4, 6 and 62 of Regulation (EU) 2020/687

Article 37, 38, 100 and 101 of Regulation (EU) 2017/625

5.1.1 Registration

1. A register currently exists for poultry and captive birds with mandatory registration required by both poultry and captive bird establishments. The NFSA confirmed that the current register is not regularly updated and during outbreaks, captive bird details had

[1] As laid down in Regulation (EU) 2016/429 of the European Parliament and of the Council and in Commission Delegated Regulation (EU) 2020/687

[2] https://www.eftasurv.int/cms/sites/default/files/documents/gopro/Consolidated_Version_-_College_Decision_32_21_COL_as_amended_by_College_Decision_33_21_COL.pdf
The Decision replaced the earlier Decision 221/96/COL of 4 December 1996.

to be updated using local knowledge. Currently, only commercial flocks have an official registration number.

2. The NFSA confirmed they are developing a new register of animal holdings and are starting with commercial poultry farms followed by registration of captive birds (also referred to as backyard flocks by the NFSA). Implementation is due to begin by the end of 2023. The new register will allocate all flocks, including captive birds, with a unique registration number.

5.1.2 Risk Assessment

3. According to the pre-audit questionnaire, the Norwegian Veterinary Institute (NVI) is contracted by the NFSA to produce risk assessments on HPAI and ND. Between November 2020 and May 2023, the NVI has provided the NFSA with 23 HPAI status reports with risk assessments and recommendations. The risk assessments provide an overview of the disease situation in Europe and Norway. It includes recommendations to the NFSA on actions required for preventive measures and control strategies e.g. identifying high risk areas for the introduction of HPAI to poultry, advice on the need to house poultry and advice on cleaning and disinfection.

5.1.3 Biosecurity

4. The national Regulation on animal health (FOR-2022-04-06-631, Ch VII, Section 32) includes the requirement that operators in facilities with commercial animal husbandry must have routines that ensure good infection control. These requirements include, *inter alia*, a written biosecurity plan, floor plan with animal and personnel flowlines, special requirements for veterinarians and others in contact with other livestock facilities etc.

5. The NFSA annual control plan sets, *inter alia*, areas for prioritisation of official controls and minimum frequencies for these controls. The NFSA confirmed that the annual control plan for 2023 sets biosecurity visits to poultry establishments as a priority.

6. Information on biosecurity is available to poultry sector via the NFSA website (https://www.mattilsynet.no/dyr/dyresykdommer/fugleinfluensa) and the website of a private sector organisation which acts as a liaison between the NFSA and the poultry industry (https://www.animalia.no/no/Dyr/fjorfe/fugleinfluensa2/). In addition, this organisation requires an annual biosecurity declaration update from keepers and plan an industry inspection every 3-4 years.

7. In one region, the audit team visited a department which dealt with the greatest number of outbreaks of HPAI / ND in poultry. Officials confirmed they are responsible for official controls in more than 200 commercial poultry establishments. The officials confirmed that at the time of the audit, they had not completed any on-farm biosecurity controls prioritised in the annual control plan for 2023. The same officials confirmed that in 2021 they carried out a digital inspection of a number of poultry biosecurity plans.

8. In another region, the department visited was responsible for official controls in a very small number of poultry establishments. The department had completed most of their biosecurity visits and inspection reports were available.

5.1.4 Completeness of the Contingency Plans

9. The NVI, on behalf of the NFSA, has established an expert group on HPAI and ND to assist the NFSA in the event of an outbreak. The expert group consists of pathologists, epidemiologists and specialists in poultry diseases and zoonoses to assist. The

establishment of this group is in compliance with Article 43(2)(d)(iii) of Regulation (EU) 2016/429.

10. The NFSA confirmed that their contingency plans consist of several documents i.e. an administrative emergency plan, a general animal health contingency plan with guidelines and specific contingency plans for listed diseases. In more detail:

    - The administrative emergency plan includes central agreements with contractors responsible for e.g. depopulation, cleaning and disinfection and an agreement with the Norwegian Veterinary Association concerning compensation, etc., for veterinarians when they are ordered to work on behalf of the NFSA. Guidance is also included on how to keep a record of activities in the NFSA's case processing and decision support tool (MATS).
    - The general animal health contingency plan contains information common to many listed diseases e.g. an overview of relevant regulations, disease control measures in the event of a suspicion / confirmation of a listed disease, establishment of protection zones, surveillance zones, etc. The plan includes action cards for officials describing what has to be done e.g. killing animals in the field and a field manual describing practical issues such as tracheal & cloacal sampling of poultry.

11. Contingency plans for avian influenza (AI) and ND – the NFSA confirmed both documents are currently being drafted. The HPAI contingency plan will replace the document "Guide for requirements and exceptions Regulation (EU) 2020/687 in relation to HPAI 2021" which was drafted following the first outbreak of HPAI in poultry in 2021.The draft contingency plan for HPAI includes relevant legal requirements and describes what officials have to do but does not fully describe how they should do it e.g. no details how to perform documentary checks or how to check infection control measures have been applied in a restricted zone. In one department visited, which dealt with the majority of HPAI outbreaks in 2021 and 2022, officials confirmed they reviewed their capacity to deal with multiple outbreaks of HPAI in poultry at the same time. They concluded they would not be able to deal with more than three outbreaks at the same time, even factoring in additional staff from other regions. No strategy was provided to the audit team explaining how this was being addressed at regional or central level.

12. The same department confirmed that during the first HPAI outbreak in 2021, complete guidance was not available e.g. the NVI had to be contacted for sampling advice and there was no detailed guidance available on how to deal with manure or dispose of the dead birds on infected premises. Department staff further confirmed that their actions during the 2022 outbreaks were based on experience gained in the earlier outbreak rather than on available guidance.

13. In another department which dealt with an HPAI outbreak in 2023, the NFSA confirmed they had to request advice from the NVI in relation to cleaning and disinfection of an outside area at the infected premises as detailed guidance was not available in the contingency plans. In the same department, the audit team observed equipment required for dealing with a listed disease (disinfectant and swabs with virus preserving medium) which were out of date.

14. In another region which dealt with a large outbreak of HPAI in wild birds in 2023, there had been uncertainty about how to deal with the carcases which were initially treated as household waste. The NFSA provided details of meetings involving the NFSA, municipalities, the county governor and waste companies which took place following the primary outbreak, when the collection and disposal of dead birds was discussed. Approximately one month after the primary outbreak was reported, co-ordinated guidelines from the NFSA and the Norwegian Environmental Agency were published.

Representatives of the municipality involved confirmed there was a period of approximately one week during the outbreak when carcases accumulated as there was uncertainty as to how they should be disposed of.

15. In one department visited, official staff confirmed they organise a simulation exercise annually. It is organised entirely at regional level and the most recent one (2023) focussed on HPAI. The same region plans to organise further simulations on whole house killing using gas, cleaning and disinfection and repopulation related to poultry. The NFSA confirmed there was inter-regional co-operation during these simulation exercises but no headquarters involvement.

5.1.5 Early detection

16. According to the pre-audit questionnaire, the NVI has a co-ordination and operational responsibility for avian influenza (AI) and ND surveillance programmes. Each year the NVI drafts the surveillance programmes, provides a list of farms for sampling distributed throughout the regions and provides this to the NFSA.

17. The programme for active surveillance in poultry requires sampling of:

a) All breeding flocks - sampled annually on farm during the production phase
- layer and broiler breeders (each flock, AI x 10 samples & ND x 60 samples),
- turkey breeders (AI x 10 samples and ND x 60 samples) and
- duck and geese breeders (AI x 50 samples and ND x 60 samples)

b) Non-breeding flocks – annual sampling of a selection of:
- layer flocks [table eggs] (AI x 10 samples) tested on farm,
- all turkey flocks (AI x 10 samples)
- all duck and geese flocks (AI x 50 samples)

NFSA provided data on the number of flocks / birds sampled for AI in 2022 – see Table 3 below.

Table 3: Number of flocks / birds sampled for avian influenza in 2022

Species	Certified breeder flocks		Commercial flocks		Total	
	Flocks	Birds	Flocks	Birds	Flocks	Birds
Chicken	67	680	82	815	149	1495
Turkey	5	50	47	490	52	540
Duck	1	50	6	300	7	350
Goose	0	0	1	32	1	32
Sum	**73**	**780**	**136**	**1 637**	**209**	**2 417**

18. The programme for active surveillance in wild birds requires sampling of 400 ducks and geese which are sampled by hunters and 100 seagulls which are sampled during ringing.

19. Under the Norwegian Food Act § 6, there is an obligation on farmers to report if they suspect the presence of a transmissible animal disease. Failure to do so in a timely manner can result in reduced compensation for losses incurred due to eradication measures (FOR-2022-09-26-1643 §3) and is intended to act as an incentive for early notification.

20. Veterinarians and laboratories are obliged to report terrestrial animal diseases (FOR-2022-04-06-631 §39).

21. In relation to passive surveillance, the awareness of HPAI has been raised for farmers and captive bird keepers and the public via the NFSA website, press coverage etc. and additionally farmers have been advised directly through industry communications e.g. newsletters and industry website. The number of HPAI suspicions reported (to October 2023) are shown in Table 4 below.

Table 4: The number of HPAI suspicions reported (to October 2023)

Category	2020	2021	2022	2023
Commercial poultry	5	17	18	7
Hobby flock	13	28	14	16
Zoo / other captive birds	1	1		1

22. The NFSA confirmed they receive guidance from the NVI on which wild birds to sample e.g. predator birds and certain species. In one department visited, officials confirmed that if there were several dead wild birds together, they would sample but not if it was only a single dead wild bird.

23. The NVI produce an annual report summarising the outcome of the surveillance programme for AI in poultry. The most recent report relating to 2022 surveillance for AI concludes “all flocks tested in the surveillance programme for influenza were negative for influenza A virus subtypes H5 and H7 antibodies.” (file:///C:/Users/imajro/Downloads/2023_2_OK_AI%20in%20poultry%20in%20Norway%202022%20(2).pdf).

24. According to additional data provided by the NFSA after the audit, not all breeding flocks were sampled for AI and ND in 2021 and 2022 as described in the surveillance programme (see paragraph 17).

5.1.6 Laboratory

25. The Norwegian Veterinary Institute (NVI) has been designated by the NFSA as, *inter alia*, the national reference laboratory for AI and ND. It is the only official laboratory in Norway for AI and ND and there is a co-operation agreement between the NFSA and the NVI.

26. According to the pre-audit questionnaire, molecular testing is the primary analysis performed in suspect HPAI and ND cases. In suspect HPAI cases, samples are first tested for AI virus using a generic real time reverse transcription polymerase chain reaction (rRT-PCR) targeting the matix gene. In case of positive results, samples are further analysed using type specific H5 and H7 RT-PCRs. Positive results are followed up with pathotyping by cleavage site sequencing to confirm highly pathogenic avian influenza (HPAI) or low pathogenic avian influenza (LPAI) virus infection. In suspect ND cases, samples are analysed for the presence of avian orthoavulavirus type 1.

27. The pre-audit questionnaire confirms that serology is used for surveillance. For the detection of HPAI antibodies, samples are first tested using a commercial multispecies enzyme linked immunosorbent assay kit (ELISA - IDvet). Samples with positive results

are repeated and if still positive, followed up by hemagglutination inhibition test (HI), using H5N3 and H7N7 antigens. For ducks and geese, H5N8 antigen is also included in the primary screening. Positive results are followed up by HI test to additional antigens H5N1 and H7N1. For the detection of Avian paramyxovirus serotype-1 (APMV1) reactive antibodies, samples are tested by HI test to APMV1, APMV2, APMV3 and pigeon paramyxovirus type 1 (PPMV1).

28. According to the accreditation document for NVI issued by Norsk Akkreditering on 10 March 2023, the avian influenza haemagglutination test for AI and real-time PCR tests for Influenza A virus and paramyxovirus are accredited methods. The haemagglutination inhibition test for ND is not currently accredited and this is not in accordance with Article 37(5)(a) of Regulation (EU) 2017/625.

29. The NFSA confirmed that the NVI plans to get the haemagglutination inhibition test for detection of antibodies to ND virus accredited by the end of 2023. They plan to prepare a verification report using recent EURL proficiency tests and inter-assay and inter-operator variations based on standards used for diagnostic testing. This report will be evaluated internally by designated staff. Subsequently, the method will be included in the NVIs accreditation portfolio for evaluation at their next annual Norsk Akkreditering audit.

30. The NVI participated in the proficiency testing for AI and ND organised by the European Union reference laboratory for AI and ND (EURL) - Istituto Zooprofilattico Sperimentale delle Venezie – in 2023. The proficiency testing was for virus genome detection, virus antigen detection and antibody detection for both AI and ND. All serology results were acceptable. H5 results were acceptable, H7 were acceptable with minor remarks and NVI is in discussion with the EURL to address issues associated with H9 testing.

31. For commercial poultry, the turnaround time between sampling and providing a final laboratory report for suspect cases of HPAI and ND were generally satisfactory at 1 to 2 days. In suspect HPAI cases in backyard flocks and captive birds reviewed by the audit team, turnaround time ranged from 3 to 12 days. In wild birds sampled on suspicion of HPAI and reviewed by the audit team, the turnaround time between sampling and getting a laboratory result was regularly more than 10 days in 2023. The NVI confirmed they do not report negative results for wild birds back to the regions. In one department visited, officials stated they assumed wild bird samples were negative if no results were received within a week of sample submission.

32. The NVI confirmed the analysis of suspect HPAI samples from wild birds is not carried out on a daily basis. Instead, analysis is performed in bulk at the end of the week with positive results reported to the NFSA on Friday afternoons.

Conclusions

33. Contingency plans are in place which currently describe what to do in an emergency but do not fully describe all the information required to launch a rapid response. The plans do not address all control measures and the ability of the NFSA to deal with multiple outbreaks at the same time as this scenario has not been simulated. During outbreaks, the lack of comprehensive contingency plans caused delays in initiating certain control and eradication processes.

34. The NVI provides a rapid diagnostic service for suspect cases of HPAI in commercial poultry holdings which supports the NFSA in implementing control measures. However, there are regular delays in reporting results from suspect cases of HPAI in captive birds and wild birds. Surveillance programmes for AI in wild birds should act as an early warning for possible HPAI introduction into poultry. Delays in reporting

laboratory results for many wild bird samples reduces the possibility for early intervention measures to control the disease.

35. The serological test used for ND is not accredited. This partially undermines test results though this is mitigated to some extent by successful NVI participation in a recent EURL proficiency test.

36. National requirements for biosecurity are in place and poultry keepers met were aware of these requirements. Notwithstanding, biosecurity measures were not adequately verified by the NFSA. This reduces the NFSA knowledge of biosecurity standards and restricts their ability to take enforcement action to correct deficiencies in order to reduce the risk of introduction and spread of HPAI to poultry establishments.

5.2 Findings on Control and Eradication – Implementation of Contingency Plan

Legal Requirements:

Articles 13(1)(a), 57, 60, 61, 62, 64 and 65 of Regulation (EU) 2016/429

Articles 7(4) and (5), 12, 15 to 17, 19, 21 to 23, 25 to 26, 39, 41, 57, 59 to 61, 62 to 67 of Regulation (EU) 2020/687

5.2.1 Communications systems and chain of command

37. According to the pre-audit questionnaire, central and regional levels of the NFSA are involved in crisis management. In case of outbreak of a listed disease, national and regional crisis centres are established. The national crisis centre is responsible for, *inter alia*, co-ordination of control measures and personnel at national level, communication with international organisations, the Norwegian press etc. The regional crisis centres co-ordinate measures taken within their regions and are responsible for providing departments with sufficient personnel. It is the departments who perform and organise the field tasks at local level e.g., serving restriction notices, establishing restriction zones, depopulation and communication at a local level.

5.2.2 Dealing with suspects and confirmation of cases.

38. In one region visited, actions taken by a department, which dealt with recent outbreaks of HPAI and ND in commercial poultry, were reviewed by the audit team. These actions included, *inter alia*, an immediate farm visit by the NFSA once notified of suspicion, sampling for AI, issue of a written movement restriction notice and preventive killing based on the epidemiological situation - all on the same day as notification. An epidemiological enquiry was carried out which included movements on and off farm e.g., hatching eggs which were traced and the previous 21 days production from the infected premises were destroyed as required by Article 19(2)(b) of Regulation (EU) 2020/687. In addition, national legislation establishing restriction zones due to HPAI and ND were drafted by the NFSA.

39. In another region visited, the audit team reviewed a department's handling of a recent suspicion of HPAI in a layer flock.

- Day 1 - farmer initially contacted his private veterinarian due to increased mortality and reduced egg production. The private veterinarian contacted the NFSA emergency number and reported the findings which were recorded as a suspicion of AI. An oral restriction on movements was placed on the farm by the NFSA.

- Day 3 – the NFSA visited farm and took samples which were submitted to the NVI. Sample submission form recorded the reason for submission as “suspect AI”. Written movement restriction notice issued by the NFSA.
- Day 4 – NVI reported negative AI results.
- Day 5 – Notice served to lift movement restrictions.

The delay between notification of suspicion of a category A disease and the NFSA visiting the farm does not fulfil the NFSA responsibility to immediately conduct an investigation to confirm or rule out the presence of a suspected listed disease as required by Article 6 of Regulation (EU) 2020/687.

40. According to data provided in the pre-audit questionnaire, the time between sampling and laboratory confirmation for poultry outbreaks was 1 to 2 days and for outbreaks in captive birds the time ranged from 2 to 17 days. The NFSA provided data on the number of HPAI suspicions notified in backyard flocks and captive birds in Norway in 2022 and 2023. The time between sampling and final laboratory reporting of these backyard and captive birds ranged from 1 to 23 days with an average time greater than 5 days.
41. EEA countries are required to report primary outbreaks of listed diseases within 24 hours of confirmation to the European Commission/ESA and other Member States via the Animal Disease Information System (ADIS). In all four outbreaks of HPAI in domestic poultry this was done. However, for the three outbreaks in captive birds the average time for reporting was more than two days. Reports to ADIS of primary outbreaks in wild birds are regularly delayed for at least 72 hours due to the NVI arrangements in place whereby the NVI analyse wild bird samples in batches and report the results to the NFSA on Friday afternoons. Consequently, the NFSA reports these outbreaks to ADIS the following Monday resulting in delayed notification. This is not in accordance with Article 3(1) of Regulation (EU) 2020/2002.
42. Secondary outbreaks of listed diseases must be reported via ADIS on the first working day of the week and cover the previous week. In one recent outbreak of HPAI in wild birds, discussed during the audit, a secondary outbreak was reported to ADIS after one month and only following a request for information from ESA. In addition, complete information required for ADIS notification on outbreaks of listed diseases was not always provided e.g., the estimated number of wild birds found dead has not always been included in ADIS notifications as required by Annex II (14)(a)(iii) of Regulation (EU) 2020/2002.

5.2.3 Depopulation

43. The administrative emergency plan includes, *inter alia*, the contract for depopulation. This requires the selected company to respond within 12 hours and have the necessary staff and equipment available. Data provided by the NFSA confirmed that all commercial flocks infected with HPAI or ND were either pre-emptively slaughtered or killed on the day of confirmation or the day after confirmation of the listed disease. The contractor implemented whole house gassing using carbon dioxide and the NFSA confirmed this was supervised by an official veterinarian as required by Article 12(1) of Regulation (EU) 2020/687. The NFSA also confirmed that the contractor was responsible for helping set up biosecurity points and the collection and disposal of dead birds.
44. In one department visited, the NFSA confirmed they did not always supervise the removal of carcases and preliminary cleaning and disinfection in affected establishments carried out by the contractor i.e. there was no direct official veterinarian supervision of carcase removal and transport from the affected establishments or

supervision of the preliminary cleaning and disinfection as required by Article 12(1) and (2) of Regulation (EU) 2020/687.

5.2.4 Restricted areas.

45. The NFSA established restricted zones based on the minimum radius from the outbreak required by EEA legislation i.e., 3km radius for protection zone and 10km radius for the surveillance zone. In one department visited by the audit team, lists of poultry and captive bird establishments in the restricted zones were established using data held in MATS and local knowledge for hobby flocks and captive birds not currently registered. Early contact by text message allowed the NFSA to provide information on e.g., inspections, the need to notify any suspicions etc. All establishments in the protection zone had an official veterinarian visit and at least 25% of all holdings in the surveillance zone had an official veterinarian visit based on advice from NFSA central level and a departmental risk assessment which considered issues such as e.g., proximity to wetland areas and knowledge of on-farm biosecurity.

46. The audit team reviewed records from official veterinarian visits in protection zones and noted their activities included e.g., control of documentation related to mortality, health and production, clinical examination of kept animals of listed species and biosecurity as required by Article 26 of Regulation (EU) 2020/687. In one department visited, the NFSA confirmed that a third of commercial establishments and a similar proportion of backyard / captive flocks received official veterinarian visits during outbreaks. In another department visited, the same approach was taken i.e., lists of poultry / captive birds were established in the protection zone and the surveillance zone. The owners were contacted, advice provided and all protection zone establishments and a proportion of surveillance zone establishments were visited by official veterinarians.

5.2.5 Application of measures in protection and surveillance zones

47. In one region, the NFSA established a dedicated team to deal with requests for movements concerning animals, products and other materials within, from or to the restricted zone. According to the pre-audit questionnaire, this team evaluated whether derogations for movement could be granted according to legislation and carried out a risk assessment based on the category of movement, local knowledge and advice from the NVI.

48. The audit team reviewed movements from the protection zone to a slaughterhouse outside the restricted zone. Documentation available included, *inter alia*, application for transport from the protection zone to slaughterhouse, a route plan, confirmation of clinical examination before movement and in selected cases, laboratory results were available for AI or ND prior to the movement taking place. This approach is in accordance with Article 28(2 – 5) of Regulation (EU) 2020/687.

5.2.6 Lifting of restrictions and repopulation

49. The audit team reviewed the NFSA procedures for repopulation. In one example followed this included the laboratory examination of samples from poultry intended to be used for repopulation (to rule out the presence of HPAI prior to their introduction), written approval to repopulate the establishment from the NFSA, an official veterinarian visit to the affected establishment on the last day of the 21 day monitoring period / before 30 days from the date poultry were placed, clinical inspection and collection of samples to confirm or rule out the presence of HPAI. These measures are in line with the provisions laid down in Article 59 (1), (2), (3) and (5) of Regulation (EU) 2020/687.

Conclusions

50. In commercial poultry establishments, the NFSA implements control and eradication measures for HPAI and ND in a timely manner.
51. The NFSA did not always conduct an immediate investigation to confirm or rule out the presence of a suspected category A disease. This delay in investigation can increase the risk of spread of the disease.
52. Delays in obtaining test results for suspect captive birds and wild birds may, in the event of a positive diagnosis, delay the setting up of restricted zones and implementation of disease prevention measures.
53. Reports to ADIS of primary outbreaks of HPAI in wild birds are mostly delayed, the majority for at least 72 hours. This is related to NVI arrangements to batch samples for testing during the week and report positive results to the NFSA on Friday afternoons. Consequently, the NFSA reports these outbreaks to ADIS on the following Monday. In addition, complete details of primary and secondary outbreaks of HPAI in wild birds are not always reported to ADIS in a timely manner.
54. The procedures followed by the NFSA to allow repopulation of establishments affected by outbreaks of HPAI are adequate to ensure there is no risk of residual infection being present in the establishment or introduced with the poultry intended for repopulation.

6 Final meeting

A final meeting was held on 18 October 2023 at NFSA headquarters in Oslo with representatives from the NFSA and the Ministry of Agriculture and Food. At this meeting, the audit team presented their main findings and preliminary conclusions from the audit. The competent authorities did not express disagreement with these.

7 Recommendations

In order to facilitate the follow-up of the recommendations hereunder, Norway should notify ESA no later than **5 April 2024**, by way of written evidence, of additional corrective actions planned or taken other than those already indicated in the reply to the draft report. In case no additional corrective actions have been planned, ESA should be advised. ESA should be kept continuously informed of changes made to the already notified corrective actions and measures, including changes of deadlines for completion and completion of the measures included in the timetable.

No	Recommendation
1	The competent authority should ensure that all outbreaks of listed diseases are notified through ADIS within the prescribed timeframes and that all relevant information is included in the notification. Recommendation based on conclusion: 53. Associated finding: 32, 41 and 42. Legal basis for recommendation: Article 3 of Regulation (EU) 2020/2002.
2	The competent authority should ensure that the accreditation scope of official laboratories they designate includes those methods of laboratory analysis, test or diagnosis required when it operates as an official laboratory.

	Recommendation based on conclusion: 35. Associated finding: 28 and 29. Legal basis for recommendation: Article 37(5) of Regulation (EU) 2017/625.
3	The competent authority should ensure that contingency plans are kept up to date and provide sufficient detail to ensure a high level of disease awareness and preparedness and the ability to launch a rapid response in the event of an occurrence of a listed disease. Recommendation based on conclusion: 33. Associated finding: 10, 11, 12, 13 and 14. Legal basis for recommendation: Article 43 of Regulation (EU) 2016/429.
4	The competent authority should ensure that in the event of suspicion of a category A disease in kept animals in an establishment they shall immediately conduct an investigation to confirm or rule out the presence of the suspected listed disease. Recommendation based on conclusion: 51. Associated finding: 39. Legal basis for recommendation: Article 6(1) of Regulation (EU) 2020/687.
5	The competent authority should have procedures and / or arrangements in place to identify and correct shortcomings in their official controls to ensure their effectiveness and appropriateness. Recommendation based on conclusion: 33, 34, 35, 51, 52 and 53. Associated finding: 7, 11, 14, 24, 31 and 39. Legal basis for recommendation: Article 5(1)(a) of Regulation (EU) 2017/625.

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

ADIS	Animal Disease Information System
AI	Avian influenza
APMV	Avian paramyxovirus
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
ELISA	Enzyme linked immunosorbent assay
ESA	EFTA Surveillance Authority
EU	European Union
EURL	European Union Reference Laboratory
HPAI	Highly pathogenic avian influenza
LPAI	Low pathogenic avian influenza
MATS	NFSA's case processing and decision support tool
ND	Newcastle disease
Norsk Akkreditering	Norwegian accreditation body for technical accreditation
NRL	National reference laboratory
NVI	The Norwegian Veterinary Institute
PPMV	Pigeon paramyxovirus type
rRT-PCR	Real time reverse transcription polymerase chain reaction

Annex 2 - Relevant legislation

The following legislation will be taken into account in the context of this audit:

a) The Act referred to at Point 11b of Part 1.1. of Chapter I [of Annex Ito 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 sectoral and the specific adaptations referred to in Annex I to that Agreement;

b) The Act referred to at Point 13 of Part 1.1. of Chapter I of Annex I to the EEA Agreement, Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law'), as amended and as adapted to the EEA Agreement by the sectoral and the specific adaptations referred to in Annex I to that Agreement;

c) The Act referred to at Point 13a in Part 1.1. of Chapter I of Annex I to the EEA Agreement, Regulation 2018/1882 Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases.

d) The Act referred to at Point 13e in Part 1.1. of Chapter I of Annex I to the EEA Agreement, Regulation 2020/687 Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases.

e) The Act referred to at Point 13g in Part 1.1. of Chapter I of Annex I to the EEA Agreement, Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs.

f) The Act referred to at Point 13h in Part 1.1. of Chapter I of Annex I to the EEA Agreement, Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases.

g) The Act referred to at Point 13k in Part 1.1. of Chapter I of Annex I to the EEA Agreement, Commission Implementing Regulation (EU) 2020/2002 of 7 December 2020 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Union notification and Union reporting of listed diseases, to formats and procedures for submission and reporting of Union surveillance programmes and of eradication programmes and for application for recognition of disease-free status, and to the computerised information system.

h) The Act referred to at Point 13l in Part 1.1. of Chapter I of Annex I to the EEA Agreement, Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC.

i) The Act referred to at Point 13n in Part 1.1. of Chapter I of Annex I to the EEA Agreement, Commission Delegated Regulation (EU) 2020/2154 of 14 October 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards animal health, certification and notification requirements for movements within the Union of products of animal origin from terrestrial animals.

j) The Act referred to at Point 13p in Part 1.1. of Chapter I of Annex I to the EEA Agreement, Commission Implementing Regulation (EU) 2021/403 of 24 March 2021 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates and model animal health/official certificates, for the entry into the Union and movements between Member States of consignments of certain categories of terrestrial animals and germinal products thereof, official certification regarding such certificates and repealing Decision 2010/470/EU.

k) The Act referred to at Point 13s in Part 1.1. of Chapter I of Annex I to the EEA Agreement, Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs.

l) The Act referred to at Point 9b in Part 7.1 of Chapter I of Annex I to the EEA Agreement, Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation).

m) The Act referred to at Point 9c in Part 7.1 of Chapter I of Annex I to the EEA Agreement, Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive, as amended and as adapted to the EEA Agreement by the specific and sectoral adaptations referred to in Annex I to that Agreement.

n) The Act referred to at Point 2a of Part 9.1 of Chapter I of Annex I to the EEA Agreement, Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing, as amended and as adapted to the EEA Agreement.

o) EFTA Surveillance Authority Decision No 032/21/COL of 21 April 2021 regarding approval of disease-free and non-vaccination statuses and eradication programmes of Norway and Iceland or certain zones or compartments thereof as regards certain listed diseases in accordance with Regulations (EU) 2016/429 and Delegated Regulation (EU) 2020/689.

Annex 3 – Corrective Action Plan

Description	Action: Title	Action: Description	Action: Updates	Action: Due date
Recommendation 1: The competent authority should ensure that all outbreaks of listed diseases are notified through ADIS within the prescribed timeframes and that all relevant information is included in the notification.	Incident management workshop	We are hosting a workshop on incident management on January 19, 2024, where, among other things, we will go through how to report on dead wild birds.	The workshop was successfully conducted with the section for animal health on January 19th 2024.	Completed
	Establishment of a reporting group	We have established a dedicated reporting group consisting of those who carry out the reporting. The person on duty for reporting is responsible for carrying out the reporting within the applicable deadlines.	The reporting group has been established.	Completed
	Reporting of dead wild birds	The reporting group is also tasked with reviewing incidents, reporting, including the reporting of dead wild birds, and registrations at a regular meeting every week.	The reporting group is established, and weekly meetings are planned.	Completed
	Timeframe for reporting of analysis results for dead wild birds.	We will conduct a meeting with the NVI regarding changing the reporting of wild birds to Thursdays instead of Fridays. This will result in the reporting of wild birds being possible on Fridays.		30.04.2024

Description	Action: Title	Action: Description	Action: Updates	Action: Due date
	The notification procedure	The notification procedure, including the NVI's notification to the NFSA, how the NFSA internally and externally notifies, is under revision. The goal is to make it even clearer on how and when notifications should take place.		30.04.2024
Recommendation 2: The competent authority should ensure that the accreditation scope of official laboratories they designate includes those methods of laboratory analysis, test or diagnosis required when it operates as an official laboratory.	Accreditation of the AI and ND methods used	Inform the laboratory of the accreditation requirement.	The laboratory has successfully accredited its methods for both AI and ND, including the hemagglutination inhibition tests, which was used. The real-time PCR test for ND was accredited already.	Completed
	Requirement for accredited methods for surveillance programs	If results obtained in connection with the monitoring program are utilized for official control decisions, the analyses must be accredited.	This is addressed within the OK Coordination Group, and the column for validated /accredited" methods, will be changed to "accredited" in the templates for OK program contracts, enclosure 1 from 2025. The contracts for 2024 are now being signed."	Completed
Recommendation 3: The competent authority should ensure that contingency plans are kept up to date and provide sufficient detail to	Revision of contingency plans	Both the general contingency plan and the contingency plan for AI and ND are under revision. The absence of a detailed contingency plan will be addressed with the		30.04.2024

Description	Action: Title	Action: Description	Action: Updates	Action: Due date
ensure a high level of disease awareness and preparedness and the ability to launch a rapid response in the event of an occurrence of a listed disease.		regions, and necessary local adjustments will be implemented.		
	Emergency preparedness exercise	The NFSA head office will participate in an emergency preparedness exercise on a Category A disease.		31.12.2024
	Annual animal health preparedness day	We will introduce an annual preparedness day (or days) for everyone involved in animal health preparedness, both centrally and in the regions, where preparedness is reviewed, including a review of equipment and planning.		31.05.2024
Recommendation 4: The competent authority should ensure that in the event of suspicion of a category A disease in kept animals in an establishment they shall immediately conduct an investigation to confirm or rule out the presence of the suspected listed disease.	Incident management workshop	We are hosting a workshop on incident management on January 19, 2024, where, among other things, we will provide information on how incidents where HPAI or ND cannot be ruled out should be handled.	The workshop was successfully conducted with the section for animal health on January 19th 2024.	Completed
	Communication of details in contingency plans	We will make it clearer to the regions that they must create their own contingency plans detailing the regional/local handling.		30.04.2024
	Revision of NFSA notification procedure	The notification procedure, including the NVI's notification to the NFSA, how the NFSA internally and externally notifies, is under		30.04.2024

Description	Action: Title	Action: Description	Action: Updates	Action: Due date
		revision. The goal is to make the process even clearer regarding how and when notifications should occur.		
Recommendation 5: The competent authority should have procedures and / or arrangements in place to identify and correct shortcomings in their official controls to ensure their effectiveness and appropriateness.	New operational plan	The NFSA is implementing an operational plan from 2024 onwards that includes corrective measures in cases where we have failed to carry out official control as intended in the plan.	NFSA sin nye operative plan ble vedtatt i desember og har trådt i kraft fra 1. januar 2024.	Completed
	Reporting and follow-up of new operational plan	The NFSA is in the progress of creating requirements for reporting for both the regions and headquarters, explaining how reporting and follow-up according to the operational plan should be done.		01.03.2024
	Implementation of control verification procedure	The NFSA established a control verification procedure in mid-2023. The procedure is still in the process of being implemented in different areas.		31.03.2024