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Final report

EFTA Surveillance Authority's mission to Norway from 20 to 29 May 2019 in order to evaluate animal health controls in relation to aquaculture

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. Comments from Norway to the draft report are included in Annex 4 and information on the corrective actions already taken and planned are included in Annex 5 to the report.

Executive Summary

This report describes the outcome of a mission carried out by the EFTA Surveillance Authority in Norway from 20 to 29 May 2019.

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

It is not clear that Commission Implementing Decision (EU) 2015/1554 of 11 September 2015 laying down rules for the application of Directive 2006/88/EC as regards requirements for surveillance and diagnostic methods has been fully or properly made part of the Norwegian legal order. Norway has not formally notified the Authority how this Decision is implemented and the relevant administrative procedures for surveillance of listed fish and molluscs diseases, which Norway claims implements the Decision, does not reflect all the provisions of the Decision.

At the time of the mission there was no reliable system in place in Norway enabling identification of farms which have been granted ISA-free status. Moreover, in the majority of cases, such status has been granted without or with very limited involvement of the NFSA staff prior to the stage when the formal application is forwarded to the NFSA. The lack of official verification by the NFSA of surveillance activity undertaken to prove freedom from ISA casts significant doubt on the reliability of the statements included in the declarations of free status for compartments submitted by the NFSA since it is not in a position to ascertain the accuracy of the information being certified or ensure that no conflict of interest compromises the process.

Norway has submitted several declarations for dependent Infectious Salmon Anaemia (ISA)-free compartments; i.e. sites which are dependent on the health status of the surrounding waters. However, in these cases Norway does not apply additional disease surveillance activities to confirm that the sea waters surrounding elements of the dependent compartment (e.g. neighbouring salmon farms or susceptible species of wild fish) can also be considered free of ISA. The mission team considers that due to the lack of surveillance in surrounding waters and the absence of any additional measures to prevent introduction of ISA to sea sites declared free of ISA, such dependent compartments should not be declared and certified for intra-EEA trade and export to third countries as ISA-free compartments.

Current certification arrangements attesting the free status of aquaculture production businesses from Bacterial Kidney Disease lack transparency regarding the disease surveillance programme and which entities are considered by the NFSA as compliant with the relevant requirements.

A network of diagnostic laboratories has been designated by the competent authority and independently accredited. The national reference laboratories for all listed diseases of aquatic animals participate in proficiency testing organised by the relevant EU reference laboratories and, in addition, organise periodic ring tests of diagnostic procedures at national level with the designated private laboratories to ensure standardisation. This ensures that the laboratory network can provide a reliable diagnostic service for listed aquaculture diseases.

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 mission took place in Norway from 20 to 29 May 2019. The mission team comprised three inspectors from the EFTA Surveillance Authority (the Authority) and 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.

A pre-mission questionnaire was sent by the Authority to the Norwegian Ministry of Agriculture and Food on 28 February 2019. A reply ('the pre-mission document') was provided on 27 April 2019.

The opening meeting was held with representatives of the Ministry of Trade, Industry and Fisheries and the Norwegian Food Safety Authority (NFSA) on 20 May 2019 at NFSA headquarters in Oslo. At the meeting, the mission team confirmed the objectives and the itinerary of the mission and the Norwegian representatives provided additional information to that set out in the pre-mission document.

Throughout the mission, a representative of the NFSA accompanied the mission team. In addition, representatives of NFSA regional offices participated during meetings and visits to the different operators.

A final meeting was held at the NFSA premises in Oslo on 29 May 2019, at which the mission team presented its main findings and preliminary conclusions from the mission.

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

2 Scope and Objective of the mission

The main scope of the mission was to assess the application by the Norwegian competent authority or authorities of the following European Economic Area (EEA) Acts, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement, and related EEA legislation:

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

b) *Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals*, as corrected and amended;

The main objective of the mission was to evaluate the official control system in place for the control of diseases affecting aquaculture animals and laboratories involved in the monitoring and analyses of samples taken during official controls related to the scope of this mission.

The assessment was carried out based on, and related to, the EEA legislation referred to in Annex 2 to this report. The assessment was further based on the pre-mission document.

The evaluation included the gathering of relevant information and appropriate verifications, by means of interviews/discussions, review of documents and records and on-the-spot inspections, 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 meetings with the competent authorities and the visits to laboratories, to aquaculture production business operators ('ABOs') to verify compliance with animal health requirements during the mission are listed in Table 1.

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

	Number	Comments
Competent authorities	3	An initial meeting and a final meeting between the mission team and the Norwegian competent authority. An additional meeting with the NFSA personnel was held to seek further clarification on the system of official controls in certain areas
Regional offices	2	NFSA regional offices in Central (Midt) region and Southern and Western (Sør-Vest) region
Laboratories	3	The National Reference Laboratory for diseases of aquaculture animals (Norwegian Veterinary institute (NVI)), The National Reference Laboratory for mollusc diseases (Institute of Marine Research Laboratory) and one private laboratory designated by the Competent authority to carry out analysis of diseases affecting aquaculture animals
Aquaculture production businesses	5	A selection of ABOs
Fish slaughterhouses	1	Establishment slaughtering salmon
Animal by-products plants	1	Category 2 and 3 establishment
Transporter of fish	1	One well boat

3 Legal basis for the mission

The legal basis for the mission was:

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

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

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

d) Article 45 of *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the* verification *of compliance with feed and food law, animal health and animal welfare rules,* as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

e) Article 58 of Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals.

Legislation relevant to this mission is listed in Annex 2.

4 Previous missions and information on production

4.1 Previous missions

A mission regarding application of EEA legislation in relation to fish health was carried out in 2010 and concluded that the situation was, from a general point of view, satisfactory concerning official controls carried out by the NFSA. Relevant activities were mainly in conformity with the EEA requirements laid down in Directive 2006/88/EC and related legislation. The final report from this mission can be found on the Authority's website[1].

A fact-finding mission regarding aquaculture was carried out by the Authority in Norway in 2015. This mission was one in a series of fact-finding missions to EEA states carried out in cooperation with the Food and Veterinary Office (now DG Sante, Directorate F) of the European Commission. A mission report, prepared in co-operation with DG Sante, concluded, among other points, that the designated competent authorities for the aquaculture sector had an adequate structure, organisation and legal powers permitting effective risk based controls at an appropriate frequency. EEA rules for aquaculture official controls were implemented with a high level of expertise and supporting the development of the sector as a whole. As the objective of the fact-finding mission was to gather information on official controls on aquaculture, no recommendations were made. An overview report from the series of fact-finding audits in EEA countries can be found on the European Commission's website[2].

4.2 Information on production

Production data for 2017 and 2018, as provided by the NFSA in the reply to the pre-mission document, is summarised in Annex 3.

[1] http://www.eftasurv.int/media/food-safety/565617_Report-2008-NOR-on-fish-health.pdf

[2] http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=95

5 Findings and conclusions

5.1 Legislative and implementing measures

Legal Requirements

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

Findings

1. According to information provided by Norway in its reply to the Authority's pre-mission document, EEA legislation regarding aquatic animal health is implemented in Norway.
2. The pre-mission document states that Commission Implementing Decision (EU) 2015/1554 of 11 September 2015 laying down rules for the application of Directive 2006/88/EC as regards requirements for surveillance and diagnostic methods ('Decision (EU) 2015/1554') is implemented by administrative procedures for surveillance programmes and chapters on Infectious salmon anaemia (*ISA*), Viral haemorrhagic septicaemia (*VHS*), Infectious haematopoietic necrosis (*IHN*) and Bonamia ostreae (*B. ostreae*) and Marteilia refringens (*M. refringens*) specified in the Norwegian Food Safety Authority's Instruction for OK programs 2019 ('OK 2019'). However, it is not clear to the Authority if OK 2019 incorporates all provisions of Decision (EU) 2015/1554 and/or is legally binding.

Conclusions

3. It is not clear to the Authority that Decision (EU) 2015/1554 has been made part of the Norwegian legal order. Norway must formally notify the Authority of any implementation, including a precise explanation of the method of implementation so as to be binding under Norwegian law and whether such implementation is partial or full.

5.2 Competent authorities

5.2.1 Designation of competent authorities and organisation of official controls

Legal Requirements

Article 54(1) of Directive 2006/88/EC, Article 4(1) of Regulation (EC) No 882/2004

Findings

4. The responsibility for food policy and for the management of foodstuffs from production to delivery to the consumer is shared between the Ministry of Agriculture and Food, the Ministry of Trade, Industry and Fisheries and the Ministry of Health and Care Services. In addition, the Ministry of Agriculture and Food is administratively responsible for the Norwegian Food Safety Authority (NFSA), which is the central competent authority in Norway for food and feed safety, animal health and welfare.
5. Official controls within the scope of Regulation (EC) No 882/2004 are the responsibility of the NFSA. Detailed information on the structure and organisation of

the Norwegian competent authorities is provided in the Country Profile for Norway[3] published on the Authority's webpage and in the Multi-Annual National Control Plan[4] (MANCP) available on the NFSA webpage.

6. The NFSA is organised into two administrative levels, the head office and the regions. The head office carries out directorate and governance tasks. The regional level consists of five regions, each divided into local departments (with 70 office locations altogether). The local departments perform the official controls in defined geographical areas, i.e. regions.

Conclusions

7. The competent authority responsible for delivery of animal health official controls in aquaculture have been clearly designated.

5.2.2 Personnel and training of staff

Legal requirements

Article 4(2)(c) and Article 6 of Regulation (EC) No 882/2004

Findings

8. Available manpower and resources are described in the Country Profile for Norway, part 1.
9. According to information provided by Norway in its reply to the Authority's pre-mission document, the NFSA runs general competence development programs at both national and regional level to ensure the appropriate competence and training of all staff. In addition, it was stated that the NFSA's strategy for competence development in the years 2019-2021 will have a special focus on fish health. However, none of the NFSA staff met during the mission was able to provide further details regarding this. During the meetings with the regional offices, it was seen that staff participated in various trainings, some had taken the online course on fish health and welfare offered by the Norwegian University of Life Sciences (NMBU) in co-operation with the NFSA.
10. An online course on aquaculture is available to the NFSA staff at all levels and the mission team saw evidence of participation of inspection staff from local offices in the regions in this course.

Conclusions

11. The competent authority has sufficient staff available to deliver official controls related to aquaculture animal health efficiently and effectively. These staff are in general suitably qualified and experienced.

[3] http://www.eftasurv.int/media/food-safety/Country-profile-NORWAY---July-2017---Part-1.pdf

[4] https://www.mattilsynet.no/om_mattilsynet/multiannual_national_control_plan.23956

5.2.3 Documented control procedures and reporting on official controls

Legal requirements

Article 8(1) and Article 9 of Regulation (EC) No 882/2004

Findings

12. The NFSA has issued a number of relevant guidelines and administrative procedures to help its staff in performing the official controls, including in relation to authorisation of establishments and authorisation and inspection of transporters of aquaculture animals. These are published on the NFSA website.
13. The guidelines for authorisation and inspection of transporters describe the procedures for granting of authorisation and include requirements for hygienic and welfare-friendly operation, routines for cleaning and disinfection, handling of dead fish, monitoring of water quality, withdrawal of water quality samples and record keeping. In addition, the guidelines include the requirement that each well boat must automatically inform the NFSA every half an hour of its position. This information is recorded on the Barentswatch[5] website and is consequently publicly available. A requirement that all well boats be equipped with water treatment installation is applicable from 2021. The well boat seen by the mission team, which had transported fish from a farm with a confirmed ISA outbreak, had been authorised in accordance with these guidelines and had UV disinfection system and ozonisation water disinfection installation on board.
14. The NFSA's OK 2019 includes procedures for surveillance of listed fish and molluscs diseases. However, detailed guidelines on the process of obtaining and maintaining ISA free status are not included. (See also section 5.3.6.1).
15. A check-list available in the NFSA database for official controls (MATS) is used by inspectors for controls on fish farms. Inspection reports concerning establishments visited are issued on the basis of this check-list. Copies of reports, both from routine visits by NFSA as well as investigations of increased mortality carried out by NFSA, were present at aquaculture farms visited.
16. The latest NFSA inspection reports were reviewed by the mission team at all fish and mollusc farms visited. The inspection reports checked were comprehensive and covered all relevant issues, including biosecurity, aquatic animal health and welfare.

Conclusions

17. Documented control procedures are in place for official controls related to animal health on aquaculture farms. Reports are drawn up on official controls carried out describing the results of the official controls and, where appropriate, action that the business operator concerned is to take. This should facilitate that legislative requirements are implemented uniformly throughout the country.

[5] https://www.barentswatch.no

5.2.4 Authorisation of ABOs

Legal requirements

Article 31 of Regulation (EC) No 882/2004, Article 3 of Regulation (EC) No 854/2004, Article 4, Article 6 and Annex II, Article 33, Article 38 and Article 59 of Directive 2006/88/EC, Commission Decision 2008/392/EC

Findings

18. The requirements for authorisation of aquaculture production businesses and processing establishments are laid down in Regulation NO of 17 June 2008 No 823. Guidelines regarding authorisation of establishments, the administrative procedures for authorisation of aquaculture production and for licence applications have been issued by the NFSA. All ABOs visited were authorised in line with national legislation.

19. The mission team noted that there are no requirements or system in place to ensure that existing authorisations of ABOs are updated to cover all relevant requirements when new legislation enters into force. Consequently, ABOs already in operation before application of Directive 2006/88/EC in Norwegian law are authorised but these authorisations do not reflect all requirements of that Directive. For example, provisions concerning recording obligations, implementation of good hygiene practice, biosecurity and ensuring a risk based animal health surveillance scheme are not adhered to in all existing authorisations, contrary to Article 4 of Directive 2006/88/EC.

20. The mission team noted that the NFSA authorised one of the ABOs visited in accordance with Directive 2006/88/EC in 2012, following an application from the ABO to expand an existing operation. Until that time, it operated under the old authorisation. On another aquaculture site visited, two ABOs were operating, one being a hatchery for scallops, the second being a dispatch and purification centre. Following an application for authorisation to expand the operation at the site to include the purification centre, the NFSA issued a new authorisation concerning the purification centre in accordance with Article 4 of Council Directive 2006/88/EC requiring treatments of effluents. The mission team noted that both the hatchery and the purification centre have a common system for treatment of effluents. The installation was approved for five years by the National Veterinary Institute on 23 October 2017. However, no authorisation had been obtained for the dispatch centre contrary to Articles 4(1) of the Directive.

21. Means of transporting aquaculture animals are authorised by the regional offices of the NFSA in accordance with national requirements laid down in Regulation NO of 17 June 2008 No 820. Authorisations are valid for a maximum of five years. Guidelines on authorisation of well boats issued by the NFSA require that at least one inspection of each authorised well boat be undertaken annually. Representatives of the local departments in the NFSA regions stated that it is difficult to establish routine inspections of well boats due to the specificity of the operation they carry out and that they try to inspect well boats during the inspection of slaughterhouses. Well boats are also checked and specific operational decisions (routing, closing of valves, disinfection requirements, etc.) are issued by the NFSA if the situation requires specific actions to be taken - for example, if they have to transport diseased fish to a slaughterhouse.

22. A list of authorised transporters is available on the NFSA website. The mission team noted that there is no harmonised approach for listing means of transport such as would enable their easy identification. This is particularly the case for means of transport used for transport of aquaculture animals by road. For example, in some cases a

container is listed with no means of individual identification and a well boat is listed simply as "Russian well boat".

23. In the response to the pre-mission questionnaire, the NFSA stated that all processing establishments in Norway approved for slaughtering aquaculture animals are authorised for slaughtering for disease control purposes and equipped with installations for treatment of effluent waters, pursuant to Articles 33(3) and 38(1)(a) of Directive 2006/88/EC. This was confirmed by the mission team in the slaughtering establishment visited. In addition, the NFSA authorises on a case by case each slaughtering operation of aquaculture animals for listed disease control purposes, thereby permitting application of additional *ad hoc* disease control requirements (for example, disinfection of transport water and/or prohibition of intermediate storage of fish in slaughter cages before slaughtering) if necessary.

24. Pursuant to Regulation NO of 17 June 2008 No 823, an ABO's authorisation can be withdrawn if the conditions of authorisation are not fulfilled, if there are significant changes in the animal health or welfare status, or if new knowledge indicates that changes in the type, volume or location of the operation may significantly change the animal health or welfare status.

25. A register of authorised ABOs, as well as authorised aquaculture sites, is publicly available on the website of the Directorate of Fisheries (*Fiskeridirektoratet*).There is also a map-based website (*barentswatch.no*) which provides the location of all licenced aquaculture sites in Norway. On the NFSA's website, all processing establishments, including those handling farmed fish, which are approved in accordance with Regulation (EC) 853/2004 are listed. None of these registers contain all the information required by Article 6 and Annex II to Directive 2006/88/EC and Commission Decision 2008/392 and neither do these registers collectively contain all the required information (see also paragraph 32). In particular, information on the presence of susceptible species at, or the health status of, sites, as required by Point 1 (f) and (g) of Part I of Annex II to Directive 2006/88/EC and Commission Decision 2008/392, is missing. Furthermore, there is no information on water treatment systems in place in authorised establishments, contrary to Part II(d) of Annex II to Directive 2006/88/EC and Point 5 of Annex IV of Decision 2008/392/EC.

Conclusions

26. No systematic assessment of existing licences has been carried out since the application of Directive 2006/88/EC in Norwegian law. ABOs are therefore being permitted to continue operations notwithstanding that the requirements of that Directive are not fulfilled and some businesses subject to authorisation under that Directive have never been authorised. These deficiencies potentially increase the risk of spreading disease

27. None of the publicly available lists of ABO's contains all the information required. In particular, the health status of, and presence of susceptible species on, the production site are not listed. As a result, the interested public, including trade partners cannot check the health status of animals originating from these sites.

28. Processing establishments slaughtering aquaculture animals are authorised for slaughtering for disease control purposes, and meet the requirement to be equipped with an effluent system. However, the register of processing establishments does not contain information on the effluent system.

5.3 Health status and management of listed diseases in Norway

Legal requirements

Article 4(2), Article 7, Article 10, Article 47, Article 49, Article 50, Article 52, Article 53 of Directive 2006/88/EC, Chapter V of Directive 2006/88/EC, Part B of Annex III of Directive 2006/88/EC, Article 8(3)(a) and Article 54 of Regulation (EC) No 882/2004, Commission Decision 2008/896/EC

5.3.1 Health status of aquatic animals in Norway

Findings

29. According to information provided by Norway in its reply to the Authority's pre-mission document, none of the exotic diseases listed in Part II of Annex IV to Directive 2006/88, Infectious haematopoietic necrosis (IHN) or Koi Herpes Virus (KHV) have ever been recorded in Norway. Viral Haemorrhagic septicaemia (VHS) was confirmed in farmed trout in July 2008, infection with *Bonamia ostrea* was detected by PCR in wild European flat oysters in 2009, while infection with *Marteilia refringens* was last recorded in February 2017.

30. The following health statuses are recognised in Norway in accordance with Council Directive 2006/88/EC:

    a. IHN/VHS: Disease-free in accordance with Article 49(1)(c) of Directive 2006/88/EC, as recognised by the Authority's Decision No 264/12/COL: Norway, with the exception of the Norwegian part of the catchment areas of Grense Jacobselv and Pasvik river and the rivers in between and the associated coastal region.

    b. *Marteilia refringens*: Disease-free status in accordance with Article 49(1)(c) of Directive 2006/88, as recognised by the Authority's Decision No 018/18/COL: The entire coastline of Norway is a disease-free zone with regard to *Marteilia refringens*, with the exception of the containment area in the municipality of Bømlo in the County of Hordaland in southern Norway, specifically described in § 2 of the Norwegian Regulations on the control area to fight the disease Marteiliose in molluscs, Bømlo municipality, Hordaland (Regulation NO of 8 September 2017 No 1377).

    c. *Bonamia ostreae*: Disease-free status in accordance with Article 49(1)(c) of Directive 2006/88, as recognised by the Authority's Decision No 018/18/COL: The entire coastline of Norway is a disease-free zone with regard to *Bonamia ostreae*, with the exception of the county of East Agder in southern Norway.

    d. ISA: Norway has declared a number of compartments and zones free of ISA in accordance with Article 50 of Directive 2006/88/EC. In 2009, a number of compartments and zones were declared free on historical grounds. Furthermore, Norway has, since 2013, submitted a number of declarations of ISA free status based on targeted surveillance.

    e. *Gyrodactylus salaris*: The Authority's Decision No 058/16/COL approves, in accordance with Article 43 of Directive 2006/88/EC, certain national measures that Norway may apply for limiting the impact of *G. salaris* in areas free of the disease.

31. Annex 2 to Regulation NO of 17 June 2008 No 819, last amended 25 August 2017, provides an overview of the health status of aquatic animals. Regarding VHS and IHN, Norway is category I with the exemption of certain Category III areas (as described in the Authority's Decision No 264/12/COL). The whole of Norway is considered as category III in relation to KHV, and category I in relation to *B. ostreae* and *M. refringens*, with the exemption of areas that temporarily loses this status when a decision is made to prevent, limit and eradicate the disease in question. The areas currently under restriction for *B. ostreae* are laid down in Regulation NO of 15 June 2009 No 648 and those for *M. refringens* are listed in Regulation NO of 8 September 2017 No 1377. For ISA, all of Norway is considered as category III, except if listed as free (category I) in Regulation NO of 17 June 2008 No 819, or if the status is temporarily lost when a decision is made to prevent, limit and eradicate ISA. Maps of ISA free areas[6] (farms, compartments, zones) as well as declarations[7] of ISA free status can be found on the NFSA's website.

32. The information available in the various sources mentioned in the previous paragraph in relation to ISA is inaccurate, unreliable and at times contradictory. Not all the sites included in maps of free areas (compartments, zones) are included in the Regulation NO of 17 June 2008 No 819, and vice versa. Furthermore, a compartment where the disease free status was suspended in June 2018 is still listed in this Regulation. This is contrary to Article 51 of Directive 2006/88/EC.

33. The terminology used to describe free areas in the Norwegian legislation, as well as in relevant maps, include the words segments, areas, coastal areas, continental areas and zones, comprising one or more sites. In the opening meeting, representatives of the NFSA stated that there are no zones free of ISA in Norway, only compartments.[8] In meetings with local inspectors, the mission team noted that official controls were aimed at individual sites, regardless of denomination.

Conclusion:

34. There is currently no reliable definitive list of ISA-free compartments and zones publicly available for Norway. The information currently available in Norwegian legislation and on the NFSA's website is inaccurate and contradictory. This, combined with the use of inconsistent terminology, has the potential to mislead officials and interested parties regarding which areas in Norway are disease free and from which certification and trade of live fish and products thereof may take place.

[6] https://www.mattilsynet.no/language/english/fish_and_aquaculture/fish_health/areas_declared_free_from_infectious_salmon_anaemia_isa.19431

[7] https://www.mattilsynet.no/language/english/fish_and_aquaculture/fish_health/declaration_of_areas_free_of_infectious_salmon_anaemia_isa_in_norway.8674

[8] In the reply to the draft report the CA stated that due to a misunderstanding, the representatives of the NFSA stated in the opening meeting that there are no zones free for ISA in Norway. This is not true, in Norway there are both zones and compartments declared free for ISA.

5.3.2 *Organisation of official controls of aquaculture*

Findings

35. Official controls on aquaculture are carried out by veterinarians or fish health biologists employed by NFSA. Representatives of the NFSA explained that during official controls, farms are investigated for all listed diseases. All production units are inspected to check for increased mortality, abnormal behaviour or other signs of disease and reports from health inspections carried out by qualified aquatic animal health personnel are checked.

36. The regional offices of the NFSA plan and adopt an inspection programme for their area based upon *inter alia* the budget allocation letter and OK 2019. Farms with increased mortality and disease are prioritised, as well as sites declared free of ISA or which are in the process of obtaining such freedom and sites that are under official restrictions due to an outbreak of a listed disease or which are included in any official surveillance or sampling program, e.g. for *Gyrodactylus salaris*, ISAV-HPR0, VHS, IHN or salmon lice.

37. In one NFSA region visited, a model for planning official controls was shared with the whole region. The mission team noted that in one of the departments the model had been adapted into three different versions, in general containing the same type of information. Individual sites were indicated as ISA free. However, in at least one of the documents, not all ISA free sites were indicated. Furthermore, it could not be confirmed that sites belonging to the same compartments were identified and controlled as one unit as regards ISA status. It was explained that the status of planned versus performed official controls was checked locally every two weeks, and monthly for the whole region. The mission team confirmed that official controls were carried out as planned.

38. In the second region visited, the mission team could not fully assess the system of planning and verification of official controls at regional level because nobody from the regional level was present to explain how this system worked. The inspectors that were present could not provide an overview of planned official controls or official controls carried out and were only able to present a general document outlining priorities for official controls.

39. None of the regions visited, nor NFSA's central office, could demonstrate a system in place for supervision and verification of effectiveness (for example, specific checks on proposed or approved ISA-free compartments) of official controls.

40. The mission team noted that official controls generally do not include sampling for obtaining, maintenance and restoration of disease free status for diseases listed in Part II of Annex IV of Council Directive 2006/88/EC because the majority of such sampling is carried out by private fish health services (see also paragraph 61).

41. Official controls by the NFSA include checks of reports from qualified aquatic animal health personnel and the mission team confirmed that the NFSA identified and followed up on non-compliances - for example, frequency of health inspections (a mollusc farm that moved animals from a site without health inspection) or absence of follow up on increased mortalities (increased mortalities of cleaner fish on an on-growing farm had not been investigated by the private fish health service).

42. The NFSA had carried out official controls in a hatchery, including checks prior to certifying consignments of live scallops destined for other EEA states. Non-compliance with requirements laid down in Directive 2006/88/EC were identified and

followed up by the NFSA, some of which should have been addressed at the time of authorisation (e.g. application of an animal health surveillance scheme).

Conclusions

43. Due to the absence of regional staff, the mission team was not able to fully assess the system of planning and verification of official controls in aquaculture. No system for supervision or verification of effectiveness of controls has been established.

5.3.3 Animal Health Surveillance Scheme

44. According to information provided by Norway in its reply to the Authority's pre-mission document, risk-based health checks are performed by qualified aquatic animal health personnel, which may be employed either by private fish health services or directly by ABOs.

45. Article 10 of Council Directive 2006/88/EC concerning animal health surveillance schemes is implemented in Norwegian legislation by Regulation 17 June 2008 No. 822, paragraphs 13 (general requirements), 50 (requirements for brood stock farms), 50a (requirements for on-growing farms) and 62 (requirements for hatcheries/smolt farms).

46. The frequency of health inspections (4 to 12 per year) are higher than the recommended frequencies laid down in Part B of Annex III to Directive 2006/88/EC and depend upon type of farm (e.g. brood stock, smolt or on-growing) and number of aquatic animals on the farm. ABOs must ensure that aquaculture animals taken into an aquaculture site undergo at least one health check before being moved from the site.

47. The mission team noted that all ABOs visited had access to qualified aquatic animal health personnel through private fish health services and/or directly employed by the ABO. Reports from routine health inspections, as well as follow up investigations in case of increased mortalities, were available at sites visited, with exception of the mollusc farm visited. At this mollusc farm, the NFSA inspector explained that the ABO had only recently introduced health inspection checks, after absence of such had been identified as non-compliance during an earlier NFSA inspection.

48. Inspections required pursuant to Article 10 of Council Directive 2006/88/EC are combined with specific requirements for health status, such as sampling for obtaining or maintaining disease free status as described in Part B of Annex III to Council Directive 2006/88/EC. Since these inspections may be carried out by staff employed by the ABO (see also paragraph 44), Norway cannot ensure that sampling to maintain or obtain disease free status is performed by staff free from any conflict of interest, contrary to Article 4(2)(b) of Regulation (EC) 20004/882 (see also paragraph 61).

5.3.4 Passive surveillance

49. According to information provided by Norway in its reply to the Authority's pre-mission document, ABOs are required to carry out daily checks on fish farms and weekly checks at mollusc, crustacean or echinoderm farms. ABOs are required to notify qualified aquatic health personnel and to call for additional health checks in the case of increased mortality.

50. The mission team noted that all fish farms visited had pre-determined baseline mortality rates. Mortality rates above these limits were notified to, and followed up by, qualified aquatic animal health personnel.

5.3.5 *Active surveillance*

51. All ABOs in Norway are subject to official controls and are required to have routine health inspections carried out by qualified aquatic health services (see also paragraph 35).

52. Based upon passive surveillance, additional health inspections are carried out by qualified aquatic animal health personnel. The mission team confirmed that investigation of increased mortalities on farms were undertaken and included on-the-spot inspections, post-mortem examinations and samples for diagnostic purposes, pursuant to Article 28 of Council Directive 2006/88/EC.

53. Diagnostic samples are sent to one of the designated private laboratories or the National Veterinary Institute (the NRL for diseases of aquaculture animals). The NVI screen for several diseases, including the non-exotic diseases listed in Part II of Annex IV to Council Directive 2006/88/EC in their routine diagnostic work in the laboratory. However, designated private laboratories generally only include requested pathogens in their work. *i.e.* does not actively target listed diseases unless requested by the qualified aquatic animal health personnel sending the relevant samples.

54. The mission team noted that in most cases notifications of suspicion are sent to the general contact e-mail of the NFSA rather than to the functional notification e-mail for the relevant office and/or department of the NFSA. Generally, the local inspector was in copy (in Cc). In one case of a suspicious outbreak of ISA, an e-mail sent by the ABO to the local inspector was not read until ten days later due to the local inspector being on annual leave at the time.[9]

55. Some of the qualified aquatic animal health personnel met by the mission team explained that they would, in the case of suspicion of a listed disease, not rely solely on e-mail but also call the local office. An example of this was presented in which an ABO notified suspicion of ISA to the local inspector by telephone following positive laboratory results.

56. In one case where samples were sent to a designated laboratory indicating suspicion of ISA, the suspicion was only notified to the NFSA by the ABO in question after the ABO had been informed by the laboratory that the test results were positive.

5.3.6 *Targeted surveillance*

57. According to information provided by Norway in its reply to the Authority's pre-mission document, requirements for the surveillance of fish diseases in Norway are detailed in annual "OK programmes". The OK 2019 comprises programmes for the following diseases listed in Part II of Annex IV to the Directive 2006/88/EC: VHS/IHN and ISA . In addition, Ok 2019 comprises programmes for *inter alia Gyrodactylus salaris* and BKD.

58. In general, the NFSA is responsible for targeted surveillance of aquatic animal health in Norway. However, the majority of sampling is carried out by qualified aquatic

[9] In the reply to the draft report the CA stated that such a delay is not in line with the guidelines on how to notify the NFSA a suspicion or disease in aquatic animals. Notifications to the functional notification e-mails are most commonly used. These e-mail addresses are listed in the guidelines on notification and the information on suspicion should be read each working day.

animal health personnel employed by private fish health services or staff employed by ABOs.

59. The private fish health services are instructed to conduct sampling in connection with increased mortality or signs of abnormal behaviour, focusing on moribund and newly dead fish.

60. OK 2019 for VHS and IHN targets salmon and rainbow trout and cleaner fish from smolt, on-growing and brood stock farms and restocking establishments. In addition, the program for 2019 includes samples of wild pink salmon (*Oncorhynchus gorbuscha*) from rivers in the north of Norway. In September, the NFSA summarises the number of samples collected, as well as which sites have been sampled. If deemed necessary, the NFSA will inspect and collect additional samples from sites that have not been sampled before.

61. The mission team noted that qualified health services that carry out targeted surveillance on behalf of the competent authority pursuant to Part B of Annex III to Council Directive 2006/88/EC may be employed by the ABOs (see also section 5.3.3). Consequently, Norway cannot ensure that these tasks are performed by staff free from any conflict of interest, contrary to Article 4(2)(b) of Regulation (EC) 882/2004 (see also paragraph 40).

62. The mission team noted that the document "OK-2019 VHS and IHN – salmon, rainbow trout and cleaner fish", enclosed in OK 2019, states that the relevant organs to be sampled for examination of VHS and IHN are the kidney and/or heart. This is contrary to Point II.1 of Part I of Annex I of Commission Decision (EU) 2015/1554, which requires the spleen, anterior kidney and either the heart or encephalon to be examined.

63. Norway informed the Authority by letter in 2015 that the control and eradication programme for BKD had been discontinued. In the same letter, the NFSA indicates that a surveillance programme for BKD is in place and that, although there is no official mechanism in the EEA agreement for declaring parts of Norway as free of BKD, the surveillance programme is designed to comply with requirements for disease freedom and Norway considers that aquaculture animals can be placed on the market in a country with a BKD free status (see also paragraph 106).

64. According to OK 2019, sampling for BKD should be carried out on all sites of compartments free of ISA that wish to trade with countries or parts thereof with approved national measures for BKD (i.e. Ireland, Northern Ireland, Isle of Man and Jersey as listed in Commission Decision (EU) 2010/221). The mission team noted that the surveillance for BKD does not cover all free ISA compartments in Norway. Furthermore, there is no overview of aquaculture sites or areas in Norway which the NFSA considers to comply with requirements for disease freedom for BKD equivalent to those laid down in Chapter VII of Directive 2006/88/EC.

65. Norway has not submitted an annual report on the approved national measures for *Gyrodactylus salaris*, contrary to Article 2 of the EFTA Surveillance Authority's Decision No 058/16/COL-D of 3 March 2016.

Conclusions

66. The reliability of targeted surveillance is compromised since staff performing sampling can be employed by the ABOs and are not therefore free from conflict of interests.

67. The targeted surveillance for VHS and IHN does not include sampling of all required organs, potentially compromising the reliability of the surveillance carried out.
68. There is no established list of sites that complies with requirements for disease freedom for BKD, consequently, it cannot be ensured that all relevant sites are subject to surveillance to maintain such freedom. .
69. Norway should verify that the approved national measures for *Gyrodactylus salaris* are applied only as long as they are appropriate and necessary and submit a yearly report to the Authority on the functioning of the national measures.

5.3.6.1 Obtaining, restoration and maintaining free status of ISA

70. According to information provided by Norway in its reply to the Authority's pre-mission document, requirements for obtaining, maintenance and restoration of ISA free status in Norway are laid down in OK 2019. Private fish health services perform most sampling. They may be assisted by auxiliaries (i.e. farm staff), in line with the programme (see also paragraph 58).
71. The number of samples required for individual sites is provided in the OK 2019:
    a. For obtaining ISA freedom: Minimum 150 samples/site continuously throughout the year for a period of two years
    b. For maintaining ISA freedom: Minimum 60 samples/site continuously throughout the year. For stripping stations for brood stock, a minimum of 30 samples/year, collected during the last 9 months before stripping and during the stripping period.
72. NFSA prioritises sampling of moribund and newly dead fish. The sampling for obtaining and maintenance of ISA free compartments is not limited to two collections of specimens. Rather, it is conducted continuously throughout the year.
73. All results of samples analysed for maintenance of ISA free status are collected in an excel work sheet. Representatives of the NFSA explained in the opening meeting that local inspectors should check their sites and verify that a sufficient number of samples are collected to maintain freedom. The mission team noted that the excel work sheet with ISA results does not identify which sites are part of the same ISA free compartments. Furthermore, the excel sheet confirmed the NFSA's statement that ISA free sites are subject to continuous sampling for ISA rather than sampling during two 1-month test periods per year in spring and autumn, as required by Part 3 of Annex I to Commission Decision (EU) 2015/1554, Table 3.B.
74. The mission team noted that OK 2019 describes two options for obtaining ISA free status on land sites, either fallowing for six weeks and re-population with fish from ISA free compartments or surveillance by inspections and sampling for a period of two years prior to submitting a declaration of ISA-free status. The NFSA confirmed in the opening meeting that for land-based compartments where there is a suspicion of ISA or a confirmation of the disease, only the second alternative would be accepted in the future. Such compartments will no longer be able to obtain freedom on the basis of the requirements laid down in Point I.2.2.2 of Part 3 of Annex I to Commission Decision (EU) 2015/1554. Following comments from EU Member States to a declaration based on this requirement in 2018, Norway have confirmed that the requirement of two years' surveillance before declaration required by Point 2.3 of Part II of Annex V to Directive 2006/88/EC would be applied in all cases.
75. ABOs are not obliged to communicate their intention to become an ISA-free compartment to the NFSA in advance. The NFSA inspectors met locally confirmed

that in the majority of cases they receive information on the application submitted by the operator only just before the declaration for ISA-freedom is filed with the NFSA. Verification is often restricted to checking the total number of samples but very limited checks on how samples were taken.

76. NFSA should inspect each site of ISA free compartments at least twice per year. At least one of the inspections should coincide in time with sampling for maintenance of ISA freedom carried out by private fish health services. In the opening meeting, representatives of the NFSA stated that the correct inspection frequency for on-growing farms was two inspections per production cycle, rather than per year.[10]

77. One ISA free site visited, populated in August 2018, was inspected by the NFSA in September and December 2018. None of the official controls coincided with sampling for maintenance of ISA freedom by private fish health services. The NFSA concludes in its report of the second visit that the site complied with the requirements for maintenance of ISA freedom in 2018. So far in 2019, the site was inspected once on 10 May 2019.

78. According to documents presented at the ISA free compartments visited, samples were collected by the private fish health services or by an auxiliary (i.e. site staff). The sampling targeted moribund and newly dead fish. However, it could not be confirmed that samples taken represented all water sources and production units at the sites, as required by Point 1.1 (c) and (d) of Part 3 of Annex 1 to Commission Decision (EU) 2015/1554.

79. One ABO explained a surveillance sampling regime put in place for obtaining ISA freedom on a sea-site, not visited by the mission team. According to the ABO, the site was populated only for short periods with a small number of fish to allow sampling. Between these sampling periods, the site was fallowed.

80. The mission team saw an example of a declaration of ISA free status for one land based compartment submitted in May 2018. In a period between May 2016 and 2017, only heart samples were analysed, contrary to Point II.1 of Part 3 of Annex I of Decision (EU) 2015/1554 which requires also analysis of mid-kidney samples. This was noted by the NFSA and the application was consequently refused. However, the NFSA subsequently permitted stored frozen samples of kidneys taken for BKD surveillance to correct the inadequate sampling and to be retrospectively used to exclude the presence of ISA in this compartment. No evidence was available, however, from which fish and by whom these samples had been taken. It was therefore not possible for representatives of the NFSA to verify that the samples were taken in line with Point 1.1 (c) and (d) of Part 3 of Annex 1 to Commission Decision (EU) 2015/1554.

81. Norway has submitted several declarations for sites which are dependent on the health status of the surrounding waters ('dependent ISA-free compartments'). However, no additional measures to prevent introduction of the disease from neighbouring areas, including measures to confirm that waters surrounding the dependent compartment can be considered free of ISA (for example, inspection of neighbouring aquaculture sites

[10] In the reply to the draft report the CA made a comment which reflected the changes in their procedures done in the period between the time when mission took place and their reply to the draft report. New procedures requires that both inspections should coincide in time with sampling for maintenance of ISA freedom. The sampling should be carried out by fish health services not employed by the ABOs. In addition, at the opening meeting, representatives of the NFSA stated that the correct inspection frequency for on- growing farms which are not in category I or II was two inspections per production cycle, rather than per year.

or susceptible species of wild fish) are applied, contrary to Point 2.4 of Part II, Annex V to Directive 2006/88/EC.

Conclusions

82. Limited involvement by the NFSA in the process of declaring compartments/zones disease-free precludes the NFSA from being able to verify compliance with surveillance requirements throughout the process or ensure that no conflict of interest compromises the process.

83. The fact that the surveillance program establishes sampling throughout the year rather than during two 1-month test periods per year, combined with absence of official verification by the NFSA of surveillance undertaken to establish freedom of ISA, undermines the reliability of the statements included in the declarations of disease free status of compartments submitted by the NFSA. This, along with insufficient description of the disease control systems in place in such declarations, precludes a proper assessment of the underlying guarantees provided by the NFSA and weakens the overall procedure for granting ISA-free status.

84. The absence of additional measures in relation to dependent ISA-free compartments further reduces the reliability of the system in place. In particular, since such compartments are a potential source of fish to independent compartments, this potentially exposes all ISA free compartments in Norway to fish from Category III areas.

5.3.6.2 Withdrawal of ISA-free status

85. According to information provided by Norway in its reply to the Authority's pre-mission document, the criteria and administrative procedures for declaration, maintenance, suspension and restoration of a zone or a compartment within Norwegian territory free of a non-exotic disease are in accordance with Article 50, 52 and 53 of Directive 2006/88/EC.

86. ISA free status will be withdrawn in case of suspicion, or confirmation, of ISA in a zone or compartment or in case of breach of the conditions of maintenance of ISA-free zones or compartments – for example, insufficient number of samples, intake of biological material from areas of lower health status or inadequate biosecurity measures. The regional offices of the NFSA have legal competence to suspend disease free status upon suspicion of ISA, while the head office has the competence to withdraw disease free status following confirmation of the disease in a relevant compartment or zone.

87. The mission team noted that the OK 2019 states that, in case of withdrawal, ISA free status will be withdrawn for the entire compartment and all sites within. However, Point 6 of the "Instruction for suspension and withdrawal of ISA free status" (*ILA-fritt segment og ILA-fri sone – instruks om suspensjon og tilbaketrekking for tilsynet)* outlines an option of partial withdrawal.

88. Following a suspicion of ISA on a sea site, the NFSA suspended the ISA free status of a compartment close by. The disease free status of the compartment was suspended by a regional office of the NFSA in June 2018, two days after initial suspicion of ISA on the neighbouring farm. Nevertheless, the site number still appears on the list of ISA-free compartments in Annex 2 to Regulation NO of 17 June 2008 No 822.

Conclusions

89. Due to delays in withdrawing ISA free status, compartments that no longer fulfil the requirements of ISA-free status still appear on the list of ISA-free compartments in the relevant Norwegian legislation. This precludes the possibility of relying on that list to ascertain conclusively that aquaculture animals originate from ISA free areas.

5.3.7 Measures for control of diseases of aquaculture animals

90. According to information provided by Norway in its reply to the Authority's pre-mission document, the animal health surveillance scheme and private fish health services (see also paragraph 44), along with the designated laboratories, supplements the work of the NFSA and NRL in preventing and managing disease outbreaks in Norway.

91. Diseases which affect aquatic animals are listed in Regulation NO of 17 June 2008 No 819. List 1 (exotic diseases) and list 2 (non-exotic diseases) correspond to the diseases listed in Part II of Annex IV to Directive 2006/88/EC. List 3 diseases are subject to national control measures and include Bacterial kidney disease (BKD), infection with *Gyrodactylus salaris*, Viral nervous necrosis (VNN), Furunculosis, Pancreas disease (PD), Heart and skeletal muscle inflammation (HSMI), Francisellosis, infection with Lepeophtherius salmonis (Salmon louse) and crayfish plague.

92. Disease management depends on the health status for the disease in question (see also section *5.3.1*), and the NFSA has prepared several contingency plans for aquatic animal health, including one for handling exotic fish diseases listed in Part II of Annex IV to Council Directive 2006/88, one for handling ISA outside free compartments and zones and one for emerging diseases.

93. The Norwegian Food Act introduces a general requirement on ABOs and others to notify the NFSA if there is reason to suspect a listed disease. In addition, Regulation NO of 17 June 2008 No 822 requires notification of increased mortality, suspicion of listed disease or any other conditions which may affect the fish welfare, including disease, injury or technical failure of equipment (see also paragraph 49).

94. In case of diseases listed in Part II of Annex IV of Directive 2006/88/EC, the following measures are applied. The suspected affected farm is initially placed under official surveillance and no aquaculture animal can leave or enter the affected farm unless authorised by NFSA. If the farm is officially declared infected by NFSA (based on a qualified laboratory diagnosis given by NRL), a containment area is established (including a protection and surveillance zone) and an epizootic investigation is carried out. Aquaculture animals in farms or areas with a confirmed non-exotic disease shall according to the general contingency plan as a principal rule be removed as soon as possible under NFSA supervision. Animals showing no sign of disease may be harvested for human consumption. Transport and harvesting shall be carried out under conditions preventing the spread of pathogens. No restocking takes place and no aquaculture animals are moved into, within or out of, the containment area unless authorised by the NFSA. The European Commission and EFTA Surveillance Authority shall be notified within 24 hours in case of confirmation of the diagnosis, except for ISA confirmed in Category III areas.

95. The mission team noted that the NFSA handles suspicion of ISA in the same way, regardless of whether the suspicion is based on increased mortality with suspicion of ISA or on a PCR positive analysis from one of the designated laboratories or the NVI. There is a significant delay in official confirmation of an outbreak of ISA or of its

absence following an initial notification of suspicion. Furthermore, the average time between the disease being confirmed and establishment of surveillance and protection zone is, according to the NFSA, 25 days. In one case noted by the mission team, 21 weeks passed before the containment area was established following a confirmed ISA outbreak.

96. In the majority of cases, control measures in the period between first suspicion until establishment of the containment area were limited to the individual farm only. In one case seen, suspicion of ISA was notified based on positive laboratory results. Two days later, the regional office suspended the ISA free status on a neighbouring farm.

97. In another case, only the farm with the confirmed outbreak was placed under restriction by a decision issued from the regional NFSA on 16 April 2019. The mission team could establish the following timeline for the outbreak in a Category III area: Routine samples collected on 8 April by the ABO were PCR positive for ISAV. Additional samples were collected by the ABO on 15 April. The results from the designated laboratory were produced on 24 April and confirmed by the NRL on 30 April. The NFSA officially confirmed ISA on 3 May. At the time of the mission, a containment area was not yet established around the confirmed outbreak, and consequently movements from adjacent farms and movements of well-boats in the future protection area and surveillance area were not restricted.

98. The mission team also noted:

    a. an example where brood stock was moved from a dependent ISA-free compartment *(farm 1)* in the period between initial suspicion of ISA and official confirmation of the disease on a neighbouring farm *(farm 2)* not belonging to the same ISA-free compartment. Furthermore, another movement was recorded in Barentswatch from *farm 1* to *farm 4* outside of the ISA free compartment after the official confirmation of the disease, before the containment area was established.

    b. On *farm 2*, the private veterinarian took samples on 24. 8. 2017 after a suspicion found during pathological examination and send them to the laboratory as ISA suspect. The laboratory on 29 August confirmed that 3 out of 8 samples were PCR positive. The next day the NFSA took additional samples and send them to the NVI, which on 6 September confirmed the infection with ISAV. On 7 September the NFSA officially confirmed the disease. In the meantime on 6 September the broodstock from *farm 1*, which was within 10km ISA temporary circle (8.5km according to Barentswatch.no from *farm 2*) was moved to another on-growing farm *(farm 3)* out of 10km ISA temporary circle. In addition, one movement from *farm 1* took place to another farm outside 10km ISA temporary cycle *(farm 4)* on 9 September, two day after the disease was officially confirmed on *farm 2*. The containment area was declared on 4 October.

    c. Consequently, when the NFSA established the containment area surrounding *farm 2*, *farm 1* was empty of brood stock. If the brood stock had not been moved from *farm 1, farm 1* would normally have been included in the containment area. This would have compromised the ISA free status of this farm along with the other farms belonging to this same ISA free compartment and the ISA-free status of the relevant compartment should have been withdrawn, pursuant to Article 53 of Directive 2006/88/EC. This movement of brood stock was done with the knowledge of the NFSA.

Conclusions

99. Norway has some flexibility to decide how to manage ISA in line with the minimum conditions laid down in Article 39 of Directive 2006/88/EC in Category III zones, insofar as the approach taken does not compromise the health status of zones and compartments which are officially declared ISA-free and as such certified for trade to other EEA countries.

100. The control measures are limited to suspected farms also after official confirmation until a containment area is established. This combined with delays seen in confirming outbreaks and delays from the official confirmation until a containment area is established, allows for time and opportunity to move aquaculture animals within and out of what may later be the containment area for an outbreak. Since also animals from ISA free dependent compartments are allowed to be moved under such circumstances, the ISA free status may be jeopardised as well.

5.3.8 Record keeping

Legal requirements

Article 8 of Directive 2006/88/EC

Findings

101. Records required by Article 8 of Directive 2006/88/EC (movement records, mortality records and results of the animal health surveillance scheme) were available at all fish production sites visited and checked by the NFSA inspectors during their regular visits except the mollusc farm visited. On this mollusc farm visited, no health inspection reports from private fish health services or otherwise were available because health inspection checks had only recently been introduced (see also point 47).

Conclusions

102. Updated records are kept on the production sites which enable the NFSA inspectors to check the animal health related activities on the farms - for example, checking if the necessary samples were taken in case of unexplained increased mortality.

5.3.9 Placing on the market, introduction and import of aquaculture animals and products thereof

Legal requirements

Article 12 and Article 43 of Directive 2006/88/EC, Chapter III and Chapter IV of Directive 2006/88/EC, Chapter III and Chapter IV of Regulation (EC) No 1251/2008, Annex II and Annex III of Regulation (EC) No 1251/2008, Article 3(3) of Directive 96/93/EC

Findings

103. According to information provided by Norway in its reply to the Authority's pre-mission document, Regulations NO of 17 June 2008 No 819 lays down requirements for movement of aquaculture animals, including trade with other EEA states. Aquaculture animals and products thereof must be accompanied by a health certificate if introduced into a Category I, II or IV area for farming or further processing before human consumption. It is not a requirement that TRACES is used for domestic movement within Norway.

104. The Mission team were able to verify that aquaculture animals introduced into ISA free compartments in Norway were accompanied by health certificates. However, an example of molluscs moved from an area of lower health status into a Category I area without a health certificate was seen.

105. Oysters intended for human consumption which were harvested in an area placed under restrictions due to *M. refringens* were transported to, and stored at, a purification centre. Oysters destined for farming from another part of Norway, considered free of *M. refringens*, were harvested, transported to, and kept at the same purification centre during the same period. These oysters were sent to another EEA country accompanied by a health certificate stating that they were from a EEA State or part thereof free of *M. refringens*. The NFSA explained that they were not aware that molluscs from different health categories has been present at the same time in the purification centre.

106. Certain farms in Norway are under surveillance for BKD (see also paragraphs 63 and 64), and based on this the NFSA certifies that salmonid eggs from these farms originate from a country or part thereof which in case of Bacterial Kidney Disease (BKD) complies with requirements for disease freedom equivalent to those laid down in Chapter VII of Directive 2006/88/EC. The NFSA justifies such certification on the basis of a bilateral agreement from 2012 with the competent authority in one EU member state as well as on information provided to the Authority in a letter sent by the NFSA to the Authority on 6 October 2015. The equivalence has not been demonstrated through declaration of freedom in accordance with Article 50, establishing and maintaining of updated list of free areas in accordance with Article 51 and maintenance of freedom in accordance with Article 52 of Directive 2006/88/EC.

Conclusions

107. The system in place does not provide transparency with regard to criteria for the BKD free status and which farms/sites are considered free for BKD in Norway. Consequently, when aquatic animals and products thereof are certified as free of BKD, the receiving competent authority cannot reliably verify the information given in the certificates issued.

108. Keeping molluscs of different health status at the same time in the same establishment has the potential to spread disease when the molluscs are intended for farming.

5.4 Laboratories

Legal Requirements

Article 4(2)(c), Article 11, Article 12 and Article 33 of Regulation (EC) No 882/2004, Article 56 and Article 57 of Directive 2006/88/EC, Point 1(i) of Part II of Annex VI of Directive 2006/88, Annex III of Regulation (EC) No 2074/2005

Findings

109. The competent authorities have designated National Reference Laboratories (NRLs) for listed fish, mollusc and crustacean diseases. In addition, the authorities have designated three private laboratories to provide diagnostic services for ISA, BKD and PD. The designation of these laboratories fulfils the requirements of Articles 56(1) and 57(a) of Directive 2006/88/EC.

110. The NFSA has recently designated a second NRL for molluscs. Staff at one of these laboratories stated that there was currently no agreement to determine which laboratory took the lead for disease confirmation and/or outbreak investigation related to listed diseases in molluscs. This was confirmed by the NFSA.

111. All designated laboratories (public and private) have been accredited by Norway's national body for accreditation. Accreditation includes fulfilling the requirements of ISO 17025 and the listing of specific groups of tests (which include tests for certain listed fish diseases). This fulfils the accreditation requirements of Part II and III of Annex VI to Directive 2006/88/EC.

112. The NRLs participate in proficiency testing organised by the relevant European Reference Laboratories (EURLs). In addition, NRLs organise periodic comparative (ring tests) of diagnostic procedures at national level with the designated private laboratories. Recent test results reviewed by the mission team were seen satisfactory (for both NRLs and private laboratories).

113. The NRL for fish diseases organises annual meetings with all designated laboratories. The audit team reviewed minutes of one such meeting which confirmed attendance by representatives of all designated laboratories and demonstrated good inter-laboratory collaboration.

114. Designated laboratories are required to notify the authorities of suspicion/confirmation of listed aquaculture diseases, as are ABOs and fish health services. In one laboratory visited by the mission team, the handling of a suspicion was reviewed. Submission documentation from fish health services was marked for urgent attention and requested ISA testing. The NFSA was notified via a government portal (Altinn) by representatives of the private laboratory only when a positive result (ISA) was recorded. The portal is a single entity for all government organisations to receive data and representatives of private laboratories confirmed that they had been instructed by the authorities to use this portal for all official notifications. The NFSA confirmed that it could take up to two days for this information to be redirected to them. Despite the submission form being marked urgent and testing for ISA being requested, neither the private veterinarian submitting the sample nor the private laboratory had notified the NFSA of suspicion of ISA in advance of disease confirmation.[11]

[11] In the reply to the draft report the CA stated that there is a requirement to notify them by the time of the suspicion and not wait until the results of the laboratory analysis are ready.

Conclusions

115. A network of diagnostic laboratories has been designated by the NFSA which can provide a reliable diagnostic service for listed fish diseases. However, control measures implemented by the NFSA in response to disease outbreaks may be delayed by under-reporting of disease suspicions and delay in reacting to notifications received via the government portal. For molluscs diseases there is no clear distinction of the responsibilities between the two NRLs, which may delay the implementation of disease control measures.

6 Final meeting

A final meeting was held on 29 May 2019 at the NFSA premises in Oslo with representatives from the Ministry of Trade, Industry and Fisheries, Ministry of Health and Care Services and the NFSA. At this meeting, the mission team presented its main findings and preliminary conclusions of the mission.

The representatives of the competent authority accepted the mission findings and preliminary conclusions. At the meeting, the competent authority announced that due to the seriousness of certain findings they would present an action plan indicating measures to be taken in the field of official controls in aquaculture. On 7 June 2019 the NFSA provided a general information on corrective actions taken or planned following the final meeting.

Due to the Authority's serious findings concerning official controls in aquaculture, the Authority sent the Norwegian Government a letter dated 11 June 2019 outlining a preliminary list of findings and requested urgent action from the Norwegian Government concerning official controls in aquaculture. On 25 June 2019, the Authority received a reply from Norway to that request including an updated action plan (Annex 7) of this report). On 2 August 2019 additional information was received from Norway indicating and explaining the measures already implemented by Norway by 15 July 2019 (Annex 6)

7 Recommendations

In order to facilitate the follow-up of the recommendations hereunder, Norway should notify the Authority no later than 20 November 2019, by way of written evidence, of additional corrective actions planned or taken other than those already indicated in the reply to the draft report of the Authority. In case no additional corrective actions have been planned, the Authority should be advised. The Authority 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	Ensure that Commission Implementing Decision (EU) 2015/1554 is made part of the Norwegian legal order. Conclusion: 3 Associated finding: 1, 2
2	Ensure that all ABOs and processing establishments are authorised in accordance with Articles 4 and 5 of Directive 2006/88/EC and that all information required by Article 6 and Point 1 (f) and (g) of Part I of Annex II to Directive 2006/88/EC and by Point II.d of Annex II of Directive 2006/88/EC and Point 5 of Annex IV of Decision 2008/392/EC is made publicly available. Conclusion: 26, 27, 28 Associated finding: 19, 20, 25
3	Ensure that the list of ISA-free compartments and zones is publicly available and timely updated to provide reliable and accurate information as required by Article 51 of Directive 2006/88/EC. Conclusion: 34, 89 Associated finding: 32, 88
4	Ensure that consignments of aquaculture animals intended for farming in Member states or parts thereof with approved national measures comply with the animal health requirements set out in a model animal health certificate in Part A of Annex II and explanatory notes in Annex V in line with Article 8a of Regulation (EC) 1251/2008. Conclusion: 68, 107 Associated finding: 63, 64, 106
5	Ensure that, for the purpose of obtaining or maintaining disease free status in compartments/zones, targeted surveillance is carried out when required by Article 50 of Council Directive 2006/88/EC, and verify that such surveillance and sampling is carried out in accordance with the requirements laid down for the disease in question in Commission Decision 2015/1554. Furthermore, it must be ensured that the surveillance is carried out by the competent authority or other qualified health service on behalf of the competent authority as laid down in Part B of Annex III to Council Directive 2006/88/EC, and that staff involved in the surveillance are free from any conflict of interest as required by Article 4(2)(b) of Regulation (EC) No 882/2004.

	Conclusion: 66, 82 83, Associated finding: 48, 61, 62, 73, 77, 78, 79, 80
6	Ensure that additional measures to prevent introduction of the disease from neighbouring areas, including measures to confirm that the sea waters surrounding dependent ISA-free compartments can be considered free of ISA (for example, inspection of neighbouring aquaculture sites or susceptible species of wild fish) are applied, as required by Point 2.4 of Part II, Annex V to Directive 2006/88/EC and that establishment of containment areas following initial notification of suspicion of an ISA outbreak is done in a timely manner to decrease the likelihood of spread of disease into dependent ISA-free compartments. Conclusion: 84, 100 Associated finding: 81, 95, 96, 97, 98
7	Norway must ensure that movement, or placing on the market, of aquaculture animals is undertaken in line with requirements laid down in Article 12 of and Part A of Annex III to Council Directive 2006/88/EC in order that the health status of aquaculture animals at the place of destination is not jeopardised. Conclusion: 108 Associated finding: 104, 105
8	The authorities must ensure that the two designated NRLs for molluscs have clear guidance on their roles and responsibilities to ensure that they work closely together so as to ensure efficient coordination between them, with other national laboratories and with the Community reference laboratory. The authorities must ensure that when there are any reasons to suspect the presence of a disease listed in Part II of Annex IV to Directive 2006/88/EC the suspicion is immediately notified to them. Conclusion: 115 Associated finding: 110, 114

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

Authority	EFTA Surveillance Authority
ABO	Aquaculture Production Business Operator
BKD	Bacterial kidney disease
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EHN	Epizootic haematopoietic necrosis
EU	European Union
EURL	EU Reference Laboratory
IHN	Infectious haematopoietic necrosis
IPN	Infectious pancreatic necrosis
ISA	Infectious salmon anaemia
ISAV	Infectious salmon anaemia virus
ISAV-HPR0	Low pathogenic infectious salmon anaemia
KHV	Koi herpes virus disease
MANCP	Single integrated multi annual national control plan
NFSA	Norwegian Food Safety Authority
NRL	National Reference laboratory
NVI	Norwegian Veterinary Institute
PCR	Polymerase chain reaction
PD	Pancreas disease
SOP	Standard operating procedure
VHS	Viral haemorrhagic septicaemia

Annex 2 - Relevant legislation

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

a) The Act referred to at Point 8a of Part 3.1 of Chapter 1 of Annex I to the EEA Agreement, *Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

b) The Act referred to at Point 42 of Part 3.2 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2008/896/EC of 20 November 2008 on guidelines for the purpose of the risk-based animal health surveillance schemes provided for in Council Directive 2006/88/EC,* as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

c) The Act referred to at Point 86 of Part 4.2 of Chapter 1 of Annex I to the EEA Agreement, *Regulation (EC) No 1251/2008 implementing Council Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species,* as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

d) The Act referred to at Point 87 of Part 4.2 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2008/392/EC of 30 April 2008 implementing Council Directive 2006/88/EC as regards an Internet-based information page to make information on aquaculture production businesses and authorised processing establishments available by electronic means*, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

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

f) The Act referred to at Point 12 of Part 1.1 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption,* as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I thereto;

g) The Act referred to at Point 74 of Part 1.2 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States*, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

h) The Act referred to at Point 17 of Part 6.1 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 amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

i) The Act referred to at Point 8b of Part 3.1 of Chapter I of Annex I to the EEA Agreement, *Commission Implementing Decision (EU) 2015/1554 of 11 September*

2015 laying down rules for the application of Directive 2006/88/EC as regards requirements for surveillance and diagnostic methods (notified under document C(2015) 6188), as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

j) The Act referred to at Point 9 of Part 1.1 of Chapter I of Annex I to the EEA Agreement, *Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products*, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

k) The Act referred to at Point 134 of Part 1.2 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004*, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement;

Annex 3 – Production tables

Table 1: Production of live aquaculture animals and products thereof, in tonnes [1].

Species	Total Production (2017)		
	For human consumption	Restocking	Other Aquaculture purposes
Salmo salar	1,236.353 t		
Oncorhynchus mykiss	66,902 t		
Salmo trutta	97 t		
Hippoglossus hippoglossus	1,623 t		
Gadus morhua	492 t		
Salvelinus alpinus	365 t		
Other marine species	227 t		
Labrus bergylta			200,000 pieces
Cyclopterus lumpus			25,993 pieces
Mytilus edulis	2,353 t		
Pectinidae	29 t		
Ostrea edulis	17 t		
Other crustaceans	21 t		

[1]*Production of live aquaculture animals and products thereof for 2018 was not available at the time of the mission.*

Table 2: Live aquaculture animals and products thereof, placed on the market in other EEA states, in tonnes.

Species	**Intra EEA trade – placed on the market (2017)**			
	For human consumption	Restocking	For farming purposes	Other aquaculture purposes
Littorina littorea	19 t			
Salmo salar			13 t	1.7 t + 900 pieces
Other				

Species	**Intra EEA trade – placed on the market (2018)**			
	For human consumption	Restocking	For farming purposes	Other aquaculture purposes
Littorina littorea	22 t			
Salmo salar			10 t	0.325 t
Other				

Table 3: Live aquaculture animals and products thereof, introduced from other EEA member states, in tonnes.

Species	**Intra EEA trade – introduced to Norway (2017)**			
	For human consumption	Restocking	For farming purposes	Other Aquaculture purposes
Ctenolabrus rupestris				13 t
Labrus bergylta		0.15 t		117 t
Labrus viridis				8 t
Other				29 t

Species	**Intra EEA trade – introduced to Norway (2018)**			
	For human consumption	Restocking	For farming purposes	Other Aquaculture purposes
Labrus bergylta				21 t
Labrus viridis				12 t
Ctenolabrus rupestris				17 t
Other				

Table 4: Live aquaculture animals and products thereof, exported to third countries, in tonnes.

	2017
Fertilized roe, no. of eggs	
Oncorhynchus mykiss	332 t
Salmo salar	307 t
Spawn, no of individuals	
Oncorhynchus mykiss	473 t
Salmo salar	372 t
Smolt, no of ind. (unless otherw. stated)	
Oncorhynchus mykiss	371.600 pieces + 73 t

	2018
Fertilized roe, no. of eggs	
Oncorhynchus mykiss	0
Salmo salar	400 t
Spawn, no of individuals	
Oncorhynchus mykiss	0
Salmo salar	0
Smolt, no of ind. (unless otherw. stated)	
Oncorhynchus mykiss	1,349.656 pieces + 228 t

Table 5: Live aquaculture animals and products thereof, imported from third countries.

Species Common and scientific name	**Trade with third countries - Exported to third countries**			
	For human consumption	Restocking	For farming purposes	Other aquaculture purposes
Hippoglossus hippoglossus			35,475 pieces	

Annex 4 - Norway's comments to draft report

Statens tilsyn for planter, fisk, dyr og næringsmidler

Mattilsynet

EFTA Surveillance Authority's Mission to Norway from 20 to 29 May 2019- Norway's comments to the draft report

With reference to the draft report from the EFTA Surveillance Authority ("the Authority") concerning the mission to Norway from 20 to 29 May 2019 in order to evaluate animal health controls in relation to aquaculture animals.

The Norwegian Food Safety Authority ("NFSA") would like to comment on the following findings and conclusions in the draft report:

- Finding # 6: Norway suggests that the text is replaced by the following formulation: *"The NFSA is organized into two administrative levels, the head office and the regions. The head office carries out directorate and governance tasks. The regional level consists of five regions, each divided into local departments (with 70 office locations altogether). The local departments perform the official controls in defined geographical areas, i.e. regions."*
- Finding # 9: During the meetings with the regional offices, it was acknowledged that the fish health and welfare online course offer by the Norwegian University of Life Sciences (NMBU) in collaboration with the NFSA, is a measure regarding the special focus on fish health during the years 2019-2021.
- Finding # 13: the well boat visited by the mission team had a UV disinfection system as well as ozonation on board.
- Finding # 33: Due to a misunderstanding, the representatives of the NFSA stated in the opening meeting that there are no zones free for ISA in Norway. This is not true, in Norway there are both zones and compartments declared free for ISA
- Finding # 37 and 38: We suggest making no reference to the names of the NFSA's regions visited.
- Finding # 57: *Gyrodactylus salaris* and BKD are not part of the diseases listed in Part II of Annex IV to the Directive 2006/88/EC. Both diseases are on the Norwegian national list.
- Finding # 76: We suggest the following text: "NFSA *must* inspect each site of ISA free compartments *at least* twice per year. *Both* inspections should coincide in time with sampling for maintenance of ISA freedom. *The sampling should be* carried out by fish health services *not employed by the ABOs*. In the opening meeting, representatives of the NFSA stated that

the correct inspection frequency for on- growing farms *which are not in category I or II* was two inspections per production cycle, rather than per year."

- Find # 109: The private laboratories provide diagnostic services for ISA, BKD and PD, but not for VHS.
- Finding # 54: We suggest the following text: "The mission team noted that in most cases *presented to the mission team,* notifications of suspicion are sent to the general contact e-mail of the NFSA rather than to the functional notification e-mail for the relevant office and/or department of the NFSA. Generally, the local inspector was in copy (in Cc). In one case of a suspicious outbreak of ISA, an e-mail sent by the ABO to the local inspector was not read until ten days later due to the local inspector being on annual leave at the time. *Such a delay is not in line with the guidelines on how to notify the NFSA a suspicion or disease in aquatic animals. Notifications to the functional notification e-mails are most commonly used. These e-mail addresses are listed in the guidelines on notification and the information on suspicion should be read each working day.*"
- Finding # 74: During the opening meeting, representatives from the NFSA stated that Norway will not declare a land-based compartment as ISA-free based on 6 weeks fallowing *in cases where there is a suspicion of ISA or a confirmation of the disease*.
- Finding # 94: With reference to the third line, it is not clear if the "general contingency plan" refers to the "Contingency plan for exotic fish diseases (list 1 and list 2)" or another contingency plan.
- Finding # 95: The NFSA suggests the following text: "The mission team noted that the NFSA handles suspicion of ISA in the same way, regardless of whether the suspicion is based on increased mortality *with a suspicion of ISA* or on a PCR positive analysis from one of the designated laboratories *or the Norwegian Veterinary Institute*. There is a significant delay in official confirmation of an outbreak of ISA or of its absence following an initial notification of suspicion. Furthermore, the average time between the disease being confirmed and establishment of surveillance and protection zone is, according to the NFSA, 25 days. In one case noted by the mission team, 21 weeks passed before the containment area was established following a confirmed ISA outbreak."
- Finding # 114: The NFSA would like to remark that there is a requirement to notify us by the time of the suspicion and not wait until the results of the laboratory analysis are ready. See also our comments to the Finding # 54.

Please find attached with this letter the actions taken to the recommendations by the Authority described in the draft rapport.

Annex 5 - Norway's action plan for corrective actions

sN	Recommendation	Corrective actions	Deadline
1	Ensure that Commission Implementing Decision (EU) 2015/1554 is made part of the Norwegian legal order. Conclusion: 3 Associated finding: 1, 2	1. Implement the Commission Implementing Decision (EU) 2015/1554 in the Norwegian legal order.[1] 2. Notify the Authority of the implementation. 3. Publish a guide for the industry about the requirements for declare and maintain disease-free status for non-exotic diseases. 4. Publish internal guidelines for how to declare and maintain disease-free status for non-exotic diseases.	1 January 2020[2] 5 January 2020 1 April 2020[3] 1 April 2020[3]

[1] Commission Implementing Decision (EU) 2015/1554 of 11 September 2015 laying down rules for the application of Directive 2006/88/EC as regards requirements for surveillance and diagnostic methods ('Decision (EU) 2015/1554') is implemented by administrative procedures for surveillance programmes and chapters on Infectious salmon anaemia (ISA), Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN) and Bonamia ostreae (B. ostreae) and Marteilia refringens (M. refringens) specified in the Norwegian Food Safety Authority's Instruction for OK programs 2019 ('OK instruks 2019'). See attachment 1. Please note that the date of the "Ok-instruk:" is not updated.

[2] In the previous version of the table, the NFSA stated that the deadline to implement the Commission Implementing Decision (EU) 2015/1554 was 1 July 2020.

[3] In the previous version of the table, the NFSA stated that the guidelines to the industry and the internal guidelines will be publish 1 July 2020. Please also see recommendations # 3 and 7.

2	Ensure that all ABOs and processing establishments are authorised in accordance with Articles 4 and 5 of Directive 2006/88/EC and that all information required by Article 6 and Point 1 (f) and (g) of Part I of Annex II to Directive 2006/88/EC and by Point II.d of Annex II of Directive 2006/88/EC and Point 5 of Annex IV of Decision 2008/392/EC is made publicly available. Conclusion: 26, 27, 28 Associated finding: 19, 20, 25	1. Create an overview of which companies have approval the dates before the Directive 2006/88/EC was implemented in Norwegian regulations. Based on this overview, the NFSA will review whether the ABOs fulfill all the requirements. The NFSA will prepare a list of requirements that will ensure control of relevant points for use in the audit when supervising the businesses. In this way, we will carry out checks on companies that have been approved from the time before the Directive 2006/88/EC was implemented in 2008 to ensure compliance with the applicable requirements. 2. Update the list of the ABO with the information about the health status and presence of susceptible species on the production site, as required by Article 6 and Annex II to Directive 2006/88/EC and Commission Decision 2008/392. 3. Update the register of processing establishments with information on the effluent system.	1 January 2021 1 January 2021 1 January 2021

3	Ensure that the list of ISA-free compartments and zones is publicly available and timely updated to provide reliable and accurate information as required by Article 51 of Directive 2006/88/EC. Conclusion: 34, 89 Associated finding: 32, 88	1. Update the list of ISA-free zones and compartments annexed to the Norwegian legislation and on the NFSA's website, so the information available is reliable.[4] 2. Publish internal guidelines for how to declare and maintain disease-free status for non-exotic diseases (as well as publishing in Barentswatch) and include the information for the industry. 3. In addition, routines for submitting a year report to the Authority on the functioning of the national measures will be revised. These routines will be implemented to follow up the EFTA Surveillance Authority's Decision No 058/16/COL-D of 3 March 2016 [7] 4. Implement routines on how to perform inspections and controls by the head office regarding ISA-free status. These routines will include a seminar with inspectors working with ISA-free compartments and zones.	1 November 2019[5] 1 April 2020[6] 1 April 2020 1 November 2019

[4] In the letter from the NFSA to the Authority dated 2 August 2018, the NFSA stated that the list of ISA-free zones and compartments annexed to the Norwegian legislation and on the NFSA's website was updated. To update the list, the NFSA has withdrawn zones and compartments that the NFSA had a reason to believe that any of the conditions for maintaining its status as a disease-free zone or compartment had been breached. The NFSA is currently going through each zone and compartment and check which ones meets the criteria for listing. When the list is ready, the NFSA will consider further actions (see also corrective actions to recommendation # 6).

[5] Due to the amount of work required, the NFSA needs more time to update the list of ISA-free zones and compartments. We had previously suggested that the list will be updated by the 1 October 2019.

[6] In the letter from the NFSA to the Authority dated 7. June 2019, we suggested that the internal guidelines for how to declare and maintain disease-free status for non-exotic diseases will be implemented by 15 July 2019. To implement this action, we request longer time. Please see also recommendations # 1 and 7.

[7] Norway will submit an annual report on the approved national measures for *Gyrodactylus salaris*, as stated in Article 2 of the EFTA Surveillance Authority's Decision No 058/16/COL-D of 3 March 2016 by the 1 December 2019.

4	Ensure that consignments of aquaculture animals intended for farming in Member states or parts thereof with approved national measures comply with the animal health requirements set out in a model animal health certificate in Part A of Annex II and explanatory notes in Annex V in line with Article 8a of Regulation (EC) 1251/2008. Conclusion: 68, 107 Associated finding: 63, 64, 106	1. Establish a list of sites that complies with the requirements or disease freedom for BKD after the list of ILA free zones and compartments is updated.[5]	15 January 2020[6]

[5] Please find in the "OK-insurals 2019" enclosed the details about the surveillance program for ISA and BKD (attachment 1).
[6] If an ABO wishes to export live aquatic animals, eggs or gametes to Ireland, Nord Ireland, Isle of Man og Jersey before the 15 January 2020, the inspectors of the NFSA will assess if the segment or zone from which the ABO wishes to export, complies with the requirements to export to these countries.

5	Ensure that, for the purpose of obtaining or maintaining disease free status in compartments/zones, targeted surveillance is carried out when required by Article 50 of Council Directive 2006/88/EC, and verify that such surveillance and sampling is carried out in accordance with the requirements laid down for the disease in question in Commission Decision 2015/1554. Furthermore, it must be ensured that the surveillance is carried out by the competent authority or other qualified health service on behalf of the competent authority as laid down in Part B of Annex III to Council Directive 2006/88/EC, and that staff involved in the surveillance are free from any conflict of interest as required by Article 4(2)(b) of Regulation (EC) No 882/2004. Conclusion: 66, 82 83, Associated finding: 48, 61, 62, 73, 77, 78, 79, 80	1. Edit the procedures for targeted surveillance ("Ok-instruks"[10]) so: - Only staff which is not employed by the ABOs can perform sampling. - ABOs that apply for a free status shall have an approved monitoring program for granting free status.[11] - Sampling for maintenance of ISA free status should be subject to sampling during two 1-month test periods per year in spring and autumn. Inspectors from the NFSA are in charge of the surveillance for disease free status and will be present during the two sampling periods each year. - The targeted surveillance for VHS and IHN will include sampling of all required organs.	15 October 2019

[10] Please find enclosed the last version of the "OK-instruks 2019" in the attachment 1.
[11] This action is already enforced by 15 July 2019, as described in the letter to the Authority dated 2 August 2019.

6	Ensure that additional measures to prevent introduction of the disease from neighbouring areas, including measures to confirm that the sea waters surrounding dependent ISA-free compartments can be considered free of ISA (for example, inspection of neighbouring aquaculture sites or susceptible species of wild fish) are applied, as required by Point 2.4 of Part II, Annex V to Directive 2006/88/EC and that establishment of containment areas following initial notification of suspicion of an ISA outbreak is done in a timely manner to decrease the likelihood of spread of disease into dependent ISA-free compartments. Conclusion: 84, 100 Associated finding: 81, 95, 96, 97, 98	1. Inform well boat owners emphasizing the requirements in the transport regulations. 2. For each ISA-free segment in a coastal area, the NFSA will consider additional measures to prevent the introduction of diseases.[12] 3. For each ISA-free zone, a buffer zone in which monitoring program will be carried out will be established as appropriate.[12] 4. Revise the guidelines with the new procedures for establishing containment areas. The NFSA has set into force fast track procedures in order to adopt containment areas to prevent that an outbreak infect salmonids in other establishments. As soon as ISA is confirmed, a containment area will be set into force as a local regulation. 5. Enforce restrictions on moving of all aquaculture animals in or out of the establishments surrounding the possible outbreak for each case of suspicion of an ISA outbreak.	15 June 2019 1 November 2019[13] 1 November 2019[13] 1 November 2019 15 July 2019[14]

[12] The criteria to consider additional measures in an ISA-free segment or a buffer zone in an ISA-free zone are attached with this table. See attachment 2.
[13] In the previous version of the table, the NFSA suggested that the deadline for implementing these corrective actions was 1 January 2020. The NFSA has reconsider these deadlines and suggest a shorter deadline.
[14] In the previous version of the table, it was suggested that the deadline to enforce these restrictions was 1 July 2019. The correct date is 15 July 2019, as it can be seen in previous correspondence with the Authority.

7	Norway must ensure that movement, or placing on the market, of aquaculture animals is undertaken in line with requirements laid down in Article 12 of and Part A of Annex III to Council Directive 2006/88/EC in order that the health status of aquaculture animals at the place of destination is not jeopardised. Conclusion: 108 Associated finding: 104, 105	1. Publish internal guidelines for how to declare and maintain disease-free status for non-exotic diseases. The internal guidelines shall include moving of fish of fish from areas with different health status.	1 April 2020[15]
8	The authorities must ensure that the two designated NRLs for molluscs have clear guidance on their roles and responsibilities to ensure that they work closely together so as to ensure efficient coordination between them, with other national laboratories and with the Community reference laboratory. The authorities must ensure that when there are any reasons to suspect the presence of a disease listed in Part II of Annex IV to Directive 2006/88/EC the suspicion is immediately notified to them. Conclusion: 115	1. Publish a new agreement with the designated NRLs for molluscs specifying their roles and responsibilities.	1 January 2020

[15] In the previous version of the table, the NFSA suggested that the deadline for updating the internal guidelines was 1 July 2020. We suggest a shorter deadline to enforce this action. Please see also recommendations 1 and 3.

Annex 6 - Measures implemented in Norway by 15 July 2019

(Received on 2 August 2019)

Reference is made to the letter from the EFTA Surveillance Authority ("the Authority") dated 22 July 2019.

The Authority has asked Norway to send any updated information available concerning the action plan, in particular regarding implementation of those measures to be enforced by 15 July 2019.

The Norwegian Food Safety Authority ("NFSA") has implemented following measures:

I. The NFSA has stopped issuing certificates attesting ISA free status

The NFSA will temporarily not issue new certificates attesting ISA free status for live aquatic animals, eggs and gametes until further notice. The NFSA has not started issuing new certificates yet.

II. The NFSA has implemented routines to improve the response time to official confirm or rule out a suspicion of ISA.

To improve the response time, the NFSA has enforced additional routines such as:

- The NFSA's inspectors shall take out samples to verify a suspicion the first weekday after a suspicion. Sampling can be delayed by the weekend and public holidays, but the sampling must take place no later than three days after suspicion.
- The Norwegian Veterinary Institute, which receive samples for confirmation of ISA, is informed about such an improved system and will contribute to more rapid confirmation of ISA.

A new version of the "OK-instruks" has been sent out to the NFSA inspectors. In the new version, these new routines are implemented. In addition, a letter to the NFSA inspectors has been sent out explaining the new routines that entered into force by 15 July 2019. Please find the new version of the "OK-intruks" and the letter to the inspectors enclosed with this letter in Annex I and II.

III. The NFSA has imposed better routines to control areas surrounding the outbreak

To have better control of the areas surrounding the outbreak from the time of initial notification of suspicion of an ISA outbreak until measures are taken to delimit the containment area (protection and surveillance zones) surrounding a compartment or zone in which an ISA outbreak has been officially confirmed, the NFSA has revised the procedures, which establish a containment area. The NFSA shall set into force fast track procedures in order to establish a containment area. As soon as ISA is diagnosed, a containment area shall be set into force as a local regulation.

Please find a copy of the letter sent out to the industry explaining the new procedures following an outbreak of ISA in the Annex III enclosed with this letter.

IV. The NFSA will impose additional measures in ISA-free compartments dependent on the health status of surrounding waters

To prevent introduction of ISA virus from surrounding Category III seawaters, we have imposed additional measures in ISA-free compartments dependent on the health status of surrounding waters.

These measures include:

- For each ISA-free segment in a coastal area, we have considered establishment of a buffer zone around segments and part of segments in which monitoring will be carried out. Aquaculture animals that are susceptible for ISA will be sampled in the buffer zone to protect the disease-free zone. The NFSA has not yet put into practice this measure since we have not yet concluded the extension of the buffer zone.
- Increased sampling of aquaculture animals in Category III surrounding waters within the buffer zone. The NFSA has not yet put into practice this measure since we have not yet concluded the extension of the buffer zone.
- Better information to and better control of well boat traffic around ISA-free segment and zones. The NFSA has sent a letter addressed to well boats owners emphasizing the requirements in the transport regulations when it comes to transport of live fish between areas with the same or different health status. Please find in Annex IV a copy of the letter sent to the well boat owners.

V. The NFSA has implemented better routines in the procedure for granting ISA-free status

Establishments that apply for a free status shall inform the NFSA in advance, that is, before they start sampling for granting ISA-free status. The NFSA will, with this change, have a better control of establishments/areas and quality assurance of the samples that are the basis for the free status. It will not be allowed to post-analyze samples if the sets of samples are not complete. This measure is implemented in the newest version of the "OK-instruks" (Annex I).

The head office will perform inspections and controls regarding ISA-free status. This implies that the head office will participate together with the regions in inspections of sites that have applied free status or who already have free status. The head office will carry out such inspections to ensure and calibrate the implementation of control and regulatory compliance in the regions. The inspections will consist of document review and inspections of the establishments. This routine will be in place by 1 October 2019 at the latest.

VI. The NFSA has updated and made publicly available list of compartments and zones declared free for ISA

The Authority pointed out that there is an absence of a reliable, up to date and publicly available list of compartments and zones declared free from ISA in Norway. To solve this problem, the following measures have been taken into consideration:

- The head office, together with the NFSA's regions, has conducted a check of the establishments that are declared free from ISA in Norway are in line with the current regulations.
- The NFSA has updated the list of ISA-free zones and compartments annexed to the Norwegian legislation and on the NFSA's website, so the information available is reliable.
- The NFSA will implement routines on how to update ISA-free segments.
- The NFSA will implement routines to publish and update ISA-free segments in Barentswatch

The updated list of compartments and zones declared free from ISA is publicly available from 15 July 2019 (See https://lovdata.no/forskrift/2008-06-17-819). The other routines mentioned above will be in place by 1 October 2019 at the latest.

Attachments:

- Annex I: OK-instruks
- Annex II: Letter to the NFSA inspectors
- Annex III: Letter to the industry
- Annex IV: Letter to the well boat industry

Annex 7 - Actions proposed by Norway in reply to the Authority's request for urgent action

(Received on 25 June 2019)

Answer to the request for urgent action by Norway concerning animal health requirements for aquaculture animals

Reference is made to the mission of the EFTA Surveillance Authority ("the Authority") to Norway from 20 to 29 May 2019 in order to evaluate official controls of animal health requirements for aquaculture animals.

The Norwegian government is required to provide the Authority with its comments on the principal findings - including proposing a comprehensive remedial action plan with specific details of how changes will be effected within a timetable reflecting the urgency of the situation.

The principal findings for the mission to Norway are:

I. Management of Infectious Salmon Anemia ("ISA")
   i. significant delay in official confirmation of an outbreak of ISA or of its absence following initial notification of suspicion of an ISA outbreak;
   ii. insufficient control of surrounding areas from the time of initial notification of suspicion of an ISA outbreak until measures are taken to delimit the containment area (protection and surveillance zones) surrounding a compartment or zone in which an ISA outbreak has been officially confirmed, thereby failing to prevent continuation of activities in surrounding areas with potential to spread disease such as movement of well-boats bringing and taking animals to and from the relevant compartment or zone;
   iii. failure to impose additional measures in ISA-free compartments dependent on the health status of surrounding waters in order to prevent introduction of ISA from surrounding Category III sea waters;
   iv. limited and late involvement in the procedure for granting ISA-free status, precluding the possibility of effectively controlling compliance with surveillance and related sampling requirements prior to submission of a formal declaration of ISA-free status or of ensuring that such procedure is not compromised by conflicts of interest;

v. inability to detect inaccurate or missing information in formal declarations of disease-free status supporting subsequent certifications of ISA-free status, due to limited involvement in the procedure for granting ISA-free status.

II. Information on disease-free status

According to ESA, Norway has *absence of a reliable, up to date and publicly available list of compartments or zones declared free of one or more diseases listed in Part II of Annex IV of Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement.*

Reply from the NFSA

The following measures are considered:

I. The NFSA has stopped issuing certificates attesting ISA free status

The NFSA will temporarily not issue new certificates attesting ISA free status for live aquatic animals, eggs and gametes until further notice. The NFSA expects that the temporary stop of new certificates will last until the list of compartments and zones declared free for ISA is up to date and publicly available, i.e. 15 July 2019.

II. The NFSA will implement routines to improve the response time to official confirm or rule out a suspicion of ISA.

To improve the response time, the NFSA is planning additional routines such as:

- The NFSA's inspectors should take out samples to verify a suspicion the first weekday after a suspicion. Sampling can be delayed by the weekend and public holidays, but the sampling must take place no later than three days after suspicion.
- The Norwegian Veterinary Institute, which receive samples for confirmation of ISA, is informed about such an improved system and will contribute to more rapid confirmation of ISA.

To shorten the time between suspicion and confirmation of a diagnosis and therefore implement these routines, it is necessary to make changes in the NFSAs internal routines, although the NFSAs inspectors will put these into practice from 15 July 2019.

To have better control of the areas surrounding the outbreak from the time of initial notification of suspicion of an ISA outbreak until measures are taken to delimit the containment area (protection and surveillance zones) surrounding a compartment or zone in which an ISA outbreak has been officially confirmed, the NFSA will:

- Revise the procedures, which establish a containment area. When there is possibility that an outbreak of ISA can infect aquatic animals in other establishments, the NFSA will set into force fast track procedures in order to establish a containment area. As soon as ISA is diagnose, a containment area will be set into force as a local regulation.
- Consider enforcing restrictions on moving of all aquaculture animals in or out of the establishments surrounding the possible outbreak for each case of suspicion of an ISA outbreak.

These routines will be enforced from the time of initial notification of suspicion of an ISA outbreak until measures are taken to delimit the containment area (protection and surveillance zones) surrounding a compartment or zone in which an ISA outbreak has been officially confirmed. To implement these routine, it is necessary to make changes in the NFSA's internal routines, although the NFSA's inspectors will put these into practice from 15 July 2019.

IV. The NFSA will impose additional measures in ISA-free compartments dependent on the health status of surrounding waters

To prevent introduction of ISA virus from surrounding Category III seawaters, we have imposed additional measures in ISA-free compartments dependent on the health status of surrounding waters.

These measures include:

- For each ISA-free segment in a costal area, we will consider establishment of a buffer zone around segments and part of segments in which monitoring will be carried out. Aquaculture animals that are susceptible for ISA will be sampled in the buffer zone to protect the disease-free zone.
- Increased sampling of aquaculture animals in Category III surrounding waters within the buffer zone.
- Better information to and better control of well boat traffic around ISA-free compartments and zones. The NFSA will send a letter addressed to well boats owners emphasizing the requirements in the transport regulations when it comes to transport of live fish between areas with the same or different category status.

To implement these routine, it is necessary to make changes in the NFSAs internal routines, although the NFSAs inspectors will put these into practice from 15 July 2019.

V. The NFSA will implement better routines in the procedure for granting ISA-free status

Establishments that apply for a free status shall inform the NFSA in advance, that is, before they start sampling for granting ISA-free status. The NFSA will, with this change, have a better control of establishments/areas and quality assurance of the samples that are the basis for the free status. It will not be allowed to post-analyze samples if the sets of samples are not complete.

The head office will perform inspections and controls regarding ISA-free status. This implies that the head office will participate together with the regions in inspections of sites that have applied free status or who already have free status. The head office will carry out such inspections to ensure and calibrate the implementation of control and regulatory compliance in the regions. The inspections will consist of document review and inspections of the establishments.

The routines mention above will be in place by 1 October 2019 at the latest.

The Authority pointed out that there is an absence of a reliable, up to date and publicly available list of compartments and zones declared free from ISA in Norway. To solve this problem, the following measures are taking place:

- The head office, together with the NFSA's regions, is conducting a check of the establishments that are declared free from ISA in Norway are in line with the current regulations.

- The NFSA is currently working to update the list of ISA-free zones and compartments annexed to the Norwegian legislation and on the NFSA's website, so the information available is reliable.
- Implement routines on how to update ISA-free zones.
- Implement routines to publish and update ISA-free zones in Barentswatch

The updated list of compartments and zones declared free from ISA will be publicly available from 15 July 2019. The routines mention above will be in place latest by 1 October 2019, although this information will be sent out to the NFSA's inspectors and the industry so that they could put these routines into practice from 15 July 2019.